Part C -
Professional requirements

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14. Objectives

14.1. General

The Governmental Medical Centers Administration requires a LIMS (Laboratories Information Management System) for managing medical laboratories.

The Division is publishing this public tender for procuring licenses for the system, and for services including adjustment, modifications, testing, installation, training, adoption assistance, support and maintenance of the system for the governmental medical centers – general, psychiatric and geriatric, at a total of 24 medical centers at the time of publishing this tender.

General medical centers have a LABOS system (by SOFTOV) installed in them. Geriatric medical centers have a system from ILEX installed in them.

The existing state is described in Appendix C14.1 – existing state.

14.2. Entities involved

14.2.1. The principal customer

The Governmental Medical Centers Administration

14.2.2. The organizations that will be using the system

Governmental medical centers as defined in the glossary in Section 2 above.

14.2.3. Users

The system has several types of users

a. Workers and managers of medical laboratories at each medical center
b. Physicians at the medical centers and workers whose function is to take samples from the patients
c. Referents, implementation workers IT infra structure personnel and system administrators at the medical center and at the Division's management

14.3. Objectives and goals

The system must manage the activity of the medical laboratories as set forth below:

a. The key clinical laboratories:
    - Clinical biochemistry
    - Serology, immunology and virology
    - Hematology

- Microbiology
- Endocrinology
- Pathology
- The blood bank

b. The key work processes include: ordering tests, receiving specimens, performing tests, verification of results and distribution of results, including quality assurance processes of tests and instruments and information on the system's activity, as set forth in the documents of this tender.
c. The system must include warning mechanisms that indicate flawed work processes / input of illegal data or values that are out of the normal range.
d. The system must be based on parameters and tables in order to provide for maximum flexibility in adding new laboratories, changing or updating work processes in the laboratory, adding instruments, etc., and is adapted to differences between the various laboratories at the medical centers and the differences between the various medical centers.
e. The system will support recording and managing test results using common clinical codes such as the codes ICD- LOINC, CPT4, SNOMED, general diagnosis codes, absolute values and free text.
f. The system will interface with laboratory instruments and other IT systems using standard technologies (transfer of files by HL7, XML, Web Services, FHIR, etc.).
g. The system will allow for fully computerized management of taking samples remotely and their exact assignment to a test order and patient.
h. The system must comply with all medical information security rules as defined by the Division in Appendix B5 – Information security.
i. The system must be convenient and friendly for all types of users.
j. The system must include rules for defining user types based on their function and the laboratory in which they work, assignment to specific laboratories, including different authorizations and display options according to the worker's definition.
k. The system will support generating reports by different profiles based on the information stored in it.

14.4. Challenges in the existing state

Today, there is a system of a service provider operating at the general medical centers. The engagement with the provider is about to end.

The system of another service provider is in use at geriatric medical centers.

The existing state is elaborated in Appendix 14.1 – existing state.

14.5. Challenges that the system creates / may create

a. As is the case for any introduction of a new system or replacing an existing system, the challenge of installation and adoption is a significant one.
   The system and the supplier must provide tools for rapid, convenient setup of the system at every site and for efficient, effective introduction into use.
b. In addition, all information in the existing system must be kept available for access from the new system.

14.6. Objectives of the organization

Providing information and communication technology solutions and providing governmental medical centers service, while maintaining a high level of service, availability and efficiency of solutions, with the aim of promoting the quality of the medical services provided by the governmental medical centers.

14.7. Annual work plan

Operation and deployment of the system at the governmental medical centers will be done in several stages as determined by the Division and as set forth in this tender.

14.8. The time horizon

14.8.1. The engagement period within this tender is for 10 years. The Division has a right to choose to expand or and/or extend the engagement period by 2 additional periods, each of 5 years, as stated in the agreement (part B) and subject to the provisions of the Mandatory Tenders Law. Right to exercise the choice will be exercised automatically as long as the Division has not announced otherwise, subject to the needs of the Division, approval of the automatic data processing committee and budgetary restrictions. The agreement will be renewed according to the conditions of the original agreement or conditions that benefit the Division and the customers of the service. The

total period will be no more than 20 years, including the option period.

14.8.2. The Division is allowed to exercise more than one option period by giving a single notice and announce this to the supplier by advance written notice.

14.8.3. The Division has the right to terminate the engagement at any time, during the original engagement period and during each of the option periods, by announcing this 6 month in advance and according to its sole discretion.

15. Functional Requirements

15.1. Glossary

Term	Explanation
Responsive site	Has a responsive user interface
Simple report	A report that displays data with the use of a simple query of up to 7 parameters, basic sorting (ascending / descending) for 2 fields at most.
Complex report	Report that displays data with the use of complex queries / several queries or that involves complex business logic or complex sorts and breaks.
Department / Unit / Sub-laboratory	An organizational entity that comprises the laboratory. Certain laboratories operate according to sections.
Simple Interface	Includes up to 2 messages /files pertaining to the import / export of information and simple business logic
Complex interface	Includes up to 4 messages / files pertaining to the import / export of information and complex business logic
Responsive user interface / responsive interface	A graphic user interface of a website / Web-based system, with features that allow it to adapt its configuration to screen size, and subsequently adapt the website / system to various platforms (computer screen, tablet, cell phone, etc.)
TAT	Turn Around Time

15.2. Users and interfacing information systems

15.2.1. Users

System users are divided into several types:

~~l.~~a. Parties ordering tests: physicians near the patient's bedside in the department, in the ER or in the clinic

~~m.~~b. Parties ordering external tests: external entities that have an agreement with the medical center to perform tests. The orders from external entities largely arrive as computerized lists.

~~n.~~c. Parties collecting samples: nurses and phlebotomists**.**

~~o.~~d. Personnel of the various laboratories and Laboratory Division management

~~p.~~e. IT Division in Governmental Medical Centers

~~q.~~f. Employees of the Directorate of Governmental Medical Centers, Ministry of Health

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15.2.2. Interfacing systems

15.2.2.1. General

a. The systems will include interfaces for laboratory devices, operating systems and information systems in medical centers, such as human resources system, attendance system, payroll system, Medical Center Management System ("NAMER"), Chameleon, Prometheus and other systems to be defined during the detailed solution design stage.

b. Additionally, external entities (parties ordering external tests) will have one or more interfaces for data transfers.

c. The system will support two-way communication for data reception and data transmission to the organizational information system whenever necessary as well as a two-way interface with various laboratory devices.

d. The interface will be developed by the product supplier based on the priorities established by the division (the interfacing side in the division systems will be the division's responsibility).

e. If the interfacing system changes the interface on its side after going live, the division will instruct the LIMS system supplier to change the interface on its side, for a fee, in accordance with the Procedure for modifications and Improvements specified in Section 29.6.4

15.2.2.2. Medical Center Management System ("NAMER")

The "NAMER" system, a Medical Center Management System developed over SAP infrastructure, includes the patient's demographic information, hospitalization details and financial coverage.

15.2.2.3. Financial module in "NAMER"

The system will support accounting with internal and external parties by interfacing with the financial management module in "NAMER".

15.2.2.4. Clinical system / patient file

Different centers employ various systems to manage and display clinical information of patients and of the medical unit on an individual and unit level.

Listed below are the types of clinical systems:

a. Chameleon / **META VISION** / Prometheus – comprehensive patient file management systems used by medical and nursing staff.

b. **COVIEW** – a control and command system for patient status in the medical unit.

c. Apollo – A smartphone-based system that makes hospitalization data and medical unit data accessible to the patient and the patient's family

d. The Physician Space System– operates on a cell phone and displays to the attending physician a summary of the clinical information.

e. **BI** System – a divisional system that stores information from various disciplines for the analysis and display of various cross-sections.

f. Other clinical systems – different Governmental Medical Centers may need to connect the laboratory systems to other systems such as Gastro.

15.2.2.5. External systems

a. General

Interfaces must be able to work with many national systems that compile information from hospital laboratories for operative and research purposes.

Data is transferred using simple **CSV TXT** files, with a specific information protocol for each type of system.

b. List of systems

1) COVID-19 / Monkeypox System – a national information compilation and control system for COVID-19 and monkeypox
2) Infections system – a national system for reporting infections discovered in various medical institutions
3) System for reporting “Notifiable Diseases” – a report of test results for notifiable diseases according to Ministry of Health regulations.
4) "Eitan" System – a system for compiling the patient’s clinical information (personal clinical file) in all treatment sites in the country that is capable of displaying data needed to treat the patient.
5) "Malbam" ICDC (Israel Center for Disease Control) – an interface for dispatching information on results that revealed certain types of cancer

c. A solution must be found to enable these interfaces to also operate in the FHIR protocol.

15.2.2.6. Large external customers

The system will allow orders to be received and results reports/expert opinion to be directly dispatched to large customers through a dedicated safe or in any other manner approved by the division.

15.2.2.7. Service to other medical centers

The system will allow the specialist (such as a pathologist) or specialist laboratory to also provide service to other centers.

15.2.2.8. Interface with the test devices

The system will incorporate a specific interface that is adapted to the work protocol of the test device in the laboratory.

The interface communication with the device will be one-way or two-way, depending on the device settings and capabilities, for more information see Appendix C 12.5 – Laboratory Devices.

15.2.2.9. Various systems in laboratories

The system will facilitate two-way communication of information to and from other laboratory systems such as IMS in the Pathology Laboratory (Digital Pathology)

16. General System Requirements

16.1. Language support

16.1.1. Working from right to left

The system will support work from right to left and from left to right depending on context, including work with a tab based on the correct order of the fields, with a combination of Hebrew/English/numbers with each of the strings being written in a manner that is natural to it. The "ABC 12" string will be entered as A B C 1 2

16.1.2. Language support – user interface

The system will include a user interface in Hebrew. Professional terms may be displayed in English, subject to division approval.

16.1.3. Language support – data

The system will support data in Hebrew, English, numbers and mixed data. In certain cases, a field will contain information that combines Hebrew and English letters as well as numbers.

16.2. Actions Log – Auditing

a. The system will fully document (**LOG**) all actions performed in the system.
   The system will record every action performed in the laboratory's log along with the username, date and hour:minute:second. Additional information about the action (such as test tube identification, device identification, etc.) will be recorded in the log on a need basis and will be defined during the detailed solution design stage.
b. The system will compile and store detailed **usage logs** for all actions and will support the deletion / archiving of logs after a predetermined period of time.
c. The system will compile and save the **audit log** of all actions as well as provide display and search options in this log.
d. The system will allow information from the log to be retrieved and displayed /printed/sent via e-mail/saved.
e. The system will allow information displayed from the log to be sorted.

16.3. Entering data into the system

a. The system will allow data to be manually entered through a keyboard or barcode reader (where relevant).

b. The system will allow data to be selected from a list / table or via free text (where relevant).
c. The system will support the insertion of user comments from a table or as free text in both Hebrew and English.
d. The system will also support a two-dimensional **QR** barcode.

16.4. Displaying results

The system will display the results in numbers, tables, graphs, etc. depending on what is needed.

16.5. Interfaces to laboratory devices

The system will support interfacing and the reception of results from devices via one-way / two-way communication on a need basis, ~~as specified in~~

16.6. Authorizations and positions

a. The system will support defining authorized users, and a user hierarchy of in-process authorizations using Active Directory when applicable.
b. The system will allow for personalization of user authorizations to perform position-based actions – for example, not every user will be able to reject a test or verify results or approve a test that involves unusual behavior.
c. The positions of the **super user** will also be defined for the center, the laboratory and laboratory section. These positions may define various settings during system **setup** and during its life.
d. The varying levels of authorization will be defined for ordering tests, for example: specific types of tests may only be ordered by a senior physician, department director, etc.

16.7. Identification and system entry

The proposed solution will allow system entry by:

a. Identification via username and password.
b. Ability to define various levels of identification according to the position in the system. Certain positions may need to have a **2FA** defined, for example: identification by employee tag / SMS / biometric identification depending on the division's requirement.
c. Identification against **AD** (Active Directory) or the center's identification system

Once successfully entered, the system will display a small ID photo of the user in the corner of the screen.

The system will support standard identification methods to allow easy collaboration between medical centers if needed.

As a minimum, the system should have the ability to import/use external authenticator for such needs

16.8. Electronic signature

The system will allow electronic signatures in every stage of the process based on the center / laboratory / laboratory unit setting and in accordance with the Ministry's requirements and guidelines on electronic signature as defined in the detailed solution design stage.

The system should use the electronic signature that is used by the Ministry.

16.9. Data buffering

a. The system will allow for the storage of extremely large amounts of information (**raw data**). Information that will not be dispatched to the patient's file.
b. Long-term storage of **raw data** (up to 25 years, depending on the type of laboratory) will be available to enable a return to the information at a later time in accordance with clinical demand.

16.10. Monitoring

a. The system will allow for the various stages for all samples to be monitored and will route the samples between the various stations, from the moment the order is received, to implementation of all stages in the preparation of the material and finally to the entering of test results and diagnosis.
b. The system will display a **customized dynamic dashboard** to the user based on the level of the user's authorization. For example: the laboratory director will be able to view the information relevant to that lab, while the laboratory division director will be able to view the relevant information for all laboratories in the center. Every user will be able to customize their own dashboard and to choose the components required.

17. Cluster of General Laboratories and General Processes

17.1. General

This chapter introduces the general requirements and processes that are relevant for all laboratories.

a. The system will handle all incoming samples to the laboratory (including blood, urine, spinal fluid, other bodily fluid, stool, etc.) in accordance with the laboratory's standard work processes that are specified in these tender documents.
b. Ordering tests – creating a patient with the demographic details and ordering tests required in the department / clinic / institute or the laboratory itself.
c. Receiving and identifying samples in the laboratory – once the order is created in the department / clinic and the sample is received in the laboratory.
   The sample will be sent for testing on the device as a single sample or in accordance with the work lists for samples and receiving results – run according to accepted laboratory work methods.
d. Verification and distribution of results once testing has been completed.
e. Archiving samples and locating archived samples
f. End of day procedures
g. Ongoing control of laboratory work and displaying alerts (**dashboard**)
h. Generating reports

17.2. Creating an order

17.2.1. Performing entities

a. Department / clinic of the medical center
b. Laboratory
c. Outside parties that electronically send the work list

17.2.2. Patient identification

a. The system will support patient identification via ID or temporary ID or Case No. or by any other unique number assigned by the medical center and will in any event display the two numbers on every work screen.
b. The system will allow for patients to be searched by name.
c. The system will document changes in patient details such as change in ID and will allow patient files to be consolidated if necessary.

17.2.3. Patient identification in a mass casualty incident

a. The regulation for patient identification in a mass casualty incident involves premade barcode labels that include 2 numbers as specified below, with each of the two numbers being unique.
   1) Iron number – unique case number.
   2) Unique number – 5-digit number. The unique number will be created by activating the algorithm of the iron number.
b. The laboratory system will receive the patients' details including the unique number and save it in a dedicated field.
c. The ID labels on the orders and samples to be sent to the laboratories will include the Iron number and the unique number.
d. In addition to the iron number, the laboratory screens will visibly display the unique number that will support additional patient identification.
e. The blood bank labels and the laboratory reports must have a unique number visibly printed on them.
f. The physician receiving the units for infusion will be able to identify the patient according to the ID wristband label and the blood units according to two parameters: Iron number + unique number.

17.2.4. Ordering tests

a. The system will support remote ordering and will allow orders to be filled in the referring unit (departments, operating rooms, etc.) or in the laboratory / blood bank.
b. The system will allow orders to be placed for single, complex tests, tests with dynamic time and test profiles. The screen will display the list of the tests for the patient and will allow the user to cancel / add tests.
c. The system will number the order and will allow labels to be issued according to the format determined by every medical center.
d. The party ordering the test will enter the test code / test name for the requested tests into the system or will select the test from the formatted screen or help window.
   1) Mandatory fields on the order screen: Demographic details of the patient, order number, sample number, date and time of the sample collection, site of sample collection (microbiology, pathology), date and time when order was received, department/clinic and name of the ordering physician, various fixed comments for the patient, "Urgent" indication for the order, marking "Fear of risk / caution when treating..." the sample, marking indicating an attached file to the order, reason for referral for the test (to a cell marker laboratory, for

example: MRD monitoring/diagnosis/treatment monitoring). If there is a connection to the medical file, the clinical information and/or warnings may be received in the system interface.

2) The requested demographic details can be retrieved from the "patient management" system and other related systems (such as Population Registry). When there is no communication between the systems, the laboratory system database will be searched. If the patient does not exist in the system, the demographic details will be manually entered and automatically checked against the "patient management" system once communication is reestablished. Once the review of the demographic details has been completed, a mismatch report will be produced by the system.
3) The system will allow for the addition of either preformatted comments or free text – the order screen will include a mandatory field for incidental comments (regular medication, week of pregnancy or any other information that is important for the laboratory to know). The number or characters for a comment will be unlimited and the font can be changed.
   Laboratory – dependent
   The system will support a time limit on related comments for the patient (e.g. medication that affects the test results of a patient on the medication for a limited period of time). Laboratory / test dependent.
   The incidental comments for the patient such as: change in the reference values or change in the test method will be time limited at the user's request. When deleting the comment, make sure that it retroactively remains in the system.
4) If the selected test requires additional data, a window will open that will allow the data to be entered based on the setting in the system tables. For example, in the protein urine test, the volume and collection time must be entered to calculate the protein concentration. This window will be flexible and can be defined by the system administrator and laboratory director. There will also be an option to define a sub-laboratory.

e. The party ordering the test can add (scan) test forms, medical diagnoses or any other document.
f. The system will include tables of findings / diagnoses as well as a smart search mechanism that will allow codes to be located through unlimited free text.
g. The system will support the smart and automatic ordering of test profiles:
   1) Based on the sending party
   2) Based on the time when the tests were ordered
   3) Based on the ~~barriers~~ values to be established by the laboratory and the department
   4) Based on the patient's history

The profiles will be defined by super user – the system administrator / laboratory director / unit director in the laboratory.

h. The system will allow the tests to be ordered from various laboratories on the same order screen – for example, tests from the chemistry and hematology laboratories along with tests from the microbiology and pathology laboratories.

i. The system will allow for the entry of several sending parties and the display of up to 3 contact telephone numbers for each sending party if a telephone message is necessary.

j. For an external patient, the sending party will remain permanent, derived from a table containing external organizations' details.

k. The system will allow the same test to be ordered from two different laboratories.

l. The party ordering the test can indicate its request for manual confirmation only if the test has automatic confirmation.

m. The system will alert the party ordering the test of any previous (valid/unexpired) tests of the patient and will display the details of these tests (including previous results) when ordering. The system will allow an unexpired test to be defined by department, result, age, sex or any other parameter. The system will allow automatic rejection of an order or may require confirmation from senior staff if the same test was recently ordered.
The criteria for validity (expiration period) of a test and the parameters for rejection / requirement for confirmation will be defined by a super user – the system administrator / laboratory director / unit director in the laboratory.

n. In case of any concern regarding the handling of the sample, i.e., any concern of AIDS, CJD or hepatitis, the information will be automatically retrieved from the medical file. The user can also enter a relevant comment (such as “Caution when Handling the Sample”) into the system that will be visibly displayed on the screen.

o. The system will display comments regarding the collection of the sample / control to be written by the party ordering the test for specific tests (such as coagulation) for the laboratory / field, the comments will be predetermined based on the bank of comments that was entered into the system or in free text. Every laboratory will have the option of adding comments to the bank based on user authorization.

p. Once the order has been created, the system will recommend the quantity and type of tests / material needed to perform the tests as well as the laboratories or workstations to which they must be sent.

17.2.5. Bulk ordering of tests – ordering party in a laboratory

a. For an ordering party in a laboratory, the system will allow for a consolidated reception of orders and samples. The system will allow selecting the tests to be performed from a sample screen or selecting the tests to be performed for this sample from a test screen.
b. The system will support order details to be fixed in the bulk orders. If several tests are selected for a patient, the ordering party will select the patient details only one time. The ordering party will not be asked to select / enter the patient details for every test.
c. The system will allow tests to be added to several orders at the same time in accordance with the criteria or the existing work list.

17.2.6. Addition / update / cancellation of tests

a. The ordering party can add or cancel tests and may update the patient's details and tests both before and after confirmation of results (authorization-depending).
b. The system will provide an option to change / add a type of sample in accordance with the test process. For example: DNA extraction from blood or stool, etc.
c. The system will allow the user to order repeat / additional tests on the sample, on the same device or in another device, in the same laboratory or in a different laboratory.
d. When adding tests, the system will save the date, hour and create an order. Furthermore, the date on which the test was added will be documented in a manner that would allow for the separate measurement of the TAT of the additional tests.
e. The ordering party can add tests to a sample, and a sample to an order even if all of the originally ordered tests were conducted and distributed. The addition of tests for a sample will be limited by time based on the type of test and activity of the performing laboratory.
f. The system will not allow an order to be deleted or the patient's details to be changed following confirmation or distribution of the results. The only option to cancel an order is rejection, i.e. registering the order status as rejected.

17.2.7. Electronic orders from external parties

Authorized external parties may electronically send work lists directly to the system. The system will, through an automatically activated independent and computerized process, create orders for these lists.

The process will check the patient's settings in the hospital and, when necessary, will even convert the order codes to standard codes in the hospital.

17.2.8. Special orders

a. The system will allow for the receipt of samples not solely based on the patient's name, e.g. sample marking, criminal case number, prisoner number, number for various studies. A search may be conducted based on these fields: sending party, range of dates or the required test. The system will also allow orders and samples to be accepted from external parties, such as defense officials who wish to maintain the confidentiality of the patient's details. In these cases, the "employee" (or reference) number of the referring party will be entered as another key, and the entry of all details will not be required.
b. An option will be available (depending on authorization) to change the date and hour at which the order was entered and the sample collected. Future orders will be allowed whose sample status may be tracked ~~-~~(early order, in progress, concluded, approved, distributed). The system will block or correct the data during a current attempted collection for a future order.
c. For special samples such as displays or customers such as: rehab centers or defense services, the fields for name of physician/ sex / date of birth etc. can be changed to fields that are relevant to the customer.
d. The system will allow for "anonymous patients" to be entered by managing temporary numbers (e.g. during a mass casualty incident) and the option of consolidating files once the event has concluded, all of which interfaces with the hospital's patient management system.
e. The system will support a search of all details entered in the order including the patient's name, ID No., Case Number, Sending Party, Passport Number, Reference Number.

17.2.9. Order Integrity Test

a. The system will allow the activation of blocks or the issuing of alerts regarding orders for tests from external parties when information is missing. For example, the blocking of therapeutic drug monitoring or the issuing of an alert on the absence of a financial undertaking to perform the tests.
b. When placing the order or adding a test for a patient, the system will display the name of the insurer to verify that all tests are covered under the agreement with that insurer.
c. Some tests require the approval of a professional/administrative party (for example, an infectious disease specialist). Orders for these tests will be suspended until the approval of the relevant party is received.
d. The system will displayallow the previous result to be displayed to the ordering party. The ordering party and its decision onwill decide whether to place a newn order. will alert the

~~ordering party of a test for which there is a resu~~based ~~It~~ For specific tests (to be defined) , the system will issue an alert if they weren't ordered within a period of time (to be defined) ~~in addition to the existing result~~.

e. The system will display automatically / upon demand previous results for the same patient, from other laboratory cultures or tests.

