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Contents

1. PURPOSE

The purpose of this manual is to document the information available for patients and users of the laboratory services. The information includes as a minimum the following list:

a) The location of the laboratory (Chapter 4.1);
b) Types of clinical services offered by the laboratory including examinations referred to other laboratories (Chapter 7);
c) Opening hours of the laboratory (Chapter 4.5);
d) The examinations offered by the laboratory including, as appropriate, information concerning samples required, primary sample volumes, special precautions, turnaround time, (which may also be provided in general categories or for groups of examinations), biological reference intervals, and clinical decision values (Chapters 7 and 8 and website);
e) Instructions for completion of the request form (Chapter 5 and website);
f) Instruction for preparation of the patient (Chapters 4.6 and 5);
g) Instructions for patient-collected samples (Chapter 5);
h) Instructions for transportation of samples, including any special handling needs (Chapter 6);
i) Any requirements for patient consent (e.g. consent to disclose clinical information and family history to relevant healthcare professionals, where referral is needed) (Chapter 5.2);
j) The laboratory's criteria for accepting and rejecting samples (Chapter 5);
k) A list of factors known to significantly affect the performance of the examination or the interpretation of the results (Chapter 6 and website);
l) Availability of clinical advice on ordering of examinations and on interpretation of examination results (Chapter 7);
m) The laboratory's policy on protection of personal information (Website);
n) The laboratory's complaint procedure (Chapter 9).

The laboratory has additional information available for patients and users on its website, that includes an explanation of the clinical procedure to be performed to enable informed consent. Importance of provision of patient and family information, where relevant (e.g. for interpreting genetic examination results), is explained to the patient and user. This manual

is therefore freely available to patients of which they are informed at each visit to LABdeMED and its outreach locations."

2. SCOPE

This manual applies to the entire organization of LABdeMED, in accordance with the sections indicated in this procedure having direct responsibility for the handling, collection, transportation and examination of primary samples.

This manual covers the requirements mentioned in Article 5.4.2 of ISO 15189. The manual is part of LABdeMED's documented management system. This system is an electronic document system with hyperlinks to all Standard Operating Procedures (SOP), referred to as "procedures" and all work instructions. All documentation of the management system is in compliance with ISO/TR 10013 "Guidelines for quality management system documentation".

The Test Directory sections of the manual outlines the tests performed, the specimen required, turnaround time, reference range and other information regarding specimen collection. The test directory may be updated without updating the entire document. Notification if deemed necessary will be issued regarding the updates.

When key changes are made to either the tests or the services identified in this manual, the customer population will be notified. A simplified version of this manual in Papiamento with all of the key information will be made available to personnel.

3. QUALITY POLICY

LABdeMED's mission, vision and quality policy and objectives are displayed openly as a sign of our pride and commitment and as a clear reminder of our focus and direction. Our mission and vision statements are documented in Section 1 of the electronic Management Manual, and the quality policy statement is documented in Section 4 of that manual.

4. GENERAL INFORMATION

4.1 Location

LABdeMED's main office building is situated at the following address:

Kaya Flamboyan 3
Plasa Roi Katochi
Curacao

LABdeMED has multiple affiliated outlets for samples collection or phlebotomy. These outlets are also called "Outreach Locations". The samples collection outlets are conveniently located for ease of access on the following locations spread over the island of

Curacao:

	Location	Address	Telephone number
1	**Sentro Médiko Barber**	Weg naar Westpunt z/n	736-1030
2	**Mahaai Medical Centre**	Schout bij nacht Doormanweg 10	736-1030
3	**Sta. Rosa Medical Center**	Sta Rosaweg 353	736-1030
4	**Sentro Médiko Caracasbaai** (Med. Office Dr. Marchena)	Caracasbaaiweg 193	736-1030
5	**Master Caribbean Medical Services**	Caracasbaaiweg 193	736-1030
6	**Edifisio Botika Nos Deseo**	F.D. Rooseveltweg 191	736-1030
7	**Sentro Médiko Mahuma** (Med. Office Dr. Rog-Warner)	F.D. Rooseveltweg 280	736-1030
8	**Practica Medica Garcia Telez** (Med. Office Dr. Garcia-Fernandez)	Kaya Bethancourt z/n	736-1030
9	**Sentro Médiko Punda** (Med. Office Dr. Den Ouden)	Kaya Junior Salas 20	736-1030
10	**Sentro Médiko Souax**	Souax 23-A	736-1030
11	**Plexus Medical Center**	Periclesstraat 2	736-1030
12	**Sentro Médiko Seru Fortuna** (Med. Office Dr. Middelhof-Rosario)	Kaya Yobida 21	736-1030
13	**Sentro Médiko Speransa**	Kaya Americo Vespucci 1, Saliña Harbour View	736-1030
14	**Sentro Médiko Aesculapius**	Schout bij nacht Doormanweg 47	736-1030
15	**Sentro Médiko Shekinah**	Jan Noorduynweg 32E	736-1030
16	**Sentro Médiko rondeklip**	Rondeklipweg 1	736-1030

4.2 Postal Address

The postal address for postal correspondence and specimen delivery is:

Kaya Flamboyan 3
Plasa Roi Katochi
Curacao
Website: www.labdemed.org
Email: info@labdemed.org

4.3 General Enquiries

The general phone number for enquiries is: +5999-736-1030.

Advice on interpretation of results and sampling procedures will be directed to the appropriate department.
The FAx phone number is: +5999-736-1130.

4.4 Contact Information

Key members of staff are listed below including their position and contact information.

Laboratory Director +599-9-736-1030
Rudy LeBlanc, MMSc. rleblanc@labdemed.org

Clinical laboratory Specialist +599-9-736-1030
Eddy Balentien, PhD. MMSc. ebalentien@labdemed.org
Rudy LeBlanc, MMSc. rleblanc@labdemed.org
Royston Gijsbertha, MSc. rjgijsbertha@labdemed.org
Cesar Ponce, M.D. cponce@labdemed.org

Human Resources
Mw. Arriana Lo-A-Njoe aloanjoe@labdemed.org

Finance manager
Mr. Shazany Winklaar swinklaar@labdemed.org

ICT manager
B.Sc. Norvel Roosje nroosje@technoforte.com

Manager Laboratory
Mr.Hilbertico Petronilia hpetronilia@labdemed.org

Quality Manager
Drs. Nadia Brito nbrito@labdemed.org

4.5 Laboratory Hours

The laboratory hours are:

b. From 7.00 am to 5.00 pm at the main office building at Kaya Flaboyan 3.
a. From 7.00 am to 12.00 pm at all affiliated samples collection outlets.

4.6 Phlebotomy Service at LABdeMED

To facilitate samples collection, phlebotomy service is offered at the samples collection outlets throughout the island. This service is to facilitate ease of access and to assure the

quality of samples collection. Routine specimens collected outside the LABdeMED outlets or by third parties will be processed on the next routine working day, if these specimens arrive after the deadline. Processing schedules are adjusted to meet the varied workflow of holiday seasons but required urgent testing is provided as needed, if urgent testing is required ensure specimens must be marked **urgent/stat/cito**.

5. LABORATORY REQUEST FORMS AND SPECIMEN CONTAINERS

This section deals with the information that is required to be documented on the laboratory request form and the specimen bottle or container, prior to the analyses of samples.

5.1 Laboratory Request Forms

At LABdeMED two (2) types of request forms are available:

1. A LABdeMED's general Laboratory Test Application Form for all sorts of medical laboratory services. This is the most commonly used. All forms from other laboratories or entities may be used for test requisition.
2. A specific drug test request form for tests to be performed specifically on urine specimens for determination of use of controlled substances.

Instructions for completion of the Laboratory Test Application Form (Item 1):

The Laboratory Test Application Form is a pre-printed standard form with a layout to facilitate application. Each test or service request is selected by marking (cross out or check mark) the corresponding check box.

The Laboratory Test Application is deemed valid for further processing through application and intake with the following:

Customer Identification:

- ❑ The patient or customer must be identified;
- ❑ Gender and date of birth of customer for test result interpretation purposes;

Service Requests:

- ❑ Legible requests of the examinations to be performed (check marks);

Service Applicant:

- ❑ Identification of the medical or paramedical applicant mentioned on the form being the physician, specialist or medical institution (signature and stamp);
- ❑ Acknowledgement of the applicant being an approved applicant;
- ❑ Destination of the test report.