17.3. Work processes in the laboratory

17.3.1. General

a. The system will allow two types of confirmation of receipt of samples (automatic / manual).
Automatic confirmation – Sample reception and distribution device (Sorter) / the test device receives the test tube and dispatches to the receiving system.
Manual confirmation – a laboratory staff member reads the barcode on the test tube.

b. The system will check the match between the order and the sample. For example: the system will compare the sample type that is suitable for the tests with the type of sample received in the laboratory, including preanalytical conditions such as: ice and darkness.
For barcoded test tubes – the system will check barcode compatibility with the type of test that was ordered. The center itself defines the compatibility required for the center / laboratory / unit in the laboratory.

c. Once the samples are received in the laboratory, the system will display the comments of the ordering party – only the comments that are relevant to the laboratory.

d. The system will support the double reception status – sample reception at the reception center and pre-analytical processing, and its later reception in the performing laboratory.

e. The system will support a display of the list of samples to be handled at every station and for every user, and will manage the work while recording the relevant data.

f. The system will display the samples that it is handling, the handling at the station and other details such as special instructions, comments, etc. to the user at every stage. Every screen will be adapted to the stations' activities and the system will support the performance of the tests.
Among the items to appear will be the reception data, numbering, special requested tests, reason for the referral, the referring party, etc. as to be established during the detailed solution design stage.

17.3.2. Future tests of samples received in the laboratory

a. The system will support the reception of samples for future tests that are not performed that day.

b. The system will support an automatic update or a manual update by a user of the date and time the test tube was received for future orders that arrived early.

17.4. Sample Identification

a. Every sample will be assigned a unique ID number that links the sample to the order. The patient will be identified by case no. and/or ID No. The system will support the creation of several samples in one order.
b. Some of the sample vessels will be ordered from the manufacturer with a unique sample number imprinted on them, in these cases the system will support scanning the sample number imprinted on the sample vessel and will affix this number to the order.
c. When the samples are not numbered in advance:
   1) The system will automatically number the sample or, alternatively, the user will enter the number into the system either manually or through a barcode reader from prepared labels.
   2) The system will generate barcode labels with the sample number or any other ID number to be determined during the detailed solution design stage, based on the format and quantity to be defined at every station.
   3) The number may include a serial number along with letters to symbolize the sample type, laboratory, station, etc. The system will allow the barcoded sample vessel to be automatically associated with individual tests or a set of tests.
   4) The system will consecutively number orders, but the order may also be manually numbered and not in consecutive order.
d. The system will allow the laboratory to add an additional internal ID number to the prenumbered sample number, whereby the system will print another ID number that will be entered into the system in addition to the main number indicated on the sample vessel.
e. When the sample is collected from a patient who is not identified in the system (such as test of breastmilk for infant, fetal samples in utero, pre-insemination sperm tests or tests of external organs). The user will enter the ID of the “passive subject” and the results will be retained in the system for both subjects.

17.5. Performance of the test

17.5.1. Performance priorities

a. The system will set the priorities for performing the test based on fixed criteria such as type of test, referring unit, etc.
b. The system will allow the user to manually change the test priorities.

c. The system will allow the definition of several levels of urgency based on the types of tests / departments and other criteria.
d. If the test is marked as urgent, the system will monitor it until the result is distributed and will clearly alert the user in the laboratory and other recipients to be defined of any delay.

17.5.2. Work method

a. The system will allow for the testing of a single sample or work according to work lists as specified below.
b. The system will allow for the simultaneous testing of various dilutions for the same sample based on the user definition for many of the devices that are part of the group.
c. If a manual dilution is ordered, the dilution factor can be entered when creating the demand for dilution and not only during the stage in which the result is received, including from devices that are part of the group.

17.5.3. Work lists

a. The system will support work with work lists, will manage the transfer of samples to devices and will support the rerouting of a sample for testing following a demand for retesting or a device malfunction.
b. The work list format is also used to enter and/or confirm results for every sample in the list. The system will allow work lists to be prepared according to an order / sample / test / reception / previous results, etc.
c. The system will make it possible to simultaneously add uniform comments to all components participating in the work list.
d. The system will allow for the work list to be flexibly defined based on every parameter and status. For example: orders for tests that are still open in the system, samples with future tests, tests that were performed and demands for retesting, as well as tests that were added to an existing order. The lists will be presented in order of the user definition, which is based on the order of receipt or urgency or any other parameter
e. The system will allow work list settings to be saved by test, device, sample number range, performing party, urgency of the tests, flags, order reception time, batches of the reagent performing the test, etc.
f. The system will display the work list in a flexible format of the laboratory's choosing. The display will include the various fields selected by the user such as: demographic details, order reception date, sample number, order number, test result, flags, status, time of confirmation of

receipt, time of confirmation of the result and its receipt from the device, sending party, volume of urine sample, field of reference and units of the test performed, archiving of the test tubes after testing.

g. The work list will be displayed on the screen and printed at the user's request. As a default, the printed list will be identical to the list displayed on the screen. The system will allow flexibility in displaying work lists including change in page order and classification, with the user being able to reprint the list at any time.
h. The system will allow the work list to be exported to Excel or PDF and printed.
i. In the work list, the user can insert a comment for a sample / test, for all tests for a sample and even for the entire list.

17.5.4. Work at the single sample level

The system will allow direct handling of a sample without a work list.

17.5.5. Consolidation and splitting of samples

The system will allow efficient and convenient consolidation and splitting of samples.

17.5.6. Information on test kit and reagents

a. The system will allow users to enter every separate test or a group of tests (e.g. based on the work list or sub set of the work list) the test kit number in use and/or the batch of material in use, both manually and with a barcode reader. The data will be stored, and the system will facilitate data retrieval.
b. The system will incorporate an interface for obtaining this information from the various devices.
c. If the kit / material has expired, the system will block the entry and/or distribution of results. The laboratory director will be left with the option of extending the validity of the batch.

17.6. Results

17.6.1. General

The system will support manual and computerized receipt of results as well as manage the monitoring of samples sent while alerting the user if the results have not been received within a predetermined period of time. Each type of test may have a different period of time.

17.6.2. Reference ranges and abnormal results

a. The system will allow results to be dispatched to the patient's file while retaining all existing details in the results report (e.g. comments, graphs and reference ranges)
b. The system will allow for the definition of reference ranges, panic, telephone report, automatic confirmation, by age, sex, sending party and any other parameter to be defined. An option will be available to add a formula and the patient's history in the definition of fields.
c. The system will support a display of alerts regarding abnormal results based on the user's definition, including exceeding the reference range, panic result, telephone report, incompatible with the history.
d. The system will allow pop-up windows to document a telephone report in accordance with the user's definitions.
e. The system will support the cancellation of the need for telephone notification if viewing of the results in the digital medical file has been approved.

17.6.3. Retesting

If necessary, the user can revert the test to performance status (once the test has been performed), while noting the specific reason and the system will allow the change of status.

17.6.4. Reception and verification of results from devices

a. The system will allow for the reception of results in two ways:
   1) Manual entry of findings and results of some or all of the stages of the process
   2) The reception of results via automatic transmission from devices while using a dedicated interface for the devices
b. The system will dispatch results once they are compliant with all quality control rules (e.g. expiration of reagents and controls, functionality of the controllers)
c. The system will support an automatic or manual release of normal results according to the laboratory definitions and type of test.

d. The system will confirm through Delta Check (absolute and relative increase and decrease values), the integrity of the result, and the user can manually confirm.
e. The manual consolidated entry of similar results to many tests on the same sample will be allowed (e.g.: positive / negative). Upon confirmation of the result, an automatic or manual reflex test will be possible.
f. In any case, the approving party will digitally sign the confirmation of the result.
g. The system will support verification of interim, partial and final results via manual entry and/or from devices.
h. The system will support reception of results in a variety of formats such as: images, image to data conversion, reception of 2D and 3D graphics, and various types of data including free text and the option of receiving PDF and various image formats JPEG, TIF, GIF.
i. The system will make it possible to display, as part of the results, tables from Excel or from analysis software using a dedicated interface.
j. The system will allow for the creation of a hierarchy of approval for test processes and results (interim and final). The hierarchy may contain several levels and will be determined according to criteria to be defined during the detailed solution design stage.

17.6.5. Displaying and distributing results

a. The system will allow for information to be stored and displayed in various formats: numerical, text, image, etc. It will also allow for documents to be scanned and added to the results.
b. The system will generate a Results Report to be distributed to all parties defined in the sample order using the method defined for each party (print, interface with medical file system, fax, secured email, etc.)
c. The system will identify results with the sign < or >and will insert an asterisk for any value that exceeds the reference range. The system can convert a numerical result from a defined field into a text result or index (positive / negative / above...)
d. The system will allow for results to be manually entered if the value is lower than the lower threshold in the reference range.
e. The user will enter the test results as text and/or in code. The system will support encryption through standard codes or from a preformatted table.
f. The results report of dynamic tests will display the time points at which the samples were collected as well as the sample numbers. The results will also be displayed in a graph.

g. The system will distribute partial / interim results and differential partial distribution in accordance with the test definition.
h. The system will allow viewing of results of related tests or previous results of tests before / during their order, even if the tests belong to different laboratories to allow the ordering party to decide whether to order the test based on past results or results of related tests that make the ordering of the test redundant.
i. The system will display test results in numerical values, text from defined tables, free text, and incorporation of formulas, codes or any combination thereof.
j. The sample screen will display the list of tests and their results for that sample, historical results of those tests and of related tests, units, reference values and comments. Also, graphs transmitted from a device should be displayed where needed (e.g. scatter plots from CBC analyzers).
k. If the result includes a formula that requires external parameters, the system will open a window for the user, allow their reception and perform the calculation, or allow retrieval from another laboratory or from the patient file. The system will save documentation for all external parameters even if they are not to be dispatched.
l. If graphs or images are dispatched from the devices in the system, the width of the columns on the sample screen to be determined by the laboratory will remain fixed for all samples.
m. Results are recorded once the test has been completed. The recording is computerized (when the test was performed on a device linked to the system) or manual.
n. The system will allow the blocking of the transmission of results for tests that were performed on the device but not pre-ordered.
o. The system will allow the blocking of the transmission of some results from a panel.
p. Individual and consolidated results reports can be sent by fax or via secured email.
q. The system will allow reporting via **SMS** directly to the mobile phone of the physician who ordered the test or to a dedicated number to be established by the Risk Management Unit or any other channel to be decided upon by the Risk Management Unit in the center.
r. The system will identify that the notice reached its destination and was received. For example, the email was read, the fax was successfully sent, etc. If the report is not confirmed within a defined period of time for every test and the referring unit, the user will receive another alert and will handle it with the department or Risk Management.
s. For special tests, it will be possible to determine that the results will be immediately distributed to the physician and after a delay to the patient, in order to allow the physician to discuss the results with the patient.

17.6.6. Report of abnormal results

a. Any abnormality / error that was identified in the results report may be corrected / amended along with a comment and documentation of the abnormality simultaneous with the immediate notification / alert of the customer.
b. When necessary, a window for telephone report with the abnormal result will open in which the laboratory staff member will complete the report details.
c. The details of the reports will be stored on a log that can be displayed when necessary.
d. If necessary, the report will be documented for risk management.

17.6.7. The results report for "Notifiable Diseases"

a. The Ministry of Health is working on creating a new system for managing epidemiological studies for notifiable diseases.
b. For the system's benefit, various information, including the results of laboratory tests, must be collected.
c. The results to be dispatched will pertain solely to a group of specific diseases.
d. Only positive laboratory results will be relayed- no negative results will be dispatched.
e. Data encryption will comply with international standard SNOMED, LOINC, etc.
f. The results will be dispatched to the national database in compliance with the FHIR standard.

17.6.8. Changing results after distribution

a. If a result is changed after it has been distributed, the documentation of the change will be saved in the system. In this case, an automatic note will be added to the field that was changed "Result Changed after Distribution".
b. The laboratory can choose whether to allow the change to be viewed.
c. The system will support a notice to be sent to the ordering party (mail / SMS to mobile phone), to display a message to the user that needs to update the ordering party by telephone (similar to a panic notice)
d. The Super user can define that in certain cases, the system will automatically send a notice to the ordering party.

17.6.9. Printing the results

The system will support, based on user authorization, the results to be printed for the customer with a comment or without a comment.

a. The system will allow the import of the results report, graphs and images from devices such as: FACS device.
b. The system will allow the export of a results report in the following formats: PDF, Excel, word.

17.6.10. Import and export of results

The system allows for the import and export of results in the format to be determined during the detailed solution design stage.

17.6.11. Display of results

a. The results report will include a field for level of certainty (e.g. sigma value) and of uncertainty (e.g. CV%) of the test coupled with the value of the test result.
b. These values may be automatically retrieved from the quality management module of the system in accordance with the user's definition.

17.6.12. Finding the test / sample / result

The system will allow the test to be searched by the patient's name / ID number and serial number for the sample, name of the ordering party, the ordering department / clinic, etc. as established during the detailed solution design stage.

17.7. Control of work processes in the laboratory

17.7.1. Monitoring orders and samples

a. The system will manage the different statuses for orders and samples as well as automatically update the statuses of every procedure performed and when the sample is being transported from one laboratory to another. The order / sample status will be displayed on all relevant screens, with a key for information retrieval. A determination will be made for every status on whether or not causes the results to be distributed and or in the order being closed.
b. The system will allow flexibility in the definition of various statuses for the stages of work based on the user's demand. For example: first confirmation of receipt at the laboratory hotline and second confirmation of receipt in the performing laboratory.

c. The system will allow for samples / orders searches based on various fields, such as: all fields defined in the "Sample Reception" chapter and by the sending party, laboratory, dates, hours performed. An option will also be available to classify every existing field that contains information in ascending or descending order.
   The exact fields will be defined during the detailed solution design stage.
d. Until results are received, the system will allow comments to be added in code, or unlimited free text. The update will be made on an individual sample / test / subject or a group of samples / tests / subjects based on the field to be determined. For example, a change in the status of samples in the work list due to manual cancellation of a test and retesting.
e. The system will allow an "expiration date" to be defined for certain tests. If by this date, the test result has not arrived, it will close and a relevant notice will be sent to the user in the laboratory / ordering party in accordance with the definition.
f. The system will allow alerts at the employee and manager level based on the user's definitions of a delay in closing the response or a transition between one status to another.

17.7.2. Auditing / LOG **Activities**

a. The system will simultaneously retain, in addition to the test results, a history of events that will contain information about the test such as the identification of the performing party, the device on which the test was performed, the batch of the reagent in which the test was performed, the quality control for the test, the expiration date of the reagent, the time the test was performed, device note and any detail related to the sample/test. This data is printable. The fields to be recorded will be determined during the detailed solution design stage.
b. The system will receive device comments on the test and sample level (including dilutions, repetitions, deviations, etc.) and will document them even if they are not for dispatch.
c. The log can be displayed in various cross-sections.

17.7.3. Workloads and timetable

a. The system will facilitate ongoing monitoring of workloads at the level of the various laboratories: the entire laboratory, specific workstation and performing party, level of urgency and will display to the user the status and will provide the capacity for transferring tests between various work stations and even between various laboratories. Status display will be flexible based on the user's demands and the information to be displayed on the online dashboard.
b. The system will clearly distinguish between tests that were ordered via an original order and tests that were additions (key parameter in calculating TAT).

c. The system will allow a **super user** to define the units for TAT calculations – minutes, hours or days. The system will display the TAT compliance rate established by the laboratory.
d. The system will display upon demand the results of the periodic round time (daily, monthly...) with a cross-section that can be saved.
e. The system will allow the calculation of a round of tests on working days only, excluding Saturdays, holidays, evening/night shifts.

17.7.4. Multiple samples in one order

If the order includes multiple samples, the reception of samples, the running, confirmation and distribution of tests will be carried out separately for each sample, regardless of whether the other tests in the order were completed. In other words, every result is distributed, regardless of the availability / non-availability of other results in the same order – a "partially differential" distribution policy.

17.7.5. Transfer of samples between devices

a. The system will allow samples to be transferred from one device to another (from the combination of devices) to which the tests are referred.
   As in any stage in the system, this event will be documented in the history of events that the sample / test underwent.
b. The system will allow the repetition of tests with a different technique, while saving both the original and repeat results as well as techniques.

17.7.6. Clinical alerts and activities

a. The system will issue alerts regarding tests / samples that expired, the alert will be issued at the employee level and/or the director level.
b. The system will allow for automatic ordering of a reflex/rerun test based on the comment received from the device.
c. The system will issue alerts when tests are not performed within the defined period of time.
d. The system will issue alerts for tests that were performed by the device when the sample is without an order.
e. To alert of any possible problem in the device performing the tests, the system will calculate the average results of selected tests in a defined period of time (e.g. electrolytes).
f. The system will issue an alert of any problem in any module including distribution of results

g. The system will display the status in every stage of work to the user, including such data as samples that were received and not tested and unconfirmed results in the form of a dashboard
h. The user will select the record to be handled and the system will automatically switch to the relevant work screen. Once handling of the record has been completed, the user will return to the status screen, which will be updated accordingly.
i. The system will allow comments to be entered at the sample / order / test level.
j. The system will support the validity (expiration) of a test tube if this information is read from the sample barcode and will not allow a test tube that has expired to be associated with an order.
k. The system will allow to define delta checks for individual parameters.

17.8. End of shift

The system will generate fixed end of day reports for the station, such as a laboratory log and list of samples waiting for delayed tests.

17.9. Working with external laboratories

The system will allow tests to be shipped to an external laboratory to be carried out and will generate a report of transferred samples ("Delivery Notes").
The system will allow for samples from external parties to be received in accordance with the definition of the test and at the user's request.
The system will support the generation of a test results report in the format of a letter.

17.10. Inventory management – Advantageous

a. The system will contain an interface for laboratory inventory management software.
b. Inventory management will involve a comparison of the use of reagents, other disposable substances and disposable equipment as determined for each test in comparison with inventory levels.
c. The system will allow alerts to be issued regarding low inventory levels and expiration dates of reagents.
d. In the blood bank, the system will also enable management of blood products inventory.
e. The system will support an interface with the inventory management system for other products, if there is need in the future.

17.11. Reports

a. For all reports, the system will allow for the definition of criteria, such as range of dates, medical center, laboratory, etc.
b. The supplier must create reports based on the list elaborated in Appendix C17.11 Reports and as elaborated in this document.
c. The system will allow for the generation of reports and the monitoring of telephone reports and panic values.
d. The system will allow for the generation of activity reports including a report for premium calculations.
e. The system will allow for the generation of sample count reports for billing based on the guidelines described in these tender documents.
f. The system will allow for financial accounting and/or an interface to an accounting system.
g. System reports can be exported into Excel and PDF formats.
h. The system will allow the screen display, printing and mailing of the report.
i. The system will allow digitally secured distribution of reports (secured email or laboratory / hospital website)
j. The system will allow for the creation and editing of response templates by laboratory staff.
k. A user can sort the report by selected fields.
l. The system will include a report generator for the user and will allow the **Super user** to define additional reports.
m. The system will allow creation of flexible reports based on the tests, results, sending parties, reception time, pickup time, time of confirmation of receipt, time of result transmission, dates, disqualifications, sample comments, result comments, as well as the employee who performed the test or confirmed the result. The system will allow for reports to be generated for lengthy periods of time (years) and large quantities of data within a reasonable amount of time.
n. A results report may be generated in the format of an expert opinion as required by the court:
    1) Headline “Expert Opinion” +-
    2) Cover page that includes the expert’s accreditations, with the option of choosing from a list of several experts. This page will extract data from `LIMS that will be inserted in the text: sending party, laboratory number etc..
    3) Report of the patient’s results.
    4) Scanned documents can be attached to the results report (such as Civil Servant Certificate – CSC)
o. The system will also include a replication of the database as specified in the Technology Chapter.
p. The system will allow for reports to be generated based on the testing device (or model in the device).

18. Microbiology Laboratory

18.1. General

a. All processes described in Cluster of General Laboratories and General Processes“, Section 17 above are also relevant for this laboratory. This chapter details additional requirements specific to the Microbiology Laboratory.
b. The description below will primarily focus on the bacteriology laboratory as the serology and virology tests are associated with the “General Laboratory Cluster”.
c. The referring unit (largely) indicates the necessary test. Additionally, if the result in the first test is positive, additional tests will later be performed. For example, if the culture was positive, tests will be conducted to characterize the bacteria and its sensitivity to antibiotics.
d. The final laboratory result is immediately issued, after one or several days, and interim results are also used.

18.2. Reception of an order / sample

The process is as specified in the section on Work processes in **the laboratory 17.3** above in addition to the requirements specified below**:**

18.2.1. Specifying the material in the sample

a. What the material is (e.g. fluid)
b. The collection site (e.g. abdominal cavity).
c. Side (right / left).
d. Sample collection device (e.g. test tube, swab, sterile vessel).
e. Every laboratory can choose which fields will be mandatory or optional.
f. The laboratory also tests environmental materials such as soap, milk and water from the hospital. The ID field in these cases will be optional, and the system will provide another key field.

18.2.2. Reception of several samples

The system will allow for a bulk reception of several of the same type of samples, from different places in the body.

18.2.3. Transfer between sections

a. When samples must be tested in more than one section, the system will support two work methods:
1) Splitting.
2) Routing between sections

b. Routing to stations (sections) is manually performed by the user, e.g. during the reception, or automatically by the system according to a decision table that defines the order of work in the laboratory based on the type of material, test (if mentioned), etc.

18.2.4. Work notebook

a. The system will support documentation of the work stages in an electronic worksheet. For example, the results of the oxidase test will be included only in the electronic workbook while identification that relies on it (e.g. Pseudomonas aeruginosa) will appear as viewable data.
b. Every workstation will have a relevant menu adapted depending on the nature of the work, that will include a menu of tests and results for every test. An option will be available to select the data that will remain in the chart but not distributed for viewing.
c. Data may be entered in a work notebook on a separate chart or on the same chart, in which the viewable results will be entered. The work notebook data may be visually distinguished from viewable data by font colors, highlights, etc.
d. Data in the work chart will be entered according to stages that define the work status of the sample ("status"), so that work progress can be monitored.
e. Transition between the stages, based on the day of work on the sample will be automatically. Entering results (e.g. following identification of the bacteria in a culture), will be based on an encrypted table or done manually by the employee.

18.3. Reception of results from devices

a. In the laboratory, the following results are entered:
   1) Macroscopic test.
   2) Identification of microorganisms (bacteria, fungi, etc.).
   3) Sensitivities to antibiotics.
   4) Supplementary tests (e.g. PCR results)
   5) Basic data that will not be distributed for viewing (e.g. sequence files, images).
b. The user will enter the result and the testing technique (if necessary).
c. The system will confirm receipt of the interim results such as – "No growth, sample incubating" or "There is growth, bacterial identification performed" and will display them on the screen to the referring unit. Automatic deletion of interim results may be defined once the final result is received. For example, an interim response of "Sensitivity test will be sent" will be automatically deleted (or following employee confirmation) once the sensitivity result itself is entered.

d. The system will allow results to be received for every separate stage, or continuously, and perform the confirmation either upon reception or separately.

18.4. Sensitivity tests for antibiotics

a. The system will display a list of types of antibiotics that are relevant for the bacteria. The user can add to the list, if necessary, based on the user's level of authorization. Alternatively, the system will receive the automatic and computerized entry of sensitivity results by interfacing with a sensitivity test device with an option for manually entering the changes.
b. For every antibiotic, a sensitivity test result may be entered in two columns: numerical value (MIC) and threshold value.
c. The user or system will enter the bacterial sensitivity to the selected antibiotic. It is not necessary to enter data for each antibiotic or in any specific order.
d. The system will allow for the definition of rules for reviewing the entered data. For example, if the sensitivity result is improbable, the system will issue an alert and require a relevant response.

18.5. Confirmation of results

The system will allow the users to order additional tests and/or to send the sample to the next section for continued treatment, in the results reception / confirmation screen. If additional tests were ordered in advance and/or continued treatment is known based on the results of the current test (according to a predefined table), the system will automatically initiate additional tests and move the sample and its treatment to the next section.

18.6. Distribution of results

a. The laboratory results chart is complex and will include all detected bacteria and their sensitivities to antibiotics. The chart structure will be defined during the detailed solution design stage.
b. The system screen will display the bacteria's sensitivities to antibiotics in the order to be determined at the laboratory level. For example, the order of the names of the antibiotics, the frequency of use or in ascending order of costs of the substance.
c. The system will support reports to the Ministry of Health through designated reports, or any other authorized entity, based on various parameters, such as: station, sampling site, type of material, bacteria / fungus, and sensitivity to antibiotics. The definition will be parametric and flexible, at the end user level that includes full demographic details of the patient (age, address, etc.)
d. The system will include an option of distributing results via digital fax to more than one party and the possibility of distributing results by e-mail/secured e-mail

18.7. Status management

a. The system will manage statuses at the order and sample level.
b. The statuses in use are unique to the Microbiology Laboratory. For example, a macro test, growth, bacterial identification, sensitivity test, coding, etc.

18.8. Logic tests and alerts

a. The system will allow the definition of validity rules to review the correlation between the bacteria found in relation to the sample and the patient. For example, the dysentery bacteria that was reported for a sample collected from the ear would be identified as unlikely. The system will manage control according to tables defined by a super user.
b. The system will allow for a definition of validity rules for reviewing the correlation between the bacteria found in relation to the sample and the patient. For example, if a bacterium is found to be sensitive to an antibiotic that is normally not sensitive to, a normal alert of “Possible error, reconfirm" will be received, and if this occurs in several tests within a defined period of time, a more serious alert will be received noting “Repetitive problem in identification / susceptibility test" .
c. The system will issue an alert on the presence of certain bacteria in the hospital or in a certain referring unit based on a predefined table. For example, if a certain bacteria is discovered in a certain number of patients in the hospital, or a different number of patients in one department, or in the case of a certain bacteria whose identification will trigger a special alert.
d. The system will require continued treatment as defined for the deviation that was found. For example, the system will require two confirmations (one by an additional employee, and even an authorized employee only) or will send an alert to the laboratory director and even to the Ministry of Health, etc.

18.9. Queries / Reports Software

a. Below are the unique requirements of the microbiology laboratory regarding reports and queries.
b. Performance time reports: the software will be capable of generating performance time reports that include all interim times of the microbiological test.
c. The software will support selection of data for retrieval based on complex cross-sections, including demographic data (age, address, department, hospitalization date, etc.), test data (e.g. collection date, collection source) and full results data, including type of bacteria and sensitivity test results for every antibiotic that was tested.
d. The system will support the generation of rejection reports and monitoring based on various cross-sections.

19. Special immunophenotyping and molecular tests in the Hematology Laboratory

a. Depending on user authorization, the system will allow the type of sample received (bone marrow / blood) as well as the patient's particulars to be changed without rejecting and reaccepting the sample.

b. The system will display a table of genetic codes / mutations / amplicon / translocations and various genetic disorders that will allow data to be added. The table will be prepared by content staff in the Hematology Laboratories (with authorization) with everyone's cooperation.

c. The system will allow test results to be received from several analytical software while interfacing with the programs.

d. The system will allow results from analytical software to be received including names of genes, names of mutations and their findings as data that can later be retrieved, monitored, statistically extracted for the subject and for studies.

20. Pathology laboratory

20.1. General

a. All processes described in the "Cluster of General Laboratories and General Processes"; Section 17 above apply to this laboratory as well. This chapter details additional requirements specific to the pathology laboratory.
b. The system will display customized screens with relevant content for every workstation. The name of the screen designated for the station will be the station name. The information to be displayed will be relevant to the station.
c. The pathology laboratory management system will hierarchically display the case, the quantity of samples, the existing quantity of cassettes and slides.

20.2. Sending and receiving samples in the pathology laboratory

a. The system will allow orders for pathology tests in the clinic's computer system (departments, clinics…); the system will interface with existing systems in the hospital (Chameleon, VYSION, RIS, etc.).
b. The order for tests in the system will include an interface with the clinic system to avoid duplicate writing of information in fields known in advance, if it is not possible to include such interface the system should include all clinic diagnoses.
c. The system will allow for sample locations and the identity of the responsible party during the shipment to the laboratory to be tracked.
d. Tracking of the sample will require a reading of the unique barcode number that is to be affixed to every sample in advance by the sample collector.
e. The computerized documentation of the persons handling the sample will include the members of the clinic staff / sending department, the orderly / person transporting the sample, the recipient of the sample

at the Pathology institute (and later the remaining staff handling the sample at the Pathology Institute until a response is received).

f. The delivery system will support real-time control of the integrity of the material while monitoring the location of every sample, as well as the identity of the person responsible for the sample.
g. The system must support the monitoring of the shipment of samples in coolers while also monitoring groups of packaged samples or individual samples.
h. The system will allow for alerts and notices to be mailed (will monitor message reception). In the event of a delay in the transfer of samples, an alert will be sent to the sample recipient or to other parties according to the setting.

j. The system will allow information to be sent on the location of samples ready to be shipped in the hospital in order to streamline the delivery processes in the various departments (currently, generally based on a regular round with no reference to the quantity or urgency of samples). A dashboard is required to both support the transport personnel as they collect the samples and to display to the laboratory the samples that were created and that are waiting to be collected to enable planning. This information must be displayed online.

20.3. The Gross Room / **grossing**

a. Depending on the clinical information on the type of material and organ (that was entered into the system by the clinician), the system will automatically upload templates (forms) that will instruct the recipient of the material on the required test and data to be compiled. The requested template may be modified by the user at this station by choosing from a list of possible templates if found incompatible or by adding free text. The system will allow audiotyping (such as with a Dictaphone).
b. The system will allow pop-up reminders / requests to order additional stains for certain types of materials (i.e. the system will remind the recipient of the material to order specific stains for a kidney/liver biopsy when testing liver function).
c. The system will support macro camera interfaces and insertion of macroscopic images in the image file.
d. The system will support the interfacing of pathology laboratory imaging systems to locate clips, and to insert images in the pathology laboratory's image file.
e. The system will support a voice recognition system for the drafting of a macroscopic and microscopic description.
f. The system will allow for the tracking of delayed samples that were left in the gross room for treatment with various solutions to be monitored. Within these confines, a report may be generated or an alert

uploaded to check the condition of the delayed samples. The delay may be entered through a formatted button.

g. The system will allow documentation of the basket in which each cassette is inserted, and of the tissue processor in which every basket is inserted.
h. The system will allow interfacing with basket scanning (using basket scanner) and will allow the status of every cassette to be changed to "Inserted in the Tissue Processor".
i. The system will allow interfacing with various types of cassette printers and will allow for a cassette to be printed from a certain sleeve – based on the selected parameter (such as stomach sample – Giemsa stain – designated cassette).
j. The system will alert the director of any double printing of a block.
k. Case verification – to open a case, the pathology resident / assistant must scan the sample barcode and the patient ID barcode. Only after verification will the case open for a macro description. Confirmation of a match between the sample and the patient's ID on the form or on the sample label is critical. Alternatively, the system will allow the scanned form against the scanned sample container (when working with forms).
l. Upon concluding the case, all printed cassettes must be scanned. If a cassette was found to be incompatible, the system will issue an alert and not allow the case to be saved. If not all printed cassettes were scanned, the system will not allow the case to be saved before the surplus cassettes have been deleted

20.4. Histology

20.4.1. Removing samples from the tissue processor

The system will allow baskets removed from the tissue processor to be scanned with a designated device. Once scanned, the cassette status will be changed to "Removed from the Tissue Processor".

20.4.2. Embedding

In the Embedding screen, the system will support the continuous reading of the barcode on the block (with no need to use a mouse) while displaying the relevant information (type of material, special embedding guidelines that was sent by the recipient of the material at the previous station, the number of tissue units). the system will change of block status during its reading to "Embedded".

20.4.3. Sectioning

a. The system will display the creation of slides by reading the block and printing of the matching label / slide. The system will be able to alert the employee sectioning the blocks of any material that is not intact if some of the blocks of the case did not attain the previous status.
b. When taking the blocks to the sectioning station, the laboratory staff will change the status of the blocks to “Removed for Sectioning” and if the entire case is not removed, an alert will pop up. Status will be changed by scanning the blocks.
c. The system will alert the sectioning employee if another employee has already begun sectioning the blocks of this case to ensure that the same employee handles all of the samples and blocks of that case.
d. When scanning the block at the sectioning station, a slide will be created with a sectioned status assigned and a slide label or a slide will be printed.
e. The system will support interfacing with the slide printer or slide label printer.
f. The system will support interfacing with the automated sectioning system. The system will generate a work list for the automated system so that it will be possible to know which blocks were entered or are about to be entered in the automated sectioning system.

20.4.4. Staining

The system will support interfacing with the HE stainer. The system will change the slide status to ‘Stained’ once it has been inserted in the stainer.

20.5. Digital pathology

a. The system will support advanced communication protocols and will be updated whenever necessary. The current requirement is for an HL7 interface.
b. The system will support a two-way interface with the scanning hardware and software to display slide images of this software. The interface will confirm that the display is unique, i.e. the slide images of a certain case can only be displayed simultaneous with the screens for drafting macroscopic and microscopic response of the patient’s response. Every switch between patients in the laboratory management software or through the image viewer software will cause a change in the corresponding software.
c. The system will direct the pathologist within the confines of the work list to the cases under his responsibility and will indicate which slides were already scanned.

d. The system will allow the status of a slide to be changed to “Resend to Scanner” if requested by the physician.
e. When changing a slide's status to "Resend to Scanner" the image in digital pathology will be deleted.
f. Upon deleting the image in IMS, the status of the slide in the system will change to “Resend to Scanner” and if the case status was “Concluded”, the case status will revert to “In Work”.

20.6. Ordering of additional stains (immunohistochemistry, histochemistry)

a. The system will display a full screen of at least 400 possible stains that can be ordered by the pathologist. A search for the name of the stain will be simple, based on the name or part of the word.
b. Ordering stains will create slides with the “Ordered’ status in the system. The order will be displayed to the personnel responsible for preparing the additional sections. A report will be generated that includes a list of blocks that must be removed from the archive to be re-sectioned according to the orders. The work list for block retrieval can be automatically retrieved by sending it to the archive terminal. The sectioning of the blocks for special staining is assigned the status of a “sectioned” slide so that the issuing of another report will not result in additional removal of the same block. The system will interface with several different staining systems provided that the latter is capable of interfacing and will provide feedback once the staining process has been completed, after which the slide status will then switch to “Stained”.
c. The system will allow a transition between devices (the user can choose which device to send the test), e.g.: option to choose between Ventana Dako Leica Yekke and Sakura.
d. Another status will be upon the slides having been read and report of “delivery to the pathologist”, Alternately, this report will be part of the slide scan interface in digital pathology, “Scanned”.
e. Once all slides have been scanned, the status of the blocks will change to “Delivered”, and the status of the legend will switch from “Received” to “End of Laboratory” and will be displayed to the pathologist in its work record.

20.7. Frozen section

a. The system will support the making of a frozen section type block, for which slides will be made, which will be marked as frozen, with an option to print slide for them.
The system will support making touch type slides without making a block.
b. The system will support writing of an answer for one sample – the frozen sample, out of a whole case. When a sample is delivered from an operating room and arrives at the pathology institute, the surgeon’s digital test order form will be locked to editing for this sample only. Once the frozen sample is signed by

the pathologist, the sample will be blocked to editing on the pathologist's side too. At the same time, it will be possible to send more requests for frozen answers of the same case. And of course additional requests for ordinary samples (in formalin), which continue to form during an operation for the same case.

20.8. Cytology

a. The system will support managing of different interfaces of cytology samples, including a cell block or creating slides without a block. Support for different stains and different material types of this field.
b. The system will support interfacing with cytology scanners, staining devices, and printing of specific labels for cytology instrumentation.
c. The system will change the status of the slides to stained once they enter the automatic staining system (if it exists)
d. The system will support creating different slides for each staining type that is made.

20.9. Molecular pathology

a. The system will support adding of molecular diagnostic tests.
b. The results of the molecular test will be entered manually
c. The system will support attaching PDF files to an answer containing the sequencing answers from the various devices.

20.10. Pathologist interface

a. Managing of work lists showing relevant fields of urgency / clinician questions / clinical data, as chosen by the pathologist. Sorting according to these characteristics.
b. Option for marking a case as critical or urgent and review of treatment documentation when transferring an answer to the clinical entity (related to interfaces for distribution and data distribution control).
c. The work list will support displaying a list of cases under the responsibility of the pathologist by different work stages (entered, receiving material in progress, histology in progress, special staining in process, end of laboratory work, end of typing, end of physician work, editing, adding to results report, ready for signing, in progress – all statuses).
d. Advanced editing tools in the answer display screen, including display of answer templates by material type / organ / ICD codes, SNOMED codes. Option for flexible editing and adding images as necessary.

20.11. Answer delivery control

a. The system will support the transfer of answers to the health organizations' systems and to the sending physicians within the hospital or clinics and getting feedback on reading the answer.
b. The system will prevent in advance the input of a case without a sending physician.
c. It will support marking of cases that require special reporting, displaying them in an orderly table and an option for documentation of the reporting of each case.

20.12. Reports

a. The system will support displaying of images in the pathology report. It will support color displaying of the report.
b. The system will support display of performance data in a manner that will allow for continuous measurement of the service characteristics for customers – for patients – SLA.
c. The system will allow the user to track outputs, TAT data, various graphs and reports that will be defined by the user. All of the information that connects a sample or sub-sample to the identity of the performing worker and the time of performance will be available for displaying in report form as necessary.
d. The system will support display of various reports for laboratory processes and tracking of samples and their performance times so that a user may retrieve the report easily. The system will support a dashboard type display of various data as chosen by the user, for continuous administrative tracking of this data.
e. The system will support extracting graphic information by pushing to a user / administrator that will allow receiving of a situation report on the quantities of samples at the various work stages (quantity of samples in clinic, quantity of inputted samples, in histology, special staining, cytology, molecular pathology, etc.).
f. The system will support graphic displaying of deviation from the TAT set by the user.

20.13. Pricing control

The system will interface with the billing management system in a two-way manner, so that it may display the status of receiving the undertaking or will support creating additional charges according to additional tests that are performed on the sample.

20.14. Archiving

a. Blocks – when adding blocks to a digital archive, the block status will change to "entered archive"., When retrieving the block from the archive, the block's status will change to "taken out of archive".
   - Work lists (a list or immune orders or a list of orders for additional sections) will be sent automatically to the archive and may be retrieved without retyping them in the archive system.
b. Slides – when adding slides to a digital archive, the system will support interfacing and will change the slide status from delivered to "entered archive" and when taking it out to "taken out of archive"
c. Archiving – the system will support archiving processes of the source samples before burial. Removal of samples for burial and the removal time may be reported by scanning a barcode and changing the status of samples from which material is left for burial.
d. The system will support managing the treatment of abortuses / fetuses, including scanning of the various confirmations and control of removal for burial.
e. The system will support archiving of blocks and slides. The process will allow for reporting the extraction of samples for research purposes, for testing outside the institute and returning them, by scanning a barcode, including reporting the identity of the recipient. It will support scanning of documents confirming removal from the archive for these purposes.
f. The system will contain strong search tools that will allow finding of samples by various characteristics, including SNOMED codes, various texts in different fields, organ types, diagnoses or various flags.

20.15. Bio Bank – advantage

a. The system will support creating test tubes in addition to slide blocks. The status of the tubes will not affect the status of the case.
   Test tubes will have the statuses "available", "kept", "sent for research", "collected by the patient". The system will contain documentation of long-term storage of samples according to their location in freezers (name of freezer, shelf, rack, box, location in box).
b. The system will support attaching the patient's form of consent to keeping samples for a study.
c. The system will support interfacing with Biobank programs and will transfer the pathology answer

21. The blood bank

21.1. General

a. All of the processes described in the General Laboratories and General Processes Cluster, Section 17 above are relevant to this laboratory too. This chapter provides details on additional requirements that are unique to the blood bank.
b. The blood bank deals in performing tests on blood samples, harvesting of blood and blood products, preparation of blood and blood products and matching them to patients, dispensing blood components and managing the hospital's blood inventory.
c. The blood bank is very sensitive to the matter of reliability and control owing to the immediate danger of administering the wrong blood type to a patient, which requires the system to have control safeguards for all work processes.
d. The blood bank operates according to a national procedure of Israel's Ministry of Health, which is periodically updated. Therefore, the system must be built up in adherence to the procedure and the supplier is required to update the system according to changes in the procedure, if made. It is clarified that the Israeli Ministry of Health procedure is not identical to the U.S. or British procedure.
e. The system will use ISBT 128 codes in all work processes for all blood products.
f. The system will support convenient access to any activity, from all entities managed in it: subject, order, product and donor.
g. The system will support an overall view of the process in parallel to the separate statuses, to support connectivity between donor and donation, donor and unit, transplant recipient and donor, infant and mother and other details.
h. At each stage in the process, the system will check that the previous stage was done successfully and will issue an alert or block action if this is not the case. The system will provide flexibility in adding or removing alerts for a user according to the medical center's needs. A super user at the center may remove the alert/block without any need for programmer involvement.
i. All stages that require approval in the system will be operated by a user who has suitable authorization and may be approved from any workstation. There will be an option for a personal (electronic) signature

for certain actions, depending on the work procedure at each medical center. It is clarified that some actions require an individual electronic signature and are not subject to the medical center's decision.

j. The system will provide for managing information and approving it separately in each order or in a concentrated manner, for example by concentrating all answer to the blood tests and typing them in a concentrated manner, taking up and dispensing of a number of blood units together, etc.

k. The system will manage statuses of an order / sample and blood units. The system will update the statuses automatically at the end of each action that has been performed. In addition, it will allow the user to update the status by authorization proactively. The status codes and description will have a distinction of whether this is a status of the system or one initiative by the user. The status of the order / sample / unit will be displayed in all relevant screens and will serve as a key for retrieval of the information. For each status, a super user may determine whether it results in distribution of results or not and whether it results in closing an order or not.

l. The system will support a two-way interface with the systems managing the patient records for creating orders and dispensing units.

m. The system will include statuses related to administering units in a department, blood test results for patients from other laboratories, etc., and will support linking to information sharing systems such as Ofek, Eitan, Chameleon and others.

n. The system will provide for flexibility and modification of requirements in the work processes for special populations, such as: bone marrow transplant recipients, infants, operation candidates (extension of test expiration time), umbilical blood, samples not for transfusion, etc., at each stage of the sample (including after uptake).

o. The system will support conversion of data from previous computer systems: blood type, last antibody screening, phenotype, comments and treatments for a patient.

p. The system will support digital identification of system users, such as when taking blood for typing or for signing.

q. The system will generate sample / unit / cross-matching / dispensing labels according to minimum requirements that will be detailed subsequently, and which may be further adapted according to each medical center's requirements.

r. The system will support flexibility in entering tests, profiles, comments, reasons for disqualification and new products.

s. The system will support saving of all actions that are performed on a unit or sample, including documentation of performing worker.

t. In the work documents, in addition to the subject's identification numbers (case No., permanent and temporary identity No.), the sending party, identifiers (in an order screen), subject date of birth and age

and sex, the presence of antibodies and special treatment, subject-specific comments and indications for transplantation, additional test results from other laboratories such as selected count results, will also be displayed.

u. If the patient's blood type is known to the system, it will not be displayed to the user on the work screens of the first or second tester until both tests are performed.
v. The system must provide special attention to the transplant recipient population, including changing blood types and matching of blood products. The bone marrow transplant recipient population has another set of rules and different system behavior, which will be defined at the detailed specification stage.
w. The system data will be saved according to the Ministry of Health's procedures or at least for 30 years, whichever the longer.

21.2. Ordering of blood units / blood tests

21.2.1. General

a. An order of tests will not be dependent on an order of blood products but there will be a connection between an order of blood products and the existence of unexpired tests, according to the product type (requiring / not requiring cross matching), the degree of urgency and ordering party (for example allowing an operating room to order blood components even if there is no unexpired sample but not allowing an ordinary department to do so).
b. The system will support ordering of tests for a transfusion or not for transfusion and ordering of unique tests, if required. The system will mark the samples that are not intended for transfusion. All tests that are done on a subject, whether for transfusion or not and blood components that have been matched to him will be clearly documented under the same subject and from the same work screen and will be available for concentrated viewing.
c. When taking the sample and in the case of sending a sample without a form, the system will support identification of the patient using a unique wristband. The system must support documentation of the ordering party's details (in accordance with the procedure followed at that center). The system will support blocking of the order when necessary depending on the hospital's procedures.

21.2.2. The work process

a. The user will enter the subject's identity No. / case No. In the case of an existing subject in the patient management system, his data will be displayed on the screen and the user will be able to update it and complete missing details. If the subject does not exist in the database, his demographic

data and inpatient department will be retrieved from the hospital's central database (from the Patient Management System).

b. A blood products order includes identification of the patient and his demographic information, identification of the referring unit, identification of the physician giving the instruction (in an order for products, not an order of samples) and identification of the ordering party, the necessary component type (plasma, full unit, etc.), the quantity required and the treatments required for the component (rinsed, filtered, irradiated, etc.) and the expected date for using the product (for example in elective operations). The system will allow the user to enter a receiving unit for blood units that are ordered from a certain hospital unit (such as a department) and that are intended for use in another hospital unit (for example an operating room).
c. The system will support reviewing of a blood product order and a suitable alert in cases that are defined by the medical center at the detailed specification stage.
d. The system will support entering of relevant medical information as necessary, such as: known antibodies of the patient, name of the outside hospital from which the request arrived, special instructions for preparing the unit (regular ones of the patient or order specific), drugs and treatments that the patient is receiving, etc.
e. The system will support making blood component orders from the Patient Management System, so that the required details (component type, quantity, special treatments, etc.) will enter the patient's chart in the system directly.
f. The system will support selecting required tests, the user in the laboratory will enter the desired tests (blood type, control, blood type and antibody screening, etc.).
g. The system will display previous orders of a patient (in a defined time range) and will support selecting and updating an open order. For example, if there was a blood typing test in the past only and now there is a requirement for units, or it is necessary to increase the number of units. The system will check, according to an algorithm to be defined, whether additional samples are necessary and will notify the user and the referring unit.
h. The system will be updated with data on a contagious disease from the patient's record and will issue a corresponding alert.
i. The system will support disqualification of samples and units in cases that will be defined at the detailed specification stage.

21.3. Interfaces

a. A two-way interface to the Patient Management System / patient record system for ordering blood products and tests and transmitting results and dispensation / disqualification / status messages.
b. Interface to the Patient Management system / patient record system for transferring demography data, patient assignment and location, and information about contagious diseases and diagnoses that require administering irradiated / filtered / rinsed blood as defined in the test management subsystem, in the test order process.
c. Interface to other laboratories in the laboratories system for getting blood count and serology answers and other data if required.
d. Interface to information sharing systems such as Ofek / Eitan for sharing of information about antibodies, the need for irradiated blood, transplants between different hospitals and an option for getting alerts from these systems.
e. ~~Optional: Lambda interface for ordering blood components~~
f. An interface for transferring all results of all tests to patients and/or units from the existing instruments including panels.

21.4. Sample uptake

21.4.1. Process

a. The system will support uptake of a sample by entering the patient's identification number (or another identifier) manually or by reading the number using a barcode reader and will verify the validity of the identification number. If the identification number is invalid, nonexistent or has been changed in the central system, the sample may not be entered (except by special authorization) and a rejection message will be issued to the referring unit including a request for a new sample.
b. The system will support electronic verification of identity in the patient information from the test tube and form and will block the uptake of the sample if these are not identical.
c. The user will check the sample in terms of quantity and quality, will confirm or reject it stating the rejection reason code from a fixed list or using free text. In cases of rejection, a message will be transferred to the returning unit about the reason for rejection and a request for a new sample.
d. The system will save the approver's code, date and time of uptake of the sample in the blood bank.
e. Optional – the blood tests order must be done according to the Ministry of Health's procedure, including first and second authorized person approval and will allow them to be documented in the system. The system will be able to give an alert about an authorized person who does not exist or who has been

removed from the system for a certain reason. The information on authorized persons will come from the authorization management and physician refresher system.

21.5. Tests for samples / units

21.5.1. General

a. The system will manage the tests that are to be performed. Each test on a sample and on a blood unit (each separately) will have a screen matched to it in which the test values, the results and the technology used to perform it will be entered. The system will mandate performing certain tests twice and will support performance of the tests additional times, while saving the results of all the tests.
b. The system will make sure that all necessary tests have been done and are valid.
c. The system will support working on centralized screens in relation to the input of blood products, their testing and cancelling of cross matches.
d. A hospital will determine whether the performer of the first test may also perform the second tester's test if the medical center does not permit it, the system will block this option.

21.5.2. Blood type testing

a. If the blood type is known to the system after the uptake of a new sample, it will not be displayed on the work screens and will not be transmitted until after the test set has been finished.
b. The user will choose the manner of performing the test (testing technique), if it differs from the standard. Each test will have a screen matched to it for entering data and an algorithm for calculating the result. The system will support continuous switching from one test to another.
c. Blood typing testing is performed twice at the same workstation or different workstations, according to the work procedures at each blood test. In cases in which the blood typing test is done on two samples, the system will support input of both samples in succession or on two separate work screens.
d. The system will check the match of the two results and match to the test results in previous orders. If there is no match, the system will alert the user, will block the option of confirming the blood type and will support performing additional blood typing tests, while saving all results, including the date, performing worker and test time.
e. The system will generate the blood type according to a structured algorithm after transmitting or manually entering results. The algorithm will be determined at the detailed specification stage.
f. The system will support using of calculation tables for typing the blood of bone marrow transplant recipients and there will be attention to undefined blood types.
g. In the case of a change in blood type, the system will state in the patient screen that there was a change in the blood type and will support immediately displaying all blood types that were entered through to

the date and time of the test. In addition, upon each display of an order, the type that was established at the time of the order will be displayed. Requirement for an additional sample during a blood type mismatch and for changing the type.

h. The system will support managing different authorizations for blood typing and type changing and forcing a blood type, by patient type, whether for a bone marrow transplant recipient or another patient.
i. The user will confirm the blood type received using his electronic signature.
j. The system will support, and in certain cases will require, performing follow on tests on a sample for defined populations in cases that are Rh negative, or with a weak reaction, or at the laboratory worker's discretion. If the follow on test is not performed, the system will also be able to block the blood type confirmation. All the above is at the discretion of each medical center.
k. The system will support manual typing of molecular test results. Also, the system will support selecting out of a fixed list of common results. In such a manner, the result will be automatically interpreted on whether to treat it ads negative or positive.
l. The system will support performing special tests, such as for infants, umbilical blood, bone marrow transplant recipients and others, including support for the suitable algorithms.
m. The system will support approval of blood subgroups such as A2, A2B, etc., and will be able to match a unit accordingly.
n. The system will require a new sample in the case of "consolidation of records" (change of the patient's identity card number)

21.5.3. Antibody screening

a. An antibody screening test is done automatically or manually with the system's support for producing the result.
b. The system will allow the user to repeat tests as necessary, reject or freeze the sample / order and demand an additional sample.
c. The system will update the order of the status / sample in the system and will save the user code, date and time of performing the test.
d. The status of the test / order will also be updated in the clinical system
e. The system will support an interim status for tests for which the antibody screening has been confirmed as positive, until completion of the investigation.
f. If the antibody screening of the same sample has been changed during the investigation, the system will relate to the last test that has been performed.

21.5.4. Antigen testing

a. The system will support documentation of the adding of a number of different antigens by different workers at different times for a unit irrespective of the status of the unit or the subject and will display the results.
b. The system will support flexibility in adding new antigens to the list.
c. Any change will be accompanied by a personal signature and documentation of the action, date and time.

21.5.5. Saving of the results

a. The system will save the result of all tests that were performed, both on the patient and on units, including if a test was performed several times and using different methods.
b. In cases in which an antibody has been identified, an "identification card" containing the patient information and details on the antibody or blood type that has been found may be printed automatically. An "identification card" is a report in letter format with the patient's address for future sending.
c. The results of the test for a unit, such as: blood type and antigens found in it, will be saved in the system as data of the unit itself, and will be used in the future for review and/or in an attempt to match it to an additional patient. The system will support searching for units in inventory according to the results of these tests
d. Results of panels and other documents may be scanned into the subject's chart.
e. The system will support uptake of a sample from an outside laboratory and performing the entire range of tests on this sample but will not support dispensing of blood products based on this test (+ sample not for transfusion).
f. The system will support automatic loading of the screening data and panel into the existing monthly reagent kits of all work instrument companies and transferring of the screening and panel test results through a specific interface. Also, the ability to load a screening test / panel for different work methods according to the user's requirements is to be supported.
g. The system will document the reagents that were used for each test.
h. Advantage – the system will provide information / clues about the antibodies.

21.6. Choosing of blood units for a patient

a. The system will support the selection of blood units for cross matching for the patient on a specific screen, the system will display the patient information, the details of the sample on which the cross matching is being done and the details on the blood products and special treatments required for a unit / product.
b. The system will support electronic cross matching of units according to the blood bank's procedure.
c. The user will be able to enter into the system units manually or using a barcode reader.
d. The system will perform a match test between the unit and patient. The test includes the blood type (if necessary according to the component type), matching the unit phenotype to patients who need it, valid date, existence in inventory, status in inventory (free), special requirements for a subject (such as irradiated, filtered, washed), etc. If there is a problem, the system will issue an alert and in the cases defined, it will allow performing the allocation subject to additional approval.

After confirming the selection, the units will receive an appropriate status / will be assigned to a patient and will be withdrawn from the blood bank's available inventory. The order status will be updated accordingly.

21.7. Cross matching tests

a. The system will demand electronic identification of the sample before typing results.
b. The system will block the use of red blood cell units that have not been checked by a second checker.
c. The system will support cross matching for a patient for unexpired samples only.
d. The user will enter the test results. The system will support inputting a number of results according to the test method.
e. When the antibody screening is positive, the system will support cross matching, but will issue an alert about this.
f. If the cross matching is positive but the user decides to reserve the unit for the patient, the system will issue an alert stating "Allow dispensing?" and require the user's confirmation.
g. The system will support an algorithm for calculating cross matching results, including in unusual situations such as autoantibodies (positive cross match but less than the baseline level), etc.
h. If the test result is good using all test methods, the system will allow the user to confirm the cross match of the unit and withdrawing it from the blood bank's available inventory. After the confirmation, the system saves the user's signature and changes the unit's status to matched.
i. The system will support matching of one unit to more than one subject as an option at hospitals that require it.

j. The system will support printing of labels with clear graphics that separate the patient data from the unit data on the same label. It will support adding fields and comments to the label in accordance with the medical center's procedures. The label will contain at least the following data:
   1) Patient data including first name, last name, identification number and hospital identification number (both), the sample number and the type of antibody if existing, the unit data including unit number, product code, blood type, treatments it has had, antigens (if tested for), unit's expiration time, the ordering department, crossmatching data, crossmatching time and a room for the worker's signature. The printing will occur once crossmatching has been successfully completed, during the allocation of the unit to a patient or proactively. Both unit and patient data will be displayed numerically and in barcode format.
   2) The cross matching result will appear as "negative crossmatch" or "positive crossmatch (highlighted)" according to the crossmatching result.
   3) In the case of the blood type test (including antibody screening) having expired or not existing or not having ended, the unit will have a "without crossmatching" indication (even if crossmatching was done immediately).

21.8. Treatment of blood products

a. The system will support treating of units irrespective of their match to patients but as a separate process.
b. The system will contain all products from the ISBT 128 catalog, including product characteristics (irradiated / filtered / defrosted / washed, CMV / etc.), the system will also change the ISBT codes on the label affixed to the unit according to the final product that was prepared after the treatment, will change the unit's expiration date and product code (ISBT) according to the treatment performed and will issue a new unit label.
c. The system will allow the user to enter the treatment type provided by selecting a code from a built-in table or selecting a treatment from a list.
d. The system will issue an alert and/or permit blocking when the requirements of the unit being issued do not correspond with the patient's requirements according to the medical center's demand. The alerts will only be in the case of a unit missing required treatments but not when there are unnecessary treatments for preventing unnecessary alerts.

21.9. Blood products Dispensing

21.9.1. General

The system will mandate performing all tests before dispensing blood products. At the hospital level, it will be determined whether it is possible to dispense blood products that are not required to be crossmatched (such as plasma) without crossmatching tests and in which cases it is possible to rely on historical blood typing tests existing in the system.

21.9.2. Dispensing

a. The system will support dispensing directly from the crossmatching screen too.
b. The system will check the (physical) unit number against the number selected for the patient, will check that the unit is still of matched to the patient status, and repeated validity tests (expiration, blood type, special treatment component, etc.).
c. If all tests are good, the system will approve the dispensing. The order and unit status and blood bank inventory will change accordingly and will also be transmitted to the patient record and the ordering department, including time of dispensing.
d. The system will support automatic generation of a dispensing label containing all the data required as set forth above with the addition of the dispensing date and time and an option for adding comments to a label.
e. The system will support dispensing of blood and blood products according to the type match and subject to the Ministry of Health's procedure.
f. The system will support dispensing units waiting for a patient from a dispensing screen or patient screen alike.

21.9.3. Emergency dispensing without cross matching

a. The system will support dispensing blood units without cross matching, without the subject's name, and will support assignment of the units to the subject retrospectively.
b. The units will be dispensed to a certain patient or generally to a certain unit.
c. The system will perform checks on dispensed units, such as: whether the units exist in free inventory, the blood type, component, expiration date, etc., and will warn the user of the findings. The detailed specification document will elaborate an algorithm defined that specifies

the cases in which despite the mismatch, the system allows dispensing to go ahead, i.e., if not all typing and screening tests have been completed.

d. The user will enter the dispensing reason code and will confirm dispensing. The username, date and time will be documented.
e. The system will document the name of the confirming physician.

21.9.4. Dispensing of blood to an infant up to the age of 4 months

a. The system will support dispensing of units to an infant according to the procedure. This includes emphasizing the following points:
b. Dispensing of blood units to infants up to four months' age requires one blood type test result for the infant and one antibody screening test of the mother or infant for the entire period.
c. The system will support testing for anti-A or anti-B, when a neonate is not of O blood type and is scheduled to receive blood that does not match the mother's ABO.
d. The system will support dispensing blood units to an infant if the requirements above have been fulfilled, on the condition that the antibody screening is negative.
e. If the antibody screening of the mother/infant is positive, the system must demand matching of the blood units according to the antibody that has been found throughout the period and without a need for additional sampling.

21.10. Administering blood units in a department

a. The system will contain a digital interface from the patient record. This interface will forward blood product transfusion data from the department to the system (such as when administered, to whom and more).
b. If the patient had a reaction to the transfusion, the system will support performing the following processes:
   1) Entering data on the patient's reaction to the transfusion administered to him from a table and/or free text.
   2) If necessary, a new sample will be received on which the tests will be performed. The sample will be linked to the original order as a control sample and all tests that are performed on it.
   3) The input of the results of the tests performed as an automatic or manual control, such as: antibody screening, crossmatching and reverse crossmatching tests.
   4) If there is a mismatch between the new test results and the original test results, the system will issue an alert and will demand special approval of an authorized senior worker.
   5) The system will display a history of the subject's reactions, including reaction type.

6) The system will document the data and will display a fixed comment on the subject's work screens.
   i. The system will support generating individual reports for processing transfusion reactions and will support reporting to a central hemovigilance system.
   ii. The system will support built-in report generation according to the requirements of the national hemovigilance system.

21.11. Returns / destructions and disqualification of units

21.11.1. General

a. The system will support returning / disqualification of individual units into inventory or a cluster of units in a concentrated manner.
b. The user will define the units' destination, such as disqualification (if the unit has expired).
c. At the end of the process, the system will update the order status and the inventory of units in the blood bank will be updated accordingly.
d. The system will support generating a report of units that are about to expire and will allow the user to set the time period that will be included in the report.

21.11.2. Disqualification of a unit

a. The system will display all expired units in a daily report based on the storage method commonly used at the medical center (sorted by name, blood type, department, etc.).
b. The system will automatically disqualify expired units and will remove them from the free inventory.
c. In irregular cases, the system will support returning of expired units to inventory, depending on user authorization. It is clarified that not every user can perform this action.

21.12. Receiving blood products from outside sources

21.12.1. General

a. The system will support uptake of a "package" of blood units that have arrived together at the blood bank in a user friendly manner with a minimum of typing actions.
b. The system will tell apart units that have arrived from an outside party and units donated locally.

21.12.2. The work process

a. The system will support ordering of blood components from outside suppliers. The order will include all of the information that has to be transferred to the supplier, such as: details of the

ordering party, details of the order including blood type, component, quantity, etc. The order will be transferred by fax and/or by email or interface.

b. The system will support uptake of units in two forms:
   1) Entering a blood bank worker by reading barcode labels and/or manual typing,
   2) Input by magnetic media or interface to the supplier's system.
c. The shipment details will include the shipment number, the name of the receiving worker, date of receiving the blood and the blood supplier.
d. The unit data includes the supplier's unit number, the component type (whole blood, plasma, etc.), the blood type, unit volume, blood drawing date (donation date), expiration date, antigens in the unit (such as if a special unit has been ordered from Magen David Adom) and free text comments.
e. The system will perform logical tests on the data that has been entered, such as checking that the expiration date is later than the blood drawing date, but not more than the time prescribed in the system tables according to various criteria that will be determined in the final specification (such as the component type).
f. The system will support having a second checker when testing for blood type (differing from that performed for manual or automatic patient sampling) and will compare the results to the data that arrived with the unit. The system will require Du testing for Rh negative units and will allow the user to perform additional tests on the lot and entering the data directly into the system.
g. The system will support generating of a report for accounting with the supplier of the units for the shipment (or a number of shipments in a range to be defined), including general details (such as supplier data, the user who received the shipment, uptake date, etc.), the concentration of units that arrived and their cost.
h. The system will identify additional information on the ~~lot~~unit, if it exists, such as: phenotype tests, assignment, etc.

21.12.3. Interfaces

Interface to the blood supplier's system (MDA, other hospital), for receiving the data and confirming receipt of the shipment.

21.13. Donation of blood components

21.13.1. General

a. The system will support arranging for blood unit donations and will process their separation into different components according to ISBT 128 codes. The system will identify the medical center in a fixed ISBT supplier number that will appear on all of the units that have been produced (including mixed units) at this center
b. The blood unit and any product extracted will be numbered with ISBT 128 codes and the required mandatory tests will be performed. If the test results are good, the unit will be marked and will be added to the blood bank's inventory.
c. The system will support securing self-donations, donations into inventory and patient specific donations.
d. The system will support two-way traceability (between the unit and donor and between the donor and unit).
e. The system will support an interface to all tests performed on a donor and unit and a link to the results in the relevant laboratories.
f. The system will manage a database of donors who are interested in returning to donate again.
g. All tests that are performed on a donor and all tests performed on a unit and connected to a donor (blood type, antibody screening and serology) will be linked both to the donation (unit) and to the donor and the system will warn if results of blood typing test that were performed on the unit do not match the blood typing tests done on the donor or when a viral contaminant is found in the unit.
h. Blood typing tests that have been performed on a donor within a donation will be used both for determining the unit type and determining the donor type so that they will appear as assigned to the unit and to the donor alike. Each medical center can decide whether the tests will be performed as tests that are suitable / not suitable for transfusion.
i. The system will not permit marking of a unit if the test results are not good, including serology. It may only be marked with special approval.

21.13.2. Acceptance of donor

a. The user will enter into the system the identity number of the donor or another identification number and will open a record for him in the system.
b. If the donor exists in the Patient Management system, all existing data will be drawn. The blood bank must receive personal and clinical data on him and details that will allow him to be traced if necessary. The data types that will appear are:
c. Personal information (name, identity number, sex, age, full address, etc.), donor type (general, MDA volunteer, Ezer Mezion volunteer, etc.) dates of previous donations, donation type / component donated, donation for a specific patient (the system will support linking of the donor to a certain patient), additional, optional data such as blood count, match for pheresis donation, etc.
d. The user will enter medical disorders, if any, which disqualify the donor from giving blood. The disorders will be chosen from a table or by free text and the user will state whether the disqualification is temporary (and the disqualification time range) or permanent. This data will be saved in the donor record and will be displayed on each relevant work screen.
e. The system will support update of the donor data including current clinical data, such as: blood pressure and hemoglobin level (optional).
f. The system will allow the user to see clinical historical values of the donor, including serology results – interface to clinical system or laboratories system at the medical center.
g. The system will support different donation types and flexibility in adding additional components (blood, thrombocytes, stem cells, granulocytes, eye serum).
h. The system will support entering data on the lot that is received such as volume, quantity of thrombocytes, quantity of leukocytes, etc.
i. If a donation is being made for a specific patient, linking of the donation to the patient will be automatic. The intended unit recipient will be marked prominently on the unit. The system will support printing of specific labels for marking the donation and the attendant test tubes.
j. The system will support adding of comments to a donation
k. The system will support tracking of recipient specific units or those donated for a certain patient.

21.13.3. Tests for donation

a. The tests will be performed at the whole blood or blood component level. The system will update the test results for all components and splits of the unit (or component) on which the tests are being done, or for the tested unit only, according to the medical center’s default and the user’s request.

b. If the test results require special treatment for a unit, such as: rinsing the unit, filtering the unit or irradiating the unit, the system will warn of this.
c. The system will support ordering of tests in other laboratories at the hospital, by minimal typing of additional data. The test results will be displayed automatically on the blood bank's work screens.
d. The system will support sending tests to be performed at an outside laboratory, according to the test definition and the user's request.
e. The system will generate a report of samples transferred to an outside laboratory ("delivery certificates") and will track the samples that have been sent, alerting the user if results have not been received after a preset time.
f. The system will allow manual and digital entry of results using secure vaults. If all test results are satisfactory, the user will confirm this with his signature. The unit will be labeled and the system will add the unit into the blood bank's available inventory (see donation release process).

21.13.4. Adding a donation to the blood bank's inventory

a. The system will check that all tests required on have been performed on the unit and have good results. If not, the system will block the continuation of the unit release process.
b. A blood unit / component may not be taken up if not all tests that have been performed on it have yielded good results, according to the table of criteria managed by blood type, test type, result and situation (state of emergency, for example), subject to the user's authorization.

21.14. Splitting and dividing of units, mixing of units

21.14.1. Splitting of a unit / product

a. The system will support splitting and mixing of blood products according to the procedures in terms of components after the split / mix, the blood types and volume of the components, the system will manage a "bill of materials" of the blood and will check the "legality" of the request for splitting / mixing according to ISBT 128 codes, matching of blood types, and accordingly for the final volume of split / mixed components.
b. The system will calculate for each component its expiration date and volume, according to definition tables and based on the expiration date of the whole unit (before the split or after mixing), which serves as a baseline date for calculation.
c. The system will support full traceability of unit data before mixing / splitting.
d. Split unit:

1) If the unit was previously split, the previous splits and the expiration dates of each of them will be displayed and the user may make an additional split.
2) The system will permit the user to split the unit into a number of parts and will make sure that the requested split is correct.

e. The system will support entering the quantities / ratios between the units (half and half, etc.).
f. The system will generate barcode labels by ISBT 128 code with the unit data according to the split / division. The label structure and data that will be printed will be defined at the medical center level at the detailed specification stage.

21.14.2. Interfaces

a. Interface to outside laboratory systems for transferring samples for testing and for input of the results
b. Interface to the clinical system
c. Interface to the logistic system for updating the inventory of the blood units, if it will be managed outside the laboratories system

21.15. Management of blood and blood products inventory

21.15.1. Inventory management

a. The system will manage the blood inventory at the blood bank at the unit and component level, including treatment, and at the blood type level and preservative solution type level.
b. The record includes the following data:
   1) Details on the unit (blood type, unit number, donation date, expiration date, the product, breakdown of the history of treatments and splits), unit source (supplier).
   2) Status of the unit (free inventory, testing in progress, crossmatched and awaiting a patient, dispensed, etc.).
c. The system will support automatic inventory updating, each action on a blood unit updating its status and the inventory accordingly.
d. The system will support generating of inventory reports by hospital definition and/or user demand
e. The system will maintain a minimum inventory at two levels – ordinary minimum inventory and “iron” minimum inventory, and will issue an alert if the inventory for a certain blood type and component is approaching the minimum.
f. The system will support issuing an inventory report for emergency states at a minimum detail level by component type and blood type and will warn if this inventory crosses a red line that will be defined at each hospital

21.16. Generating reports

a. The system will support user flexibility in creating reports from system data.
b. The system will support conversion of all existing reports in the existing system.
c. The system will support automatically scheduling reports, to be saved in a network location.
d. The system will support inter alia the following reports:
    1) Inventory by components / types report
    2) Samples by date / status / test type report
    3) Donors and donations report
    4) Disqualifications for tests and units according to disqualification reason report
    5) Special units report
    6) Multi-transfusion patients report
    7) Dispensed units report
    8) 72 hour subjects backup report
    9) Special patients report (irradiation, antibodies, filtration, washing, CMV)
    10) Transplant recipients report
    11) TAT
    12) History of user activity and history of alerts for users
    13) Subject details card according to the medical center's requirements
    14) Units output by sending party / product type report
    15) Expired units

21.17. Quality assurance

a. The quality assurance of the instruments and tests is fundamentally identical to that of the other laboratories.
b. Quality assurance is done at the blood bank as set forth below:
    1) Review of performing the tests on samples / units
    2) Review of the instruments
    3) Review of storage of the units
    4) External quality control
    5) Quality control on donations

22. Tissue bank

a. This chapter presents the requirements for computerization of the system for bone marrow, cellular components for grafting, etc.
b. All the processes described in General Laboratories and General Processes Cluster, Section 17 above, are also relevant to this laboratory. This chapter details additional requirements for the tissue bank.

22.1. Background

The bone marrow transplantation laboratory deals with tests and processing of cells intended for bone marrow transplantation, whose preservation requires the cells to be stored and frozen. The work process in the bone marrow laboratory includes the following central processes:

a. Uptake of product from the collection unit or an outside source
b. Processing and freezing of the cellular product
c. Management of the product inventory
d. Product quality tests
e. Dispensing of product and forms
f. Reports

22.2. Process of uptake of the product from an internal or external harvesting unit

a. The processes must be done on an existing unit or a unit must be allowed to be set up in the system with a unit number according to the global ISB 128 standard.
b. The system will support linking a unit to a donor and a recipient and direct transition between the documents relevant to each of them.
c. The system will support allocation of samples, including a sample number, which will be linked to the unit and will be used for performing various quality tests on the unit.
d. The system will support searching for a lot by primary lot number and/or its split or linked sample number or according to donor or recipient data and displaying the data of all products relevant to that primary unit / donor / recipient, if the search is done according to the details of the donor / recipient, it is necessary for all units assigned to be displayed with an option for choosing the suitable unit.
e. The system will display the following details for each unit: unit No., source of the cells, harvesting date, fresh or frozen status, unit supplier, number of additional units from the same donation, unit volume, status – good / disqualified including reason for disquali**fication**

1) The system will display for each graft recipient the following details: first name, last name, identity number, case No., sex, date of birth, age, case No., weight, blood type (including Rh), diagnosis, contagious diseases, remarks.
2) The system will display for each donor the following details (if they exist): first name, last name, identity No., case No., sex, date of birth, age, case No., weight, blood type (including Rh), contagious diseases, remarks.

f. The system will support manual completion of details of the unit / donor / recipient that will be documented in the system (date, operator).
g. The system will support generating unit and sample from unit labels at the various processing stages (harvesting, splitting, unit for freezing and sample test tube for freezing). The system will provide flexibility in establishing the number and design of the labels according to the medical center's demand.
h. The system will maintain statuses for units during processing, for example: received / in progress / frozen / completed.
i. The system will support defining the donation / unit / donor as one of the following options: autologous, stranger allogeneic, family allogeneic, non-matching family member. In the case of an autologous donation, the system will automatically copy the details of the donor into the details of the recipient and vice versa (the donor and recipient details will be consolidated).
j. The system will provide flexibility in adding processed cell types and test types.

22.3. Treatment of products

a. The system will support rapid switching from the product uptake process to the product treamtent process, in which the product's details will be displayed automatically.
b. The system will support importation and display of results relevant to a donor / unit / sample from other laboratories such as: hematology (WBC, CD34, MNC, etc.) virology (HIV [positive/negative], HCV [positive/negative], microbiology, etc.) and will warn if there are irregular results. In addition, the system will block the continued processing of the product if results that are defined as vital by the medical center do not exist in the system.
c. The system will support documentation of the actions performed on the product: processing type (out of list of processes: reduction of volume, removal of erythrocytes, etc.), quality test including CD34, vitality tests, adding materials including batch documentation. Each action will be documented, including date and electronic signature of the operator.
d. The system will support entering comments using built-in sentences or free text in 2 languages (English, Hebrew).

e. The system will support splitting the product into bags according to a formula that will be defined at the medical center. The formula will include the following fields: volume, WBC, patient weight, additive liquid from a list.
f. The system will support updating for the final product additional data such as: volume, number of mononuclear cells MNC, total, number of cells per patient weight, CD3, total CD3, per patient weight, total CD34, CD34 per patient weight. The system will support updating of this data using a formula.
g. The system will also support treatment and documentation of a frozen product that arrives split, which is received with the test data. In this case, manual input of the split data and the product definition or updating these from the ISBT codes, if the exist, are to be supported.
h. The system will support authorizations of various degrees for uptake / processing / freezing
i. The system will document the location of the product after completing its preparation, including freezer number, cassette number, this process will be vital for completing the treatment of the product. The system will support management of freezers for storage and will support display of vacant places in a freezer, each freezer being displayed separately. The display of the vacant places will be at the level of the refrigerator number, frame number, cassette number and location in the cassette. Switching of views between refrigerators is to be supported, along with graphic display of the refrigerator's occupancy. There may be a number of statuses of a location in a refrigerator: "occupied", "vacant", 'inactive".
j. The system will support viewing, documentation and management of inventory at each stage from the unit's uptake to the end of the process and will support displaying of units by status / donor or by recipient.
k. The system will display information on a patient who has died for patient details in bone marrow system (including date and time of death), providing an alert "this unit is linked to a deceased patient" and will support issuing a report with a breakdown of the units intended for the deceased patient.
l. The system will support a unit to be taken out of inventory for dispensing / removal / disqualification.
m. The system will support dispensing one or more units for one of the following options: grafting, transfer to another department, transfer to another hospital. In the case of dispensing for grafting, the system will warn against / block the dispensing in a case of a mismatch with the recipient documented in the system. The time and date of dispensing and the operator will be documented.

22.4. Summary form

a. The system will support generating a summary form for transplantation / dispensing according to the medical center's requirement. The dispensing form must display the following details:

- Details of the recipient
  - Name of patient receiving the unit
  - Identity card No. of the unit recipient or temporary identity card No.
  - Case No.
  - Date of transplantation
  - Diagnosis – of the graft recipient
  - Weight
  - Blood type [relevant only for allogeneic dispensing]

- Details of the donor [relevant only for allogeneic dispensing, the data will be displayed alongside the details of the recipient]
  - Name of the donor
  - Identity card No. of the donor
  - Blood type
  - Donor type: allogeneic / stranger allogeneic / nonmatching family member
  - Harvesting date

- Details of the donation
  - Identification No. of the unit including barcode
  - Product types (there may be more than one product).
  - Source of the cells.
  - Harvesting dates (there may be multiple dates).
  - Number of bags (quantity).
  - Summary data for a grafting event.
    - Volume – total volume in milliliters.
    - WBC – total WBC per kg
    - MNC – total MNC per kg
    - CD34 – total CD34 per kg
  - Viability percentage [if the information exists in the component quality system from component quality tests – it will be retrieved automatically, otherwise an underline field will be displayed for manual entry].
  - Positive serology and bacteriology tests – tests that were performed on a donation for which a positive result was received. For example HIG: positive, microbiology – identification of a bacterium and result [the test data and result are to be displayed in table format].

- Comments – the comments that were written at the time of dispensing will be displayed.
  - Name of the unit dispenser [will be generated automatically from the system].
  - Signature of the unit dispenser – including an underline for manual signing.
  - Name of transplanting physician – including an underline for manual filling.
  - Signature of transplanting physician – including an underline for manual signing.

b. The system will support changing manually or by interface to the clinical record the status of the unit from “dispensed” to “transfused” for a grafted product and will support documentation of the grafting time.

22.5. Reports

a. Inventory report for patient – display of the inventory for a patient who is scheduled for transplantation
b. Units for deceased patients inventory report
c. Patients who died after transplantation report
d. Statistical reports:
    1) A report displaying the quantity of harvesting procedures in a range of dates (autologous, allogeneic, harvesting from a stranger donor)
    2) A report displaying the number of harvesting procedures that have been processed in a range of dates and which processing was done and the number of harvesting procedures performed for each processing type.
    3) A report displaying the number of transplantation procedures (allogeneic or autologous) that were performed in a range of dates.
    4) A report displaying the number of processing procedures performed for each processing type in a range of dates.
    5) A report displaying the number of transplantations performed by diagnosis and divided by donation definition.
    6) A report displaying the number of transplantations performed by age and population group. For example: children up to the age of 18.
    7) A report displaying the subject’s disorders (for example aberrations).
    8) A report displaying the number of processing procedures done per worker by processing type.
    9) It is necessary to support the use of a report generator for producing non-standard reports.
e. It is necessary to support exporting the data from the system to an Excel file.

22.6. Interfaces

a. “NAMER” (medical center management)
b. General laboratories system
c. The blood bank system
d. Clinical record

23. Genetic laboratory (cytogenomics and molecular) – an advantage

23.1. General

23.1.1. All processes described in the General Laboratories and General Processes Cluster, Section 17 above are relevant to this laboratory too. This chapter specifies additional requirements that are unique to a genetic laboratory.

23.2. General processes in the laboratory for attention:

a. Creating laboratory reports, for all work stages including work lists.
b. Ability to edit and add process for performing the test itself by the user. There are updates of processes and tests on a regular basis, so there must be an option for aiding and updating at the users level.
c. Storage of laboratory documents and records in accordance with the Genetic Information and Legal Advice Law https://www.nevo.co.il/law_html/law01/215m1_001.htm.
d. The LIMS system must support a patient record and saving all existing information including external forms and external medical clinical information (including scanned documents) and in general work records for a laboratory.
e. Support for patients and pregnancies and prenatal samples. Linking between an identity card and samples is required, including a hierarchy of the connection such as: pregnancy 1, pregnancy 2. In addition, linking between families and saving a family relation hierarchy is required.
f. For the tests, the system will manage tracking of the process and special statuses (providing cultures, the harvesting process, the PCR process, extracting DNA, etc.).

23.3. Receiving samples

a. Receiving samples and inputting them with demographic data
b. Financing source
c. Entering of general data into the computer system: patient name, identity card number, date of birth, sex, address, telephone number, P.O. Box, marital status, health organization, referring party, sample type, required test, special comments- last menses, etc.
d. Scanning of documents in the patient record
e. Confirmation of receiving a sample by the laboratory
f. Work status – received, testing underway, analysis, release
g. The system will support creating one common record for a subject that will contain different test types, different samples and different times (for example: amniotic fluid, bone marrow, peripheral blood, chorionic villi and more, karyotype, chip, FISH, molecular testing and more).
h. The system will support linking of different records of tested family members.
i. Establishing unique sample numbers and an option for issuing barcode labels for a range of test tube types (source / DNA)
j. The system will support transfer of the sample for testing in an outside laboratory and will track receiving of the results at a defined time, at the level of a test and performing laboratory.
k. The user at the laboratory will enter comments or recommendations for performing the test by free text and/or using codes and out of a structured table too.
l. Ordering of tests at a laboratory: entering requested tests for each patient according to the requirements of the physician and the referral, including options for stating urgency.

23.4. Numbering

a. The system will number the samples.
b. The system will support a number of numbering methods for the different samples:
   1) Giving a consecutive sequential number for the different test types.
   2) Giving a main number of a sample (which will include the year of receiving the test) and giving a secondary number by requested test type.

23.5. Samples storage

a. The samples are kept in various forms of storage, according to defined parameters.
b. The user will enter into the system, from the corresponding work screens, the "storage" in which the material will be kept (such as refrigerators, freezers, liquid nitrogen, room, etc.)
c. The system will support searching for the location of a material from the various work screens, and will support transfer of material from place to place and removing a certain quantity of it or all of it from the storeroom.
d. The user will enter the sample destination, such as: frozen, stored in refrigerator, sent for outside tests, etc.

23.6. Extracting DNA

a. Creating work lists for samples before extraction
b. Entering the extraction details as required
c. Required interfaces for this stage:
   Many laboratories use robots of various types for automatic extraction. It is necessary to have an interface that supports input of data between an extraction robot and the laboratory software.

23.7. Work lists

a. Creating work lists by processes and methods
b. Work lists by mutations
c. Creating work lists matched to laboratory instrumentation and an interface interconnecting them
d. Entering interim results and raw results by laboratory team and directly from the laboratory instrumentation
e. Prioritization of urgent samples and TAT alerts.

23.8. Required interfaces:

Interfaces (including loading of work lists and exporting of results) against laboratory instrumentation such as: Sanger sequencing, Nanogene, real time PCR, chromosomal microarray, next generation sequencing, automated liquid handler.

23.9. Results

a. The system will import laboratory results from laboratory instrumentation (CMA, Nanogene, others).
b. The system will support the genetic answers format (HGVS).
c. The system will support separation of input of results from verification of results.
d. The system will support a number of confirmation levels.
e. If necessary, the user in the laboratory will order additional tests for a sample for continuing investigation with an option for entering text for special instructions.

23.10. Diagnosis (summary)

a. For each case / patient, a single answer will be given, concentrating all tests that were performed for the order in question. There will be an option to concentrate all genetic tests that were performed for a given subject at all times.
b. The user will enter the diagnosis as text and/or as a code.
c. The answer will be disseminated to the ordering party after final confirmation.

23.11. Reporting of results to the ordering party

The answer will contain the following data:
- Name and address of the laboratory
- Date of harvesting the sample
- Date of the sample arrival at the laboratory
- Date of issue of the answer
- Name of the subject, identity card number and identifier number of the laboratory and the tissue being tested
- Result – according to codes and with an option for text in Hebrew / English
- Signature of the laboratory director and of the checking senior worker.
- The test results will be delivered only after a signatory authorized in this laboratory, for the test type signs them.

24. Quality control

24.1. General

The system will imitate performing a repeat test or additional test according to the results of the tests, according to a predefined algorithm for each test.

24.2. Quality assurance module

a. The software will support inputting internal quality control results by typing or directly from the testing instrument.
b. The software will make a comparison of the test results with the normal values.
c. The software will support generating reports of the control tests.
d. The software will support documentation of monitoring various parameters in the laboratory instrumentation (for example CO2 temperature), as chosen by the user, and will warn of deviation from the set values or in the case that no monitoring has been done, at the worker and laboratory director level.

24.3. Internal quality control

24.3.1. Internal quality control / industrial controllers

a. Input from controllers using a barcode reader (including batch No. and expiration date of batch), option for communication to outside sites or copying the controller values from outside sites. Option for copying of controller data from one instrument to another (when multiple identical instruments are configured in a system).
b. Option for setting independent quality controls (in addition to those of a supplier)
c. Saving of the work batches including titer batches on which the test was based over time in a system, even permanently.
d. Transfer of results of the controllers from the instruments to QC software and display of batch No. combined with the controllers' results
e. Option for manual input of control data in the case of performing tests manually
f. Option for constructing a quality control report by times and by test type
g. L-J graphs
h. Option for displaying a number of controllers levels on the same graph
Option for displaying different instruments at the same controller level on the same graph
i. Option for changing the deviation borders and target value with clear marking of the changes made
j. Option for managing / documentation of corrections after returns in quality controls

k. Option for setting automatic confirmation according to defined rules that are linked to each test, with definitions of conditions for an alert or failure in cases of deviation.
Flexibility in the ability to define rules (by number of repetitions, size of deviation)
l. Option for viewing of results of other laboratories in Israel working with the same instrumentation / same methods (like Unity) depending on the controller and batch
m. Option for an interface with software such as Unity that will also document quality controls from other suppliers
n. Receiving alerts that have a deviation in controllers according to the laboratory's definitions
o. An option for receiving an alert when the trend in the deviation is persistent – for example the laboratory will be able to decide whether the deviation is in the permitted deviation range, i.e.: in the last X readings always in the same trend.

24.3.2. Harmonization between instruments / performing manual tests by various workers

The system will display a comparison of controllers within harmonization between instruments or within a manual test.

24.4. Option for comparing instruments on true samples that were received with a unique, identical identity card number in all instruments.

a. Harmonization reports: option for determining one instrument as a reference instrument and comparison to that instrument. Option for determining a permitted deviation. Receiving graphs with marking of a target value and permitted deviation, marking of irregularities in a clear manner. Graphic display of the data.
b. Option for calculating the deviation received from the target value. Option for making calculations of monthly deviation / or average deviation for any period decided on by the laboratory
c. Receiving alerts when there is a deviation above the permitted value when performing harmonization.
d. Option for receiving an alert when there is a trend in a deviation that occurs over time – for example the laboratory can decide that if a deviation is within the permitted deviation rate, i.e., the last X readings always have the same trend.

24.5. Comparing the performance of manual tests performed by different workers

a. Unique uptake with an option for determining one worker as being a reference. Clear marking of the workers.
b. Option for receiving a graphic report
c. Option for determining a permitted deviation
d. Receiving a warning if there is a deviation above the permitted level
e. Option for providing by worker / laboratory, test type

24.6. External quality control

a. Option for input in software in such a manner that we can know that it is EQC
b. If it is EQC that is also used for comparison of workers (for example any microscopic inspection)
c. Option for building a comparison report of different results that are received from different workers in the same laboratory, like Section 2 of harmonization, but this time the reference is an EQC result
d. Option for entering target results manually and calculating the percentage of deviations for each parameter over time.

24.7. Quality control according to the results of the tested population

a. The system will support generating a graph with values of distribution of the results of the tested population by time, test types, performing instrument and sending party.
comparison of the mean and median of subjects' results between different days or times / on the same day using different instruments.
b. The system will support generating additional reports on quality control data. All requirements mentioned in Section 17.11 Reports also apply to quality control reports.

24.8. Continuous performance tracking

The system will support continuous calculation of a moving mean, average of normal values (AON), Bulls algorithm, etc.

25. Manual work process

The bidder will describe in the bid booklet how the manual work process is performed when the system is inactive.

The bidder will also describe the recovery process – how the manual information is returned to the system.

26. User interface

a. As a rule the Ministry is required to comply with the AA standard for websites and systems.
b. When developing modifications and improvements of existing systems, it is necessary to preserve the existing capabilities for complying with the accessibility standard.
c. When developing new systems, it is necessary to combine compliance with the standard during specification and development and get approval from the Ministry's agent about accessibility before the system goes live.
d. ~~The supplier undertakes to comply with development standards binding the Ministry, as announced to it after it wins the tender, by the user interface team~~The UX should be approved by the Division before development starts.
e. The supplier will be required to receive from the Ministry's team a confirmation of the deliverables' good condition and compliance with standards during the following project stages: specification, design and development.
f. Once the development is complete the supplier will be required to pass the HTML validation testing, which will be done by a representative of the Ministry, and undertakes to perform the corrections required, before the end of each stage.
g. The supplier warrants that all elements and deliverables of the system being developed will be in accordance with the Accessibility Law and its regulations and in accordance with the instructions of the accessibility commission and the instructions of the Ministry on the subject.
h. The accessibility standard that binds the Ministry is of AA level.
   In the case of websites, Internet applications, cellular apps and digital documents, the requirements of

Article G, Accessibility of Internet Services in the Equal Rights for Persons with Disability Regulations, Service Accessibility Adjustments, 5773-2013, must be met.

1) Websites in accordance with Israeli Standard SI 5568 based on the directive document WCAG 2.0 for an AA level, and subject to changes made in SI 5568.
2) Cellular applications – according to the accessibility options of the operating system manufacturers (today IOS or android) and subject to relevant success criteria from the WCAG 2.0 document for level AA.
3) Digital documents: for the reasonable accessibility options that may be performed within the software in which the document has been created or edited.
4) Because there is no accessibility standard for digital documents, the practice is to make digital documents accessible in accordance with the instructions of an accessible digital documents manufacturer.
   Word and Adobe both provide for accessibility of digital documents.
5) The connection to success criteria in WCAG 2.0 for level AA is effectively the possibilities of programs to make accessibility adjustments in the spirit of the WCAG 2.0 guidelines.
6) For example, if criterion 1.4.3 mentions minimum text to background contrast, the software manufacturers must support use of colors that meet this contrast ratio.
7) 2.0 There are two criteria that deal with headers and accordingly, software manufacturers support adding hierarchy headers to documents.

i. The supplier's deliverables will be responsible and will be adapted for work on a desktop computer, tablet and mobile device as necessary and per the Ministry's requirements.
j. Similar actions in different modules will be performed in as an identical or similar manner as possible. For example: a test order will be made identically / as similarly as possible irrespective of the type of laboratory from which the test is being ordered.
k. It is clarified that the design and performance of the user interface is at the responsibility of the supplier.

27. Access to historical data

a. The supplier will be required to provide access to historical data of the system existing at centers, whether by converting it to the proposed system or by providing a mechanism for convenient access for viewing It during the team's work process, in accordance with the decisions of the Division and the specification that the Division will provide.
b. It is clarified that access must be provided to all information stored in the existing system based on a range of considerations, including regulatory and research ones.
c. The bidder is to specify in the bid booklet the proposed solution specification and the manner of reviewing the conversion (review to ensure that all information has been converted, review quality control).

28. Technology

28.1. Glossary

Term	Explanation
Nimbus	A project for the provision of public cloud services to the Government of Israel. As of the time of writing the tender, there are two winners of the Nimbus project: AWS, Google. For further information see https://govextra.gov.il/nimbus-mr-gov-il/
DR	Disaster Recovery
RTO	Recovery Time Objective
RPO	Recovery Point Objective

28.1.1. The following common protocols for transferring medical information:

a. **HL7 (Health Level Seven International)** – this protocol is used for transferring medical information between various systems and applications in the healthcare field, and includes various medical information transfer protocols.

b. **FHIR (Fast Healthcare Interoperability Resources)** – this protocol is intended for transferring medical information in a standard, easy to use format, and is intended to facilitate exchange of medical information between different healthcare systems.

28.2. General

28.2.1. The solution will be implemented in one of the following forms:

a. On-prem or cloud as a decentralized system (separate for each medical center or cluster of medical centers)

b. Cloud system in a central configuration only

28.2.2. Independence of each center

It is emphasized that in central system configuration too, the proposed solution will provide for independence of each center in applying various subjects such as:

a. Tables and codes in the system

b. Work processes in each laboratory

c. Interfaces with external systems
d. Transition to a new version according to a scheduling decision and under the control of each center
e. Implementation of integrations with medical instruments

In the bid booklet, the bidder must specify all possible customization (-fields, processes, definitions and so ~~on) available~~on) available for each medical center.

28.3. General architecture – clarifications

a. The bidder is required to detail in the bid booklet the proposed solution architecture including hardware requirements specification, including but not limited to attention to disaster recovery (DR), high availability, replication.
b. The bidder must provide a detailed description of the interfaces, including the information flow, to include all components required for a solution within the tender answer.
c. The bidder must detail the processes in the proposed solution that allow for maintaining the independence of each hospital in central system configuration
d. The bidder must show a detailed proposal of architecture, to include all components required for implementing and securing the solution. In the bid booklet, the bidder must specify the support level for each implementation option and indicate whether each option (as set forth in section 28.2.1 above) supports a shared database or requires separate database installations.
e. It is clarified that the solution architecture's implementation is contingent to approval from infrastructure teams, information security and a cloud committee of the Governmental Medical Centers Committee.
f. After choosing the winning supplier, the division will choose which architecture to use to implement the system (cloud or on-prem), at its sole discretion.
g. ~~(S)~~ The bidder will detail in the bid booklet its proposed architecture, including an ability to install it on the cloud (Nimbus) and on-prem.
   A solution operating on the cloud (Nimbus) provides a significant quality advantage.

28.4. Scalability

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a. The solution is to be available to a large number of users who will contact the system simultaneously.
b. The bidder must make sure that the solution meets the size objectives and performance objectives and specify the maximum number of contacts that the solution will support. In addition the expected phenomena and the performance level in the case of irregular load must be specified.
c. When examining the solution architecture, solutions that are as scalable as possible allowing for automatic, simple and rapid -gradual expansion (auto scaling) of the supported services will be preferred.
d. In the bid booklet, the bidder will specify how this functionality will be implemented.

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28.5. Redundancy and availability

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a. The proposed solutions are required to operate at a minimum availability of 99.5% with the aim of supporting the activity of the medical centers 24/7/365 and prevent harm to human life.
b. The bidder must specify how the solution will meet these objectives, including attention to the manner of implementation for ensuring high availability of infrastructure.
c. The bidder must detail for each element that it has specified in the architecture:
    1) Time to repair, mean time between failures.
    2) Manner of making upgrades without downtime or with minimized downtime for infrastructure upgrading purposes
    3) Redundancy of all infrastructure elements
    4) In the bid booklet, the bidder is also to detail the following metrics and their manner of calculation, according to the architecture it will show:
        i. RTO
        ii. RPO

28.6. Backup and restoration

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The bidder undertakes to fulfill the policy of the division (see Appendix C28.6 – backup and restoration).

28.7. Response times

The minimum requirements for response times are as follows:

Operation	Minimum time
Screen is available for work (from turning on the workstation until the system screen appears)	2 minutes
Changing of screen	2 seconds
Transition from field to field	Half a second
Update in the database (commit)	2 seconds
Performing a simple query by index	2 seconds
Generating regular (daily) reports	5 minutes

Making initial contact with other systems (connect)	10 seconds
Actions performed at the client level such as moving a mouse	Immediate
Displaying an error message	2 seconds
Confirmation of updating the database, for a single record or single table	2 seconds
Complex retrieval	15 seconds
In any case of the response time for an action is expected to be more than 5 seconds, an indication is to be given to the user	

In the bid booklet, the bidder is to specify the response times according to the architecture that it has shown.

28.8. Interfaces

The bidder must satisfy all of the protocols set forth below at the time of submitting the bid.

28.8.1. Types of required key interfaces

28.8.2. API interfaces are to include documentation of data import and export. The system will support import and export of data using pull and push model for all information entities in the system

28.8.3. The interfaces of the proposed system must support Tibco. If in the future the division replaces Tibco with another product, the supplier will develop an interface with the replacing product as set forth in Section 29.6.4 Request for modifications and improvements below.

28.8.4. supporting command line us advantageous.

28.9. Data transfer protocols

28.9.1. Requirement for HL7

28.9.2. The supplier must support the Fhir standard within a year of the winning date.

Supporting the standard at the time of bid submission is advantageous.

28.10. The supplier must comply with the following standards:

a. ISO 27001 - Information security management systems
b. ISO 27799 - Information security management in health
c. If the proposed solution works on a cloud architecture, it must also comply with the ISO 27017 standard.

28.11. Control of the interface's operation

28.11.1. Batch interfaces

The receiving system will generate an input report and error entries that will be returned to the sending party

28.11.2. Online interfaces

The information is transferred in real time, is processed by the destination system and an answer is returned to the sending system

28.11.3. Codes and translations

As necessary, at the time of preparing the information for sending and when receiving information for updating the system, the interface must be able to convert the codes in the base system to the codes corresponding with the interface according to conversion tables. Conversion tables of standard codes will be part of the system. In addition, the division will be able to define additional conversion tables as necessary.

28.12. Interfaces with laboratory instruments

The solution is required to allow for continuous input and transfer of information from various laboratory instruments during work and its input into LIMS.

It is clarified that each driver developed in the product for a laboratory instrument is to include a solution at the time of setup and during the engagement period: i.e., each driver for a laboratory instrument that will be developed in the product, will be made available to the division and will be installed as part of the version.

For a central configuration system, medical instrumentation management is required to be at the medical center level and all information and functionality related to the medical center's instrumentation will be accessible only to that center.

The bidder will answer in the bid booklet whether and how it provides a solution for the following requirements:

#	Requirement	Details
1.	**Connection to devices**	Connection to different models and different manufacturers of medical instrumentation and monitoring devices. Appendix C12.5 shows the list of common instruments currently existing at the hospitals. It must be stated on the appendix by each device whether there is a solution for connection provided by the supplier or not, and the communication protocol is to be specified.
2.	**Controlling receiving of information from the medical instrument**	Telling whether the data received originates from the instrument or manual input (showing an appropriate indication to the user).
3.		Receiving continuous / discrete information for the various records, displaying an appropriate indication to the user on whether the information received is final or temporary. Receiving data at defined fixed intervals at the instrument level
4.	**Controlling the medical instrument**	A two-way interface allowing for control of the medical instrument and changing the parameters for running it by proactive action by a qualified user and/or based on a change in the patient's clinical parameters.
5.	**Connection of the instrument and manner of transfer of information**	• Support for connection in RS232 configuration. • Support for connection in TCP/IP configuration. • Support for connection in USB configuration. • Support for connection in WIFI configuration.

#	Requirement	Details
		• Support for transfer of information in HL7 configuration. • Support for transfer of information in XLM configuration. • Support for transfer of information in DICOM configuration.
6.	**Required capabilities for managing instruments**	Transmission of the tested patient information to the testing instrument or the instrument connection software.

28.13. Reviews and versions

a. The Governmental Medical Centers Division reserves the right to conduct quality reviews on the project deliverables.
b. The supplier is to show a current risk review throughout the project's lifetime and is to act to reduce the risk.
c. Version update / patch installation / new version installation will only be done in arrangement with the division, after getting its prior written approval

28.14. Software testing

a. The supplier is required to perform a code review (statistic code analysis) for each version. The Division has discretion on whether to demand a statistic code analysis for specific developments too.
b. The supplier will submit the statistic code analysis report for approval by the Division's Information & Cyber Security Department before the version is deployed, according to the Division's demand.
c. The Division is allowed to check the quality of the code using automatic tools and/or by sample expert scanning, as chosen by the Division.
d. The bidder is required to detail in the bid booklet which specific methods and work tools will serve it for QA testing and delivery tests with emphasis on tools for performing automatic tests, load tests and

penetration tests. The tools must operate in a cloud environment. It is clarified that the delivery tests will be conducted on all supported platforms.

e. Mobile tests – if needed in the future
    1) Specific software tools for QA tests in a mobile environment are required for complying with the performance, information security and quality requirements and the required overall quality.
    2) Attention must be given to app testing (if an app is developed) and for performing adapted site testing, for Android and IOS type operating systems, specifying versions / environments and each element relevant for performing the task.
    3) The bidder is required to perform the tests on real devices rather than simulators / emulators. The Division will instruct the supplier on which devices the software is to be tested.

28.15. Authentication mechanism

The authentication mechanism will be in accordance with the requirements set forth in Appendix B5 - information security requirements.

28.16. Development and maintenance tools

The bidder is required to offer a comprehensive solution based on an off the shelf product and additions of specific development for providing a comprehensive answer to all requirements of the tender.

The supplier is responsible for the system / product that will be delivered, development and performance of adjustments in it, for installations in the divisional cloud environment, for regular maintenance and for its correct activity.

If the supplier is required to perform development (adjustments), the development will be done according to the following directions:

a. An advantage will be given to development of software elements as standalone services that will allow for transverse growth according to the load at medical centers rather than as a single monolithic unit.
b. An advantage will be given to a browser (Web) based user interface, the infrastructure will be responsive according to the directions in Chapter 12 and according to the definition at the specification stage. For a browser based user interface, the screens are required to be suitable for desktop, tablet and mobile resolutions at least.
c. The development will be done according to a secure code writing standard and according to the direction in Appendix B5 – information security requirements.

d. The bidder will specify which product it uses for generating reports. It is clarified that reports will be generated without impairing the system's performance.

e. Tests, implementation and operation:

1) The supplier must prepare a development for a delivery test plan that will cover fully and adequately the functionality of the system, including complying with information security requirements as required in the tender documents and appendices, subject to approval before performance by a professional party assigned to the subject from the Division.
2) Performing the delivery test plan
3) Breakdown and performance of UI/UX tests, including accessibility according to the direction of the party in the Division.
4) Breakdown and performance of mobile tests for the processes as defined as requiring operation by mobile device too, according to the direction and approval for the issue from the Division.
5) Division's approval of good, full acceptance tests.
~~6) Changes in the database structure for imple~~ removed
~~7)~~6) Changes in the database structure for implementing modifications and improvements must be provided prior approval of the Ministry's DBA team.
~~8)~~7) Approval must be obtained from a professional party in the Ministry for the existence, quality and scope of tests before performing load testing.
~~9)~~8) Approval must be received from a professional party in the Ministry on conducting penetration tests and their quality.

f. UI/UX

It is necessary to provide a standardized, accessible and responsive user interface that is adapted for a desktop and laptop computer, as well as suitability for a tablet, a responsive design is required to include a number of breaking points according to the direction of the Ministry's user interface team.

g. General requirements

The winning supplier is required to fulfill the following directions:

1) Development of the solution is contingent to approval from parties at the Ministry: the supporting architect, information security team and cloud team.
2) Any modification to or deviation from the original planning must be approved in advance by the parties stated in Subsection 1 above.

28.17. Environmental infrastructure

Each medical center has a secondary center for DR purposes. The bidder must cover the existence of a secondary center in its pricing.

28.18. Supported browsers

a. The system will operate using terminal equipment as described and will support Safari, Chrome, Edge browsers covering each one's last two major versions.
b. The bidder is required to specify in the bid booklet the manner in which the system works on end users' equipment, supporting a range of screen sizes of instruments (from desktop computer browsers, tablets, smartphones)

28.19. Replication

Replication of the database is required in order to allow for querying, generating real time reports and connection of the existing BI tools in the Division and/or at the centers.

For a central system it is necessary to describe how the solution will allow access to the BI systems of each medical center so that each center is exposed only to its own information.

28.20. Division of Responsibility

28.20.1. The Supplier is responsible for application security, including:

- Database (DB) Security
- API Security
- Application Vulnerabilities Management
- Secure Communication (using SSL/TLS, authentication, and authorization between services)
- Authentication and Authorization (including 2FA; if the customer chooses to use an Identity Provider (IDP), authentication responsibilities will be shared accordingly)
- Cloud Architecture Security (e.g., using KMS, defining least privilege IAM roles, utilizing private subnets, security groups, etc.)

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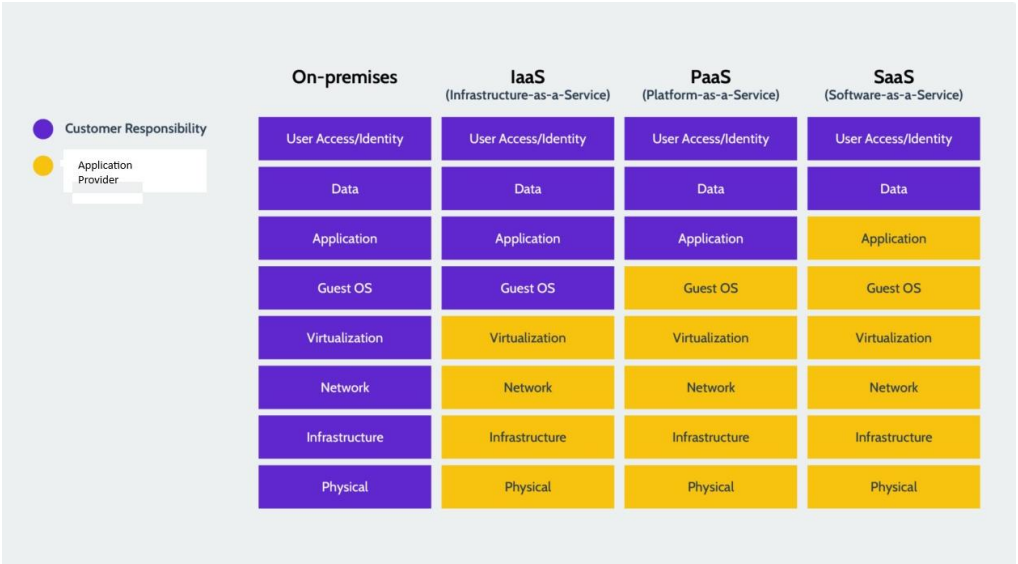
- Logging and Audit (ensuring monitoring and security event tracking)

28.20.2. The Customer (Ministry of Health / DGMC) is responsible for:

- Operating System (OS) Security – Installing EDR, security patches, and system hardening
- Cloud Identities and Account Security – DGMC is responsible for user creation and access management within the cloud, excluding IAM roles required specifically by the application
- Network Security – DGMC is responsible for securing the connection between on-premise infrastructure and the cloud

* Due to the unique needs of each solution, this answer may not cover all of the required responsibilities, and therefore, each case must be examined on its own merits.



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29. Implementation

29.1. General

29.1.1. The implementation of all stages of the project includes the full responsibility of the winning supplier for each field relevant to the system's lifecycle.

29.1.2. The implementation includes the following requirements:

a. Analysis and specification of the system requirements and gap analysis requirements versus the offered product
b. Building of data infrastructure including interfaces to the enterprise information systems existing at or outside the medical centers and interfaces to the laboratory instruments.
c. Planning and specification of the adjustments and modifications required by every medical center and the various laboratories and preparation of a detailed specification document
d. Approval of the specification document by the Division's representatives
e. Modifications development
f. Access to historical data or conversion of the data from the existing system
g. Delivery tests by the supplier and acceptance tests by the representatives of the Division and Centers
h. System installation
i. Instructing
j. Documentation
k. Support and adoption
l. Maintenance services
m. Separation plan

29.1.3. It is clarified that the Division is conducting this tender jointly for all governmental medical centers (as defined above). The representatives of the Division will be responsible with the supplier for developments and modifications in the system, and it may operate a support center that will provide the centers first line support.

29.1.4. At each governmental medical center that will choose to enroll in the project,
a project manager / referent will be appointed. The supplier must act with each center separately on all issues of maintenance, accompaniment, adoption and support (second line if the division operates a first line support center, or first and second line if the Division opts not to operate a first line support center).

29.2. Parties involved

29.2.1. General

a. It is clarified that the communication language between the supplier and the team will be Hebrew.
b. In special cases, a talk with experts may be held in English.
c. It is also clarified that the workdays and working hours are as standard in Israel and according to the Jewish holiday calendar:
d. Sun-Thu (except eves of holidays and holidays) 8:00-18:00.
e. Fridays / eves of holidays 8:00-13:00.
f. The bidder is the manufacturer of the proposed system. The implementation will be done by a team of the manufacturer that meets the conditions and speaks Hebrew or a subcontractor of the manufacturer that meets the conditions and speaks Hebrew.

29.2.2. Parties involved on the customer's side

a. Representatives of the Division
The representatives of the Division represent the medical centers before the supplier. They will be responsible for approving deliverables and milestones, answering questions, request changes, etc., and for defining work procedures throughout the project.
b. A referent of the medical center

29.2.3. Details about the bidder

29.2.3.1. Seniority and experience

The bidder will specify in the bid booklet how many years it has been engaging in the development and maintenance of a LIMS software

29.2.3.2. Customers and installation works

a. In the bid booklet, the bidder will enclose the details of at least 6 customers for which it has performed work that is similar to that being offered in the answer to this tender. At least 3 of these customers are in a country that has diplomatic relations with Israel as defined in Appendix A2.~~Section **Error! Reference source not found.** a above~~.
b. The bidder is responsible for making sure that the contact details are updated and correct as of the time of submitting the bid.
c. The division will contact some or all of these customers according to its decision in order to get opinions on the bidder and on the product.

29.2.3.3. Personnel at the company

The bidder will specify in the bid booklet the number of employees at the company and the number of employees engaging in development / maintenance of software in the LIMS field.

29.2.3.4. ~~Representation unit in Israel~~Local professional team

The bidder will specify in the bid booklet the contact details of the representation unit in Israel and the work assignment between the bidder and the representation unit.
It is clarified that the representation unit in Israel will be responsible for the specification stage and documents, instructing, operating the local support center and will include at least the following key workers: activity coordinator in Israel, a systems analyst and adoption and support manager in Israel.
In addition, the representation unit will include additional workers who are required for its full functioning such as application, support representatives, assimilation workers, instructors and others.
These functionaries will be fluent Hebrew speakers and Israel residents.

A bidder that has a representation unit in Israel at least two years prior to the date of submission the tender, will get an advantage at the quality score stage.

If the bidder is not an Israeli company, it is to attach a a signed declaration as set forth in Appendix B7.

29.2.4. Project specific personnel – key workers

29.2.4.1. General

a. The bidder must detail in the bid booklet the key workers being suggested as set forth below in this section. In addition, it must attach the CV of each functionary and fill in the details of their experience and references. In addition, it must attach the CV of each functionary and fill in the details of their experience and references.
b. The Division reserves the right to interview the candidates for the key functions.
c. the Division will contact some or all of the references. If the reference is not familiar with the candidate, the reference's opinion will be scored as 0.
d. If during the engagement it is learned that the Division is dissatisfied with one of the workers working within this tender, the Division is allowed to demand their substitution, in which case the supplier must substitute that worker within 60 days of the division's notice in that vein, with a suitable worker.
e. Upon winning, the supplier is to show the Division the candidates who are free for work, out of the candidates that it specified in the answer. The Division will be able to choose out of these candidates with whom it chooses to work. If none of them are free to work, the supplier will show additional candidates who meet the requirements, and the Division will be able to interview them and talk with references before choosing.
f. If a key worker must be substituted during the work, the supplier will inform the Division in advance of the substitution of any of the workers so that the Division will be able to approve their employment and state that they have at least the training and experience of the worker whom they are replacing. The substitution of a worker will not cause a delay in the schedules or impair the quality of the product being supplied. It is clarified that the handover period and any other activity required for introducing the new worker into work will be at the supplier's expense.
g. Notwithstanding the foregoing, the substitution of key workers in the first 18 months of the engagement will entail a fine for the supplier as set forth in Section 29.6.5 below. Notwithstanding the foregoing, if the key workers have been substituted owing to a request of the Division, force majeure, death or severe illness, the Division will not fine the supplier.

29.2.4.2. Key workers who don't reside necessarily in Israel

a. Chief architect of the product
Chief architect of the product, at the supplier's place of residence.

b. Manager of the support center
Manager of the support center of the supplier at its place of residence.

c. The project manager
Has experience in the last five years in managing at least two projects that included installation, adoption and modification of the proposed product, each project containing at least 3 laboratories of various types and at least one of the projects involving installation in a laboratory that performs at least 5M (five million) tests per year

d. Chief systems analyst
Has experience in the last 5 years in analyzing needs and gap analysis in at least two projects that included installation, modification of the proposed product, each project containing at least 3 laboratories of various types and at least one of the projects involving installation in a laboratory that performs at least 5M (five million) tests per year.

e. Development team manager
Has experience in the last 5 years in managing the development of at least two projects that included modification of the proposed product, each project containing at least 3 laboratories of various types and at least one of the projects involving installation in a laboratory that performs at least 5M (five million) tests per year.

f. Assimilation/Adoption expert
Has experience in the last 5 years in the assimilation/adoption of at least two projects that included modification of the proposed product, each project containing at least 3 laboratories of various types and at least one of the projects

involving installation in a laboratory that performs at least 5M (five million) tests per year

g. Information security officer
Will be responsible for application and tracking of all instructions as set forth in the information security chapter/appendix of this tender.

h. Customer manager
Will be responsible for all of the activities performed in this project including a work plan, account keeping, personnel management, etc.

29.2.4.3. Key workers who must be in Israel and speak fluent Hebrew (Local Israeli Professional team).

It is clarified that the key workers in this category can be manufacturer employees or subcontractor employees, if the bid meets the requirements set forth in Sections 4.2 and 5.6. ~~**Error! Reference source not found. Error! Reference source not found.**~~.

a. The activity coordinator/ Project manager in Israel
Has experience in the last five years in managing at least two software projects that included installation, deployment and adjustment of a software product.

b. Adoption manager
1) Has experience in the last 5 years in the assimilation of software products in least two projects, each project having at least 3 different physical sites.
2) Willingness and ability to travel nationwide
3) Assimilation manager who has performed a healthcare systems assimilation project – an advantage.

c. Customer_ manager in Israel
In the maintenance period, the supplier will retain a "customer manager" who will be familiar with the software, its installations at the various centers and who will provide an answer to calls of the support center to the extent required.

29.2.5. Instructing

29.2.5.1. General

a. The training apparatus will include a number of trainee populations:
   1) The people of the Division and the medical centers: infrastructure people, application people, referents and support center workers.
   2) Instructors who are people of the Division
   3) End users
b. Applier
   Engages in the operation of the laboratories system at the unit / site, customization of the tables and parameters for the new unit, adapting the system to the work processes, various upgrades, instructing of the team or instructing the instructors
c. Referent
   in addition for the responsibility for the functions of the applier also responsible for regular operation of the system and for correct activity.
   Is able to run routines / control tools to test for problems in the system
   Is able to close / run processes as necessary
   Coordinates the activity with the various parties: users of the system, medical center infrastructures team, the solution provider
   Serves as the “first line” for users calling about questions and faults
d. According to the decision of the Division, the instructing may be performed by the supplier for the instructors of the Division who will instruct the end users themselves.
e. All instructing sessions will be performed in Hebrew, frontally or online, according to the decision of the Division. There may be different manners of training at different centers / laboratories.
f. The supplier will prepare a detailed plan for instructing the infrastructure people and application people at the beginning of the project. A detailed plan for instructing the assimilation workers / instructors will be prepared just before installation works on site.
g. The plans will be forwarded for approval by the Division and will be performed when the appropriate stage in the project begins, in coordination with the Division.

h. The supplier is committed to an adequate level of training for the teams that he will be instructed. In the case of negative feedback from trainees, the supplier will immediately replace the instructor or will readminister the course, at the Division's decision.

29.2.5.2. Training materials

a. The user manuals will be provided in Hebrew.
b. Training materials for application people will be provided in Hebrew.
c. Training materials for infrastructure people will be provided in Hebrew and/or English.
d. All training materials will be shown to the trainees during the instructing and will also be available for their use after the instructing is over until the end of the engagement period.
e. The training materials will include a user manual and videos showing the manner of using the system.

29.2.5.3. Instructing the Division people and medical centers for supporting and installing the product

a. The supplier will train infrastructure people of the Division, including representatives from the medical center, for customization and supporting regular operation and installation of the product. The said courses will also include training for Tier 1 support.
b. The supplier will perform training of application people who are workers of the Division's support center and of the medical centers.
c. The supplier will perform training of referents who are workers of the Division's support center and of the medical centers, who will receive calls/incidents from the end users and will be responsible for referring them to the supplier's support center.

29.2.5.4. Training of instructors of the Division

a. In this outline, the supplier will train application teams and assimilation teams in the Division in "train the trainer" (TTT) form.
b. The Division intends to hold the training for system application and assimilation instructors at each medical center, under the organization and at the responsibility of each medical center, using instructing teams of the Division. The supplier will provide

accompaniment and consultation for preparing the training materials and syllabi in preparation for training on site.

c. The training program will be managed by the Division and the supplier will be integrated in it in coordination with the Division's project manager.
d. The courses will be conducted at the Division's sites, the number of participants in each course will be determined by the Division according to the conditions at the site.
e. Courses for users of the system – will be performed by instructors of the Division.

29.2.5.5. Training of end users on the part of the supplier

a. In this outline, the supplier will train the end users.
b. The training sessions will be performed at the medical centers for each laboratory or groups of laboratories operating in a similar manner.
c. Also, training will be performed for staff members using the system who are not laboratory workers such as physicians, nurses, lobotomists.

The bidder will detail in the bid booklet the training system available to it, the training program and the training materials being proposed.

29.2.6. Adoption/Assimilation

a. The assimilation for users at the medical centers will be done by the Division or by the supplier according to the division's decision.
b. The assimilation will be based on accompanying the various teams in their work, 7 days a week, within two shifts:
   8:00AM-5:00PM, 5:00PM-8:00AM
c. The duration of the assimilation period is estimated at one to three weeks for each laboratory according to their size and complexity.
d. At most laboratories, a single assimilation worker will be required for the laboratory in the daytime (unless agreed otherwise with the Division). At nighttime and on weekend days, a single assimilation worker may be assigned to a number of laboratories at the same medical center.
e. The assimilation will be done at the medical centers' sites.
f. If the Division decides to purchase assimilation services from the supplier, it will purchase these services, according to the supplier's bid for assimilation.

29.2.7. Installation

29.2.7.1. Environments

The supplier will install and maintain at least the following environments:

a. Test environment for Master environment (one)
b. Production environment for Master environment (one)
c. Test environment for each medical center
d. Production environment for each medical center
e. Replication environment for each medical center
f. DRP environment for each medical center

Pricing of these environments is to be included in the cost chapter.

29.2.7.2. Production environment

a. The time of initial installation as well as the times for version updates and details of upgrade plans will be arranged with the division and will be provided advance written approval.
b. The installation will be done according to the division's decision, by the supplier or by the division and hospital teams with the accompaniment of the supplier's support team.
c. Regular updates of editions and/or versions of the product will be made – primary versions and secondary versions, patches, etc., at no additional cost beside the licensing payment.
d. Version content document – each version that will be delivered, including the version content correction patch, will be accompanied by an explanations document on the manner of customizing the content and the change in the system and updating the database structure changes.
e. The supplier will adjust the system to new infrastructure versions, and the Division will inform him of a change in infrastructures. For example, when the Division upgrades the operating systems in a certain medical center, the supplier will have to prepare for such an upgrade accordingly. The time range that will be given to the

supplier to prepare for the upgrade in this case is 3 months from the day of the Division's announcement.

f. Each version will be tested by the supplier before its transfer to the division. The supplier will enclose the test documents with the version at the time of its transfer to the division.

g. The version upgrade will be performed gradually without shutting down the production environment.

h. A version upgrade will first be done in a QA testing environment and only after finishing the acceptance tests will the upgrade be done in the production environment.

i. The supplier undertakes to support all product's versions at the various medical centers until the end of the engagement period.

29.2.8. Details on subcontractors, if any

29.2.8.1. The nature of the engagement between them and the primary supplier

29.2.8.2. The division of responsibility between them and the primary supplier

29.2.8.3. All details that were asked about the primary supplier including customers and references (all sections above)

29.2.8.4. It is clarified that employing a subcontractor does not derogate from the liability of the bidder / selected supplier for the completeness of the bid and the work as set forth in Section ~~Error! Reference source not found. Error! Reference source not found.~~5.6, whether the subcontractor is included in its bid or has been enrolled in the project after winning, during the engagement period.

29.3. Work plan

29.3.1. Method

a. The supplier's project manager will be responsible for preparing the work plan, tracking performance, managing the teams, budgetary review and regular reporting to the customer.

b. The supplier is responsible for arranging with the entities at the ~~Division~~ Directorate and at the medical centers and entities of the supplier and its subcontractors (if any) as required for the success of the project, including but not limited to with technical parties on the installation works of the system before adoption on site begins.

c. It should be clarified that any going live will be arranged with the representatives of the division and with the medical center, and after completion of the risk review and implementation of information security requirements in their entirety.

~~c.~~d. It is clarified that the supplier must report its progress via the Division's project management software.

29.3.2. General work plan

a. The medical centers are interested in adopting the system as soon as possible, soon after the parties sign the agreement

b. The schedule for adoption of the system at the medical centers will be set by the division and in coordination with the supplier.

c. Exceeding the schedule will result in an "overrun fine" being imposed on the supplier as set forth in Section 29.6.5

Failure to meet the schedules will not be considered as an overrun if caused without the supplier being at fault, on the conclusion that the supplier will take any reasonable step to prevent this overrun and will inform the Division immediately upon the occurrence of factors that may cause an overrun.

d. The first stage will be referred to as a P~~p~~ilot and at its end the system will contain at least all of the requirements set forth in the tender documents and will be installed in a dedicated environment (The Master environment) at one medical center. The ~~pilot~~Pilot stage must end up to 18 months from the project kickoff meeting.

29.3.3. Specific plan for the ~~pilot~~Pilot stage

The bidder will detail in the bid booklet a work plan for the entire pilot – i.e., providing a system that meets the requirements of this tender on the dedicated environment.

a. The work plan will specify at least: a description of content for each stage, time for finishing it in workdays and resources required from the Division (for example specification approval, classroom and projector).

b. The work plan will include a Gantt chart managed using dedicated software.

c. The work plan will include at least the following stages:

#	Stage in process	Content of the stage
1.	Work plan	Preparation of work plan.
2.	Risk management	Conducting an information security and cyber risk management review and building the work plan to reduce the risk
3.	Work plan approval	The Division's approval of the work plan or giving comments for its correction. No work is to be started without getting the Division's written approval for the work plan and the service and information security plan.
4.	Detailed specification	The detailed specification document will contain a breakdown of processes and drawings of screens for the completions required for the gaps between the existing product and the tender's requirements. Division approval of the document before starting development is required. Review of progress of specification deliverables and quality will be done at a frequency of once a week or as the Division decides. specification documents will also include information security aspects according to the requirements of this tender and according to the risk management process.
5.	specification approval	The Division's approval of the specification deliverables.
6.	Design of the user interface	The design will be done according to the directions of the tender and the accessibility requirements. Providing standard, accessible and responsive HTML.
7.	Approval of the user interface	The Division's approval of the user interface's design.
8.	Development	Performing delivery tests before transferring for acceptance tests
9.	Delivery tests for development	Writing of test scrips based on the approved specification.

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#	Stage in process	Content of the stage
		Performing functional tests, load tests, accessibility tests and user interface tests.
10.	Installing the system in a test environment	Installing the version in the test environment is coordinated with the division and the medical center. If the system installed is not of a central configuration, the test environment will be separate for each medical center.
11.	Acceptance tests for development	Tests that the Division's representatives will perform for testing match to the specification documents, including customization, development, modification, adjustment and interfaces. The tests will also include laboratory tests, such as: connection of laboratory instruments to the system (drivers), interfaces to external systems, distribution to label printers and more. The tests will be performed with the accompaniment of representatives of the supplier, in accordance with the requirements of the division.
12.	Approval of acceptance tests for development	The Division's approval of the acceptance tests.
13.	historical data access / Conversion	Historical data access and/or Input of information from the previous system according to the specification document
14.	Delivery tests for historical data access / conversion	Writing of test scrips based on the approved specification by the supplier. Performing functional tests, load tests, accessibility tests and user interface tests by the supplier.
15.	Acceptance tests for historical data access / conversion	Tests that the Division's representatives will perform for testing match to the specification documents for conversion.
16.	Approval of acceptance tests for historical data access / conversion	The Division's approval of the acceptance tests for historical data access / conversion.
17.	System penetration testing	System penetration testing for all subsystems will be performed by an outside company that the supplier will employ at its expense. The supplier will correct the flaws, is any have been discovered.

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#	Stage in process	Content of the stage	
18.	Installation in a dedicated production environment (master environment)	Installation of the system and the additional required elements by the supplier and making the required settings in the test and production environments.	
19.	Instructing	Instructing for the various population groups.	
20.	Adoption and support	Preparation of accessory materials for adoption, marketing and advertising, such as user manual, presentations, videos, etc.	
21.	Approval for going live	The Division's approval for going live.	
22.	Transfer of know-how and documentation	Transfer of know-how to the Division's people, including transfer of documentation, operation procedures, backup procedures and handover with the project manager at the center.	
23.	Final acceptance of the ~~pilot~~Pilot stage	The Division's confirmation of final acceptance of the system.	

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29.3.4. Plan for deployment at the various centers

The division is interested in deploying the system at a rapid rate, at least 3 centers per year.
The bidder will detail a plan for deployment, instruction and adoption that fulfills the division's requirements.
In addition, the bidder will specify its personnel that are being provided to this end and the resources required from the division.

29.3.5. Schedules:

a. Periodically, discussions for tracking of progress will be held. For activities that are lagging behind, the bidder's project manager must present and perform corrective actions to close the gaps.
b. It is clarified that the division may be contacted in any case of differences of opinion or necessary inquiries.

29.3.6. Organization

The winning supplier will hold a kickoff meeting with the division up to 30 workdays after receiving the order.

29.4. Regular operation

29.4.1. The service period

The service will be run 24/7/365.

29.4.2. The work site

The supplier will operate at its own premises. The Division / the medical center will not provide a place of work for the supplier or its team.

29.4.3. Reports

a. The supplier's CRM system, supporting Hebrew, will be run for reporting and tracking of events and faults, including incident opening date, the conduct of the supplier in dealing with the incident, classification of the incident.
b. The supplier will forward at the beginning of each month a report of events and faults that have occurred, including a report from its CRM system, which will include number of calls, average time for dealing with a fault, number of abandoned calls, number of calls whose response time has exceeded the time required in this tender statement.
c. In the case of a critical fault, the supplier is responsible for conducting an incident investigation including providing conclusions according to the Ministry of Health's procedure.
d. The system will be exposed to the division and any medical center so that the center users will be able to view calls that have been opened and the chain of action on them. The division's users will be able to view calls of all of the centers.
e. The supplier will forward to the Division or to the center additional information on its activity related to this tender, upon demand.

29.5. Documentation

29.5.1. Documents that will be delivered to the customer:

a. Detailed specification document
b. Test plan
c. Training materials as set forth in Section 29.2.5.2.

29.5.2. Documents that will be provided during the adoption period and at the end of the project

a. Version content document. This document will also be delivered at the end of each version update.
b. Maintenance file, including:

1) Configuration, parameters and versions of system: operating system, servers and terminal stations, the Web engine (if needed) or any technology.
2) A written description of the process and all actions required for resetting the system from "zero" if necessary and disaster recovery, including server, IIS, DB, etc.

c. A user manual and tutorials including tutorial videos on how to operate the system.
d. The flat files structure (exported information)
e. The documentation deliverables except for contracts and documentation of the software manufacturers will be delivered to the Division by the time the project ends (end of installation and adoption). The documentation will be provided on updatable magnetic media and also in two printed copies.

29.5.3. Documents that will be delivered with each version update / fault repair

a. Version content
b. A description of the fault and the solution method
c. A screen will show the new features in the version.

29.6. Maintenance service

29.6.1. General requirements – software and services

The bidder undertakes to provide maintenance services for the applications and services offered as part of the annual licensing payment, including:

29.6.1.1. Consultation on problem solving and correct application of the services in accordance with the Division's needs;

29.6.1.2. Corrections of bugs arising from problems, discrepancies or deficiencies compared to the approved specification or problems in the software and in the documentation of the product for users;

29.6.1.3. Providing regular updates on the software editions and/or versions, if any, for each module that has been provided within the agreement.

29.6.1.4. Instructing of the Division's people at the time of installation of a software edition / version / patch.

29.6.1.5. Providing solutions to problems arising from bugs both in the operation of the applications by users and by the system administrators;

29.6.1.6. Maintaining the technological currency of the system elements, including: tracking of new technologies related to the system and studying them, warnings about the need for modification / upgrading / repairs in the infrastructure systems at the Division or in contiguous systems related to the operation of the system.

29.6.1.7. Notifying the system administrator in advance and providing suitable directions in any case in which a change is expected to occur in the solution components, in order to ensure the integrity and continuity of the solution for the users (for example: changes in the API, need to install a version or patch).

It is clarified that as long as the division has been unable to implement the new solution at all sites of the division following technological limitations or another limitation, the supplier is responsible for continuing to support the old product / old version until transitioning to the new one

29.6.1.8. UX maintenance – may be required in the following cases:

1) Maintenance activity of the system is required and it also has a derivative of the UX.
2) Dealing with a malfunction originating in the UX (for example, at certain resolutions one cannot see part of the screen / certain elements or there is screen behavior that is not completely clear to the users).

29.6.1.9. Documentation maintenance –documentation and training Materials update

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It should be clarified that the maintenance services (including during the warranty period) do not include repairing faults that arise from making changes in the system by any party besides the employees of the supplier or the subcontractor, and these will be repaired for additional consideration according to the changes procedure, as set forth below in Section 29.6.4
In the maintenance period, the supplier will retain a "customer manager" who will be familiar with the software, its installations at the various centers and who will provide an answer to calls of the support center to the extent required.

29.6.2. Support service

Support services are provided to the users of the system in order to solve problems that have arisen during their work on the system.

Problems may arise from a lack of knowledge or failure to succeed in performing any action in the system up to faults of bug types that require intervention and repair of the system code and/or database and/or customization and/or various processes running in the background.

29.6.2.1. Definitions

Term	**Its meaning**
System referent	A IT team member at the medical center who has been especially trained to service the laboratories IT system, both in regular operation and at the level of settings, customization, management of processes and more.
Divisional service desk	The service desk of the governmental medical centers desk, which is scheduled to be set up in the future for providing support to the users of the various systems that are under the division's responsibility. This desk may also provide service to the laboratories system.
The supplier's service desk / support desk / helpdesk	A group of supporters who have know-how and experience in the proposed system. The desk will be operated by the supplier 24/7. The desk may be contacted by telephone call, by email and in other channels that will be defined by the Division such as an instant messaging application and opening of a call by an authorized user. This desk will answer callers in Hebrew.
The supplier's product maintenance team	A team of experts of the supplier who are familiar with the system on the user side and on the side of the software code, databases and back end processes.
Time of starting to remedy a fault	Day, time and minute of starting actual remedial action (the supplier's notice of starting action through an automatic system will not count to this end).

Term	Its meaning
Ordinary fault	Inability of the system to perform the work defined in the specification document and/or in the user manual. Start of action – is not to exceed one workday from the time of notification.
Major fault	A fault that causes a disturbance that is not extreme but greatly disturbs the normal course of work / must be solved within a short time because in the near future it may cause a critical problem / creates a low risk for patients. The remedial action on a major fault will start within a maximum of 2 hours from the time of notification and will be continuous and on all days of the week (24/7) until resolved or until a workaround allowing work to continue is made, including tracking of progress of remedial action by all parties involved (helpdesk, development, etc.) until completion of its remedial action.
Critical fault	A fault that causes a major disturbance that is particularly extreme in the ordinary use and operation of the software or of any part thereof and/or does not allow a significant user group using the software vitally to use the software and/or severely disrupts major business activity of users for which there is no workaround for overcoming it. The remedial action on a critical fault will start within a maximum of half an hour from the time of notification and will be continuous and on all days of the week (24/7) until resolved or until a workaround allowing work to continue is made, including tracking of progress of remedial action by all parties involved (helpdesk, development, etc.) until completion of its remedial action.

29.6.2.2. The severity of the fault will be pronounced by the division.

29.6.2.3. In the case of multiple faults of the same type, the priority for remedial action will be determined by the division.

29.6.3. Fault handling procedure

a. The system referent at the medical center – first line of remedial action

Faults that are discovered by system users will be sent to a medical center referent or to their representative – if discovered during normal working hours in Israel or if they can wait for the normal working hours.

A medical center referent will check the fault and will try using the tools available to them to solve the fault or find a workaround overcoming the fault.

Faults that are not solved by the referent will be forwarded by the referent for action by the support center – helpdesk.

As set forth, in the case of faults that are discovered without the referent present that cannot be waited with until the system referent starts their work, the end user will contact the helpdesk.

~~If the Division runs its own helpdesk, the end user will contact this helpdesk. If the Division's helpdesk cannot solve the problem, it will contact the supplier's support center (second line) as set forth in Section b below.~~

b. The supplier's support center – helpdesk – second line remedial action

1) The support center will operate a digital call management system.
2) A telephone call will be answered within 2 minutes and will be provided 24/365.
3) The support center will provide an answer in Hebrew.
4) Remedial action for a fault will start as defined in the table section 29.6.2.1
   The support center will attempt to deal with a fault by telephone or through remote connection to the site.
5) A fault that is not solved by the support center will be forwarded for remedial action by the product maintenance team.
6) Each month, the support center will forward to each medical center an activity report on the calls that have been opened and the status of each call and its percentages of meeting the service level agreement and the sum that must be offset.

~~As an alternative, the division will be able to run the divisional support desk.~~
~~The bidder must price the two options in the pricing chapter.~~

c. The product maintenance team – third line of remedial action
The maintenance team will deal with a fault using a telephone call and/or remote connection to the site and if necessary, arrival at the site.

The continued remedial action for a major fault or critical fault that has not been fully resolved, as well as remedial action for a non-incapacitating fault will be done by the product maintenance team during the subsequent workdays and working hours until fully resolved.
The product team will forward to the medical center a predicted schedule for attending to the fault.
Once the remedial action is over, the medical center will be provided a detailed investigation report on the nature of the fault, the causes of the fault and the way in which it was resolved.
In the case of a repair of a fault that may also occur at other medical centers in which the system is installed, the supplier must install the repair in all those medical centers.

29.6.4. Request for modifications and improvements – professional services

a. This section deals with requests for modifications and improvements beyond those described in the documents of this tender and beyond the specification that will be approved by the division.
b. In the case of a change request (modification and improvement), the supplier will forward a detailed proposal up to 20 workdays from the time of receiving the request.
c. If the supplier has questions on the request, the supplier will forward a detailed proposal up to 20 days from receiving an answer to the supplier's last question.
d. The proposal is to include: content, schedules for performance of the modification and improvement, a price quotation based on an estimate of work hours of various functionaries required for completing the work and payment milestones.
e. According to the division's decision:
The modifications will be made at a fixed price that will be negotiated between the

bidder and the division and will be paid according to the payment milestones or according to actual hours spent.

29.6.4.1. Demand for information / reporting

a. Any demand for information / reporting will be answered within two workdays.
b. In the case of it not being possible to produce all of the information within this time, the supplier will notify the division in writing on the reason for the delay. This notice will be sent within the two workdays stated in Subsection A above.

29.6.4.2. No travel expenses, travel time, parking expenses or any other expenses will be paid besides the charge rate specified in the winning bid.

29.6.4.3. It is clarified that in the case of an incident resulting in malicious damage and/or damage due to negligence and/or following hardware problems that require an application repair that were not caused by the supplier / its people / subcontractors, the supplier will repair the system in accordance with the provisions of this section, but will be entitled to payment for work hours according to the modifications and improvements charge rate set forth in its bid. It is clarified that the final decision on eligibility for payment is that of the division.

29.6.4.4. The bidder will describe in the bid booklet the service mechanism that will be applied in the case of reporting a fault in the services and will show the time window in which the Division's service calls will be answered.

29.6.5. Service level agreement (SLA) and liquidated damages

29.6.5.1. The service level agreement is a tool used by the Division and the medical centers to define a policy and priorities for providing regular service and for overseeing the supplier's fulfillment of the tender conditions.

29.6.5.2. Liquidated damages – if the supplier does not meet the quality of service and service levels defined in the table below, the supplier will be charged liquidated damages as stated and agreed to in the table below.

29.6.5.3. The Division and the medical centers are allowed to deduct the liquidated damages sum specified from any payment that will be owed to the supplier or to collect them in any other lawful way.

29.6.5.4. Payment of the liquidated damages owed to the Division or to the medical centers will not release the supplier from its obligations according to the tender documents and the contract and from the duties of the supplier to indemnify the Division or the medical centers for damage sustained as a result of its work.

29.6.5.5. It is clarified that the payment of the liquidated damages does not prevent the Division or the medical centers from applying any other sanction against the supplier including invocation of the performance guarantee.

29.6.5.6. The supplier is not allowed to deduct the liquidated damages sum from the pay of its employees.

Section	The tender requirements	SLA deviation	Fine
29.2.4	Substitution of key person	The substitution of a key person in the first 24 months of their work for any reason. For the removal of doubt, such a worker leaving will constitute a fundamental breach of the agreement, and in addition to the remedy pursuant to this section the Division and the medical centers will have all statutory remedies available to them.	3 months of pay of the key person according to the charge rate that the supplier specified (176 monthly hours)
29.6.3	Answering a telephone call	More than 2 minutes	NIS 50 per additional minute in excess of 2 minutes.
29.6.3	A critical fault, start of remedial action within half an hour	More than half an hour from receiving the call to start action.	NIS 5,000 for each hour (or partial hour) of not starting to attend to the call
29.6.3	A major fault, start of remedial action within 2 hours	More than 2 hours from receiving the call to start action.	NIS 5,000 for each hour (or partial hour) of not starting to attend to the call
29.6.3	Ordinary fault: start of remedial action within a workday	More than a workday from receiving the call to start action.	NIS 500 for each hour (or partial hour) late
29.6.4	Submitting a detailed proposal for modifications and improvements	More than 20 workdays without a notice and coordination agreed to by the division before the 20 days are over	NIS 200 for each day late.
29.6.4	Demand for information / reporting	More than two days without a notice and coordination agreed to by the division before the two days are over	NIS 200 for each day late.

Section	The tender requirements	SLA deviation	Fine
29.3	Meeting a milestone in the work plan	Delay of more than 14 workdays from the work plan in providing a ready system ready for use by a center for reasons not depending on the division	NIS 2,000 per day for the first 15-24 days late. NIS 5,000 per day from the 25th day onward.
29.8	Separation plan	Failure to follow the separation plan Failure to be available to and cooperating with the division /new supplier	NIS 150,000 for each week or partial week late from the 8th day.

Liquidated damages (SLA) sections for Error! Reference source not found.

#	Event	The requirement section	Irregularity description	Liquidated damages
1	Replacement of information security officer of the supplier without updating the division.	~~Error! Reference source not found.~~ ~~Section Error! Reference source not found.~~3	Any irregularity	NIS 4,000 per case
2	Not ~~immediately~~ reporting a security incident within 24 hours from the time the supplier learns of the incident	~~Error! Reference source not found.~~ ~~Section Error! Reference source not found.~~ 8.6	Any irregularity	For the first 24 hours without compensation. NIS 2,000 for each day or part of a day after this. A sum of NIS 10,000 will be added to these sums if the tenderer or Division discovers the incident as a result of a public announcement or another source. Such a case is a cause for a fundamental breach of the contract.
3	Failure of the supplier to meet the requirement for forwarding reports and statements.	~~Error! Reference source not found.~~ ~~Section Error! Reference source not found.~~14.4	Beyond 21 workdays from the time of the request	NIS 250 for each workday or partial workday for the first 5 workdays. NIS 1,000 for each day or part of a day after this.
4	Lack of agreement in arranging a time for performing an inspection at the supplier's premises within the time frame required by the tenderer.	~~Error! Reference source not found.~~ ~~Section 6.3.1~~23	Beyond 14 workdays from the time of the request for arrangement	NIS 250 for each workday or partial workday for the first 5 workdays. NIS 1,000 for each day or part of a day after this.

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#	Event	The requirement section	Irregularity description	Liquidated damages
5	Failure of the supplier to meet the requirement for performing actions according to the schedule set by the tenderer	~~**Error! Reference source not found.** - Section 6.3.2~~ All of Appendix B5	Beyond 30 workdays from the time of the request	NIS 250 for each workday or partial workday for the first 5 workdays. NIS 1,000 for each day or part of a day after this.
6	Failure of the supplier to meet the requirement for forwarding documents or details according to the requirements of the tenderer in the case of fear of a cyberattack.	~~**Error! Reference source not found.** - Section **Error! Reference source not found.**~~ All of Appendix B5	Beyond 8 hours from the time of the request	NIS 500 per hour or partial hour up to the first 12 hours. NIS 1,000 per hour or partial hour beyond this.
7	Failure to issue a permit to the tenderer to make a check of the supplier's systems pertaining to provision of the services or supplying the products in the case of fear of a cyberattack.	~~**Error! Reference source not found.** - Section **Error! Reference source not found.**~~ All of Appendix B5	Beyond 24 hours from the time of the request	NIS 500 per hour or partial hour up to the first 12 hours. NIS 1,000 per hour or partial hour beyond this.

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29.6.6. Offsetting of payments and liquidated damages between service and maintenance level (SLA)

29.6.6.1. In the occurrence of incidents that confer compensation as set forth in Section 29.6.5 above (including its subsections), the Division will deduct the liquidated damages specified in the section from all payments due to the supplier, giving an explanatory written notice 7 days in advance.

29.6.6.2. The liquidated damages rates are maximum rates. The Division is allowed to reduce the maximum compensation rate or waive completely compensation or cancel retrospectively compensation that has already been deducted, in accordance with the circumstances of each case and the conduct of the supplier in correcting the breach and its consequences.

29.6.6.3. For example, in the case after the occurrence of the breach of the supplier having been able to reduce the damage, the Division is allowed to reduce the specified compensation rate. Another example is a case of the supplier being able to overcome lateness sustained by the project and

keeping to the original schedule, in which case the Division is allowed to reduce the compensation amount or cancel it retrospectively if already deducted.

29.6.6.4. It is clarified that the decision on whether to reduce the maximum compensation rate or cancel deducted compensation retroactively is at the sole discretion of the Division. Each decision will refer to the specific case at hand and will not constitute a precedent for other cases.

29.7. Resilience and reliability

29.7.1. Test plan

29.7.1.1. In the bid booklet, the bidder will detail the test methodology and the test plan of the software.

29.7.1.2. It is clarified that a test will be run for every installation and version update.

29.7.2. Availability and survivability

The bidder must specify the actions required for availability with attention to the following states:

1) Recovery time (uptime).
2) Attention to the time between a failure and being online again.
3) Downtimes for upgrading the system.

29.7.3. Backups

The supplier is responsible for defining a backup plan that will include a breakdown of the elements that must be backed up.

29.8. Separation plan

29.8.1. General

29.8.1.1. Two years after the date of signing the agreement, the Division can choose to notify the supplier of ending the engagement 6 months in advance.

29.8.1.2. The supplier will continue to provide service and support until the end of the separation period which is 5 years. The division may shorten this period to its sole discretion.

29.8.2. Separation outline

Upon receiving a notice from the Division of ending the engagement, the supplier will be required to act as soon as possible and without delay as set forth below:

29.8.2.1. Forwarding to the Division in an orderly manner all data, information and know-how it has accumulated during the activity and all deliverables that were created during the project, updated, readable and in the formats defined and approved in advance by the Division.

29.8.2.2. Without derogating from the foregoing, the supplier will forward to the Division all deliverables that it has prepared within the provision of the services, including a current system file including applications, tables, developments, interfaces and any other documentation that has been made in relation to the system.

29.8.2.3. The data and information will be transferred by the supplier in a manner that will prevent damage or faults or loss of continuity of service

29.8.2.4. Preparing a work plan for separation and handover in accordance with its tender bid and submitting it for the Division’s approval.

29.8.2.5. Cooperating fully with the Division and with the party defined as its successor and acting according to the plans above, to allow for the organization, substitution and correct continuation of the activity after the engagement with the supplier ends.

29.8.2.6. Allowing a representative of the Division, with the party designated as its successor, to meet with any functionary in the project (and if possible, with a former functionary in the project) for conducting a handover and/or mapping and documentation of the knowledge and information in the possession of the supplier.

29.8.2.7. Continuing to attend to all tasks under its responsibility, until ending the engagement and finishing the transfer of the information and know-how as set forth.

29.8.2.8. At the end of the separation, the supplier must delete and destroy any copy of the information in its possession, in accordance with the information security directions in Appendix B5 above, unless the Division has ordered otherwise in writing.

29.8.3. Separation plan

The bidder will detail in the bid booklet the separation and handover plan that it suggests holding with the Division and the party designated by the Division as its replacement at the end of the engagement. Within the answer the supplier will cover inter alia the following aspects:

29.8.3.1. The times for finishing the separation and the handover.

29.8.3.2. The manner of transfer of the information and data from the supplier to the Division's systems. This includes metadata, encryption keys, data tables, cataloging and any other information item that is required for reading of data and use of the systems of the Division or any delegate thereof.

29.8.3.3. Third party programs, if required, for migration of data from the supplier's systems to the systems of the Division or its delegate.

29.8.3.4. Parties on the bidder's side who will perform the handover.

29.8.3.5. Prevention of damage or faults of interruption to the continuity of service of the Division's systems during and after the termination of the engagement.

30. Cost

30.1. General

30.1.1. The bidder will submit a price quotation that includes all components of the system required in the tender.

30.1.2. The price quotation sheet to be filled in by the bidder is attached as Appendix D.

30.1.3. The bidder must specify costs in Appendix D only. Costs are not to be entered in the other chapters or in the appendices.

30.1.4. No comments or reservations are to be written in the price quotation.

30.1.5. The Division does not commit to the number of medical centers in which the system will be actually installed or their size. The quoted prices for licensing, installation and additional services will also apply to medical centers that will join in the future, if there are any and if the Division chooses to install the system proposed in this tender in them too.

30.1.6. The costs will be quoted in U.S. dollars and will include all required costs except V.A.T.
It is clarified that any mention in the tender documents and in the price quotation sheet of the term dollar refers to U.S. dollars.

30.1.7. A comparison of the bid costs among the different bidders will be done according to the cumulative cost of the bid of each bidder for 20 years, according to the number of specimens that the Division estimates, as set forth in this chapter and in section 6 (part A) above.

30.1.8. The comparison of the costs is based on the Division's estimates set forth below. The estimates have been established as a tool for comparing the bidders' bids only. The Division does not undertake to consume the actual estimated quantities in the described schedule. The Division is allowed to consume actual quantities that are smaller or greater – in accordance with the needs and decision of the Division.

30.2. Price quotation elements contained in the price quotation sheet

30.2.1. Adjustment and setup in the master environment

30.2.1.1. The bidder will state a total price for all requirements in this section.

30.2.1.2. The content of the stage:

This stage includes matching of the proposed solution to the requirements set forth in the documents of this tender. The adjusted system (after tests) will be installed in the mater environment.

a. Performing specification in a "gaps analysis" form - between the requirements of the Division and the capabilities of the products.
b. Building an architecture – consultation for building an overall technological architecture of the solution components with the Division's team.
c. Performing the adjustment and setup of the system, including all environments set forth below, including full integration and setup of the required interfaces, as set forth in the documents of this tender.
d. Delivery of the components set forth in the tender, which the supplier includes in its bid.
e. Support and consultation for setup and installation of environment / environments to the extent required.
f. Instructing the project team in the Medical Centers and the Division.
g. Performing delivery tests and supporting the acceptance tests of the Division including test scripts.
h. Delivery of documentation for the solution components.
i. Update of separation plan to the extent required.

30.2.2. Conversion of and access to historical data

In the "conversion of and access to historical data" table, the bidder will quote a price for each of the options below (as set forth in Section 27 above):

a. Provision of convenient access for viewing historical data of the existing system at the Division.
b. Data conversion – input of data into the system. The data will be received from the Division in a "flat file" format.

30.2.3. Costs of setup installation on premises or in the cloud

a. The option of installation on the cloud is not mandatory but will offer a major advantage in the quality score.
b. In this section the bidder should include any work necessary for setting up the system: setting up environments as set forth in section 29.2.7, definitions of users and more.
c. The payment for installation is one-time.
d. The supplier will enter in column E in the table all costs for installation.
e. The bid will not include the costs of using the cloud, which will be paid directly to Nimbus by the Division.
f. The bid is not to include the costs of server hardware or basic software for servers, which will be purchased by the Division.

30.2.4. Deployment of the system at the medical centers by laboratory

30.2.4.1. This stage includes deployment of the system adjusted to the requirements of the tender at the medical centers, by laboratories.

30.2.4.2. For each medical center, the stage includes:

a. 29.2.7.1Installation of all environments required as set forth in Section 29.2.7.1 environments.
b. Definitions and customization including users and interfaces, and including but not limited to interfaces to laboratory instruments. According to the choice of the center, these stages may be performed for each laboratory / laboratories group separately.

30.2.4.3. The costs of deployment (onetime)- the bidder will enter in Column E the price for each laboratory type:

- Deployment in a first general laboratory at a general medical center
- Deployment at an additional general laboratory at a general medical center
- Deployment in a microbiology laboratory at a general medical center
- Deployment in a pathology laboratory at a general medical center
- Deployment in a blood bank laboratory at a general medical center
- Deployment in a genetics laboratory at a general medical center
- Deployment in a general laboratory at a psychiatric / geriatric medical center

30.2.5. Instructing courses

- Course for users at a laboratory as set forth in Section 29.2.5
- Course for referents at centers as set forth in Section 29.2.5
- Course for application people as set forth in Section 29.2.5
- Course for infrastructures people as set forth in Section 29.2.5
- 29.2.5Course for instructors as set forth in Section 29.2.5
- A price per unit is to be filled in for each course in column E

30.2.6. Adoption support by laboratory types

- Adoption support at a first general laboratory at a general medical center
- Adoption support at an additional general laboratory at a general medical center
- Adoption support at a microbiology laboratory at a general medical center
- Adoption support at pathology laboratory at a general medical center
- Adoption support at a bank blood laboratory at a general medical center
- Adoption support at a genetics laboratory at a general medical center
- Adoption support at a general laboratory at a psychiatric / geriatric medical center
- For each laboratory type, a price for adoption support is to be entered in column E

30.2.7. Costs of professional services by function

30.2.7.1. As necessary, modifications and improvements will be ordered according to the procedure set forth in Section 29.6.4 and based on the charge rates stated in the bid of the winning supplier.29.6.4

30.2.7.2. It is clarified that the payment for professional services that are required within Sections 30.2.1 – 30.2.6 are included in the prices that the supplier specified for these sections.

30.2.7.3. An hourly charge rate is to be entered in column E for each of the functions set forth.

- Project manager
- Systems analyst
- System infrastructures person
- Information security person
- DBA
- Senior programmer – 5 or more years' experience in programming
- Programmer – up to 5 years' experience in programming

- QA person
- Senior instructor / adoption supporter – 3 or more years' experience in adoption support
- Instructor – up to 3 years' experience in adoption support
- Helpdesk support person

30.2.8. Surcharges for developing drivers and installation works according to the Division's requirements

30.2.8.1. Surcharge for a new instrument in a laboratory requiring development of a driver:

30.2.8.2. Surcharge for development of a driver for a laboratory instrument for which the system does not include a driver, including a license to use this driver for all laboratory instruments of this type at all governmental medical centers in Israel and including installation and configuration for this instrument.

30.2.8.3. Surcharge for a new instrument in a laboratory that does not require development of a driver:

A license to use the existing driver in the system for all laboratory instruments of this type at all governmental medical centers in Israel and including installation and configuration for that instrument.

30.2.9. Licensing model – including maintenance and support

30.2.9.1. General

a. Licensing cost model based on quantity of specimens for billing.
b. The price that will be quoted by the bidder in the price quotation for licensing the use of the system will also include the price of maintenance of the system and the support price as set forth in Section 29.6. above.
c. Comparison of the licensing costs between the various bidders will be done according to the cumulative cost of the bid of each bidder for 20 years, according to the number of "Specimens for Billing" (as defined in section 2 in part A) that the Division estimates.

30.2.9.2. The Division's assumptions

a. The assumptions attached serve as a tool for comparing the bids of the bidders only. The Division does not undertake to consume the actual quantities estimated in the schedule described. The Division is allowed to consumer smaller or greater actual quantities – according to the needs and decision of the Division.
b. For comparing bids only, the Division assumes that the deployment of a new system in the Division will take 5 years, gradually.

c. An existing system that is currently deployed in the Division's general medical centers does not require new deployment at the medical centers and will operate on a full scale starting from the first year of the engagement.

d. For comparing bids only, the Division assumes that the quantity of specimens at the governmental medical centers will increase by 5% per year.

30.2.9.3. Explanations and definitions in relation to the licensing costs table:

a. The "ranges of specimens" (cells A88:D92~~A86:D90~~) in the deployment of a new system, the Division assumes five staggered ranges of Specimen for Billing quantities, for each range a minimum quantity and maximum quantity of specimens has been set.

b. "Representative quantity of specimens" (cells D88:D92~~D86:D90~~): a representative number of a quantity of Specimens for Billing has been set for comparing the bids only. This number is based, owing to convenience considerations, on the median of the quantities in each range.

c. "Weight per range" (cells G88:G92~~G86:G90~~): the weight of each of the ranges, which is determined by the Division according to its considerations.

d. "Cumulative weight for range" (cells H88:H92~~H86:H90~~): is the total weight for each range, including the weight of ranges preceding it.

e. "Annual enterprise licensing cost" (cell ~~C82~~C84): the maximum annual payment sum that the supplier will be entitled to for the Division's use of the system, without a limit to the number of specimens. During deployment years, the enterprise licensing sum will be expressed only partially, as set forth below.

f. "Cost of specimens for comparison to range" (cells F88:F92~~F86:F90~~): the price of a Specimen for Billing in dollars for a range times a representative quantity of Specimens for Billing for that range. This cost will not exceed the "maximum cost for range" sum.

g. "Maximum cost for range" (cells I88:I92~~I86:I90~~): the enterprise licensing cost for each range, which is calculated according to the "annual enterprise licensing cost" in the bidder's bid, weighted by the "cumulative weight" for the range. This cost is the maximum cost to which the Supplier will be entitled in any range.

h. "Accessory table – specimen price" (cells J88:L92~~L5:M11~~) – intended to provide the bidder a tool for reviewing and following the directions for filling in the price quotation as set forth below. In the case of deviation from these directions, the table will show an error indication (FALSE).

i. "Accessory table – ~~price~~ bid ~~quotation~~ analysis by years and cumulatively" (cells A94:J110~~J86:L90~~) is a table that details each year the cost quoted by the bidder and the cumulative cost through to that year based on the directions above. For comparing the bids, the Division will choose, in each range, a "cost

of specimens for comparison to range" or a "maximum cost for range", whichever the lower. For the removal of doubt, the "annual enterprise licensing costs" constitutes the upper limit for the comparison. The figures to be shown in this table will be used by the Division for comparing bids only.

j. It should be recalled that the quantities stated in the table are for comparing bids only and do not constitute an undertaking on the part of the Division. The actual payment to the winning supplier will be based on the actual quantity of Specimens for Billing each year.

30.2.9.4. Directions for filling in the licensing costs table:

a. The bidder is allowed to enter its bid only in the cell "annual enterprise licensing cost" (cell ~~C82~~C84) and in "specimen price ~~in dollars~~" (cells E88:E92~~E86:E90~~), the other cells in the table may not be edited by the bidder.

b. First, the bidder must enter an "annual enterprise licensing cost" in cell ~~C82~~C84.

c. Afterward, the bidder must fill in the "specimen price ~~in dollars~~" column, in cells E88:E92~~E86:E90~~, its proposed charge rate for a specimen in each range, according to the directions below:

- In each range, a lower price than the range before it, is to be quoted.
- A price quoted for a range will apply from the first specimen, including to the previous ranges.
- The price quoted for the 5th and last range is a price quoted for any quantity of specimens greater than this without limit.

d. The direction of the Division is that in each range, the "cost of specimens for comparison to range" (cells F88:F92~~F86:F90~~) is not to exceed the "maximum cost per range" (cells =I88:I92~~I86:I90~~); as an accessory for implementing this direction, the bidder must make sure that the "price of specimens ~~in dollars~~' (cells E88:E92~~E86:E90~~) will not exceed the "maximum specimen price for range" (cells J88:J92~~J86:J90~~).

e. The "maximum specimen price for range" (cells J88:J92~~J86:J90~~) will be automatically updated as a result of filling in "enterprise licensing cost".

30.2.10. Bidder surcharges – additional components required for implementing the solution

30.2.10.1. If the proposed solution requires additional components for answering the tender requirements, the Supplier is allowed to add rows as necessary.

30.2.10.2. Elements whose cost is onetime must be separated from elements that have an annual cost.

30.2.10.3. The bidder must specify the name of the component in column C, the required quantity in column D and the component price in column E

30.2.10.4. and the annual cost (maintenance, etc.) for each component accordingly.

30.2.10.5. The division may buy those components independently from another supplier.

30.3. Payment Milestones

30.3.1. Payments for the ongoing period is specified in section 12.

30.3.2. Payment Milestones for setting up the system are specified below.

30.3.3. Development

Stage	Section number	Payment percentage
Specification approval	29.3.3 c 5	15%
Approval of acceptance tests for development	29.3.3 c 12	40%
Installation in a dedicated production environment (master environment)	29.3.3 c 18	25%
Approval for going live	29.3.3 c 21	10%
Final acceptance of the Pilot stage	29.3.3 c 23	10%

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30.3.4. Access to Historical data

Stage	Section number	Payment percentage
Specification approval	29.3.3 c 5	15%
Approval of acceptance tests for Historical data access		40%
Final acceptance of Historical data access		35%

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30.4. Price update mechanism

30.4.1. Definitions

Term	Meaning
Linkage	An arrangement made within the framework of a contract, which is intended to adjust the value of the asset, service or price, to changes in the price level, based on publications by the Central Bureau of Statistics, the Bank of Israel or other official and independent publications, from Israel and outside Israel. Linkage is calculated by comparing the value of the index on the determining date in relation to the base date.
Determining date	The date of submission of the invoice by the supplier.
Base date	Submission date of the bid
Determining index	The value of the index known on the determining date
Base index	The value of the index known on the base date.
Known index	The last officially published index, as of the determining date, even if the index for that month has not yet been published.

30.4.2. Method of calculating linkage

a. The linkage calculation will be performed at the time the invoices are submitted by the supplier, in accordance with the instructions detailed below in sections 30.4.3, 30.4.4.

b. Index linkage differences will be calculated as follows - if it becomes clear at the time of the update that the determining index is different from the base index, the linkage difference will be added/subtracted to the determining amount in an amount equal to the product of the determining amount for linkage by the difference between the determining index and the base index, divided by the base index.

c. On the invoice, the charge must be recorded on one line and the linkage amount on the next line.

30.4.3. Work based tasks

a. This section refers to the following tasks:

Task	Section number
Costs of setup installation on premises or in the cloud	30.2.3
Deployment of the system at the medical centers by laboratory	30.2.4
Instructing courses	30.2.5
Adoption support by laboratory types	30.2.6
Costs of professional services by function	30.2.7
Surcharges for developing drivers and installation works according to the Division's requirements	30.2.8

b. Once a year, the rates will be linked by the Division to CPI (as defined above) and will be set for the coming year. The supplier will issue an invoice at the end of each month containing the relevant rates for that month. There will be no index links during the year.

c. The linkage will be done automatically, and the supplier does not have to send any notice.

30.4.4. License fees (section 30.2.9)

a. The Supplier may, by written notice to the DIVISION not less than sixty (60) days prior to the anniversary of the tenth (10th) anniversary of the submission date, the fifteenth (15th) anniversary of the submission date, and the twentieth (20th) anniversary of the submission date, change the License Fees to be applicable to the portion of the License Term occurring from and after such anniversary, Subject to the extension of the contract for these periods.

b. Such a change may be up to the CPI change (as defined above).

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