Required documentation for application of services

The following documentation is required with each application (See also Section 5.5):

- Properly completed Laboratory Test Application Form (see above).

- Customer identification: The following are validity patient or customer identification documents (with current validity or expiration date): ID-card, driving license or passport.
- Payment Confirmation. In case of insurance coverage, the document must provide proof of the following:
  - ❑ Validity of the insurer guarantee document;
  - ❑ Validity of the insurer guarantee document mentioning proxy to LABdeMED;
  - ❑ Conformance of the customer name and ID number on the insurance guarantee and the identification document;
  - ❑ Validity of the insurance guarantee (with current validity or expiration date);

Patient consent for use of personal data

With each application, the patient is requested to freely submit the following data used as Patient Identifiers (See 5.5.1), with insurance information:

1. Surname
2. First Name
3. Date of Birth
4. ID number
5. Type of personal health care insurance
6. Insurance expiration date.

With this free submission, the patient confirms his/her consent to process his data for the purpose of the required unambiguous link of the laboratory test results with his/her self.

5.2 Verbal requests for (additional) laboratory tests

There may be situations where a physician may decide to order additional tests (i.e. by phone) to complete the medical diagnosis. Inasmuch as LABdeMED encourages the customer to limit these phone-inn requests to minimize the disruption of the ongoing work processes, the internal procedures allow for these additional services.

In case the applicant (physician) wishes to verbally request additional services, the person receiving the verbal request will do this by filling a verbal request form and attach this to the Laboratory Test Application Form. All these additional tests are recorded in the Laboratory Information System and are clearly marked on the final report to indicate which results reported is originated from a verbal request received.

5.3 Specimen Collection

5.3.1 Specimen receiving and collection is documented with allocated responsibilities in a dedicated procedure titled “Specimen Receiving and Collection”. It is the responsibility of the Phlebotomist to:

- ❑ Obtain consent from the patient where necessary
- ❑ Positively identify the patient from whom the specimen is taken.

- Take the appropriate specimen type and volume. Ensure that the specimen container is suitable for use (i.e. specimen container intact and the expiry date is not exceeded).
- Safely dispose of the materials used in the collection of specimens.
- Ensure that the test / services requested are appropriate.
- Ensure that specimens are delivered to the collection area within a timeframe appropriate to the nature of the tests requested.
- Ensure that appropriate transport containers are used (for the safety of all handlers).
- Ensure that patient confidentiality is maintained.

5.3.2 It is the policy of LABdeMED to treat all diagnostic specimens as potentially infectious or high risk. Therefore, we advise that universal precautions be taken in the collection, packaging and the delivery of specimens being sent to the laboratory for analysis.

5.3.3 Specimens should be freshly drawn venous specimens without dilution by IV fluid. Specimens should not be exposed to direct sunlight or extremes of temperature, transported at room temperature (unless for referral for cold agglutinins) as expediently as possible to the main Laboratory.

5.3.4 Specimens referred to LABdeMED should conform to the requirements for the timing of specimen collection, as defined in Section 5.3.

5.3.5 The date and time of receipt to the testing Laboratory is noted either through a date and time stamper or through the LIS.

5.3.6 On receipt in the laboratory, specimens are registered with a specimen number (Accession Number) and recorded in the LIS/registration log book, as per Standard Operating Procedures.

5.3.7 Laboratory staff will review request forms and specimens to determine if they are suitable for the tests requested. Where it is determined that the request form and/or specimen is not suitable, the requesting physician or specialist will be informed.

5.3.8 Incorrectly or incompletely labeled request forms/ specimen bottles may result in the tests not being performed.

5.4 Timing and Condition of Blood Specimens

5.4.1 **Timing of Specimens** for some tests must be collected with the patient fasting, or with knowledge of when food was last taken (e.g. glucose). Some tests must be collected in the basal state or with due regard to diurnal variations. Some tests may be performed only after prior arrangement with the laboratory e.g. stool

parasitology. Where doubt exists, a Supervisor should be consulted.

5.4.2 **Condition of sample:** Laboratory personnel must inspect prior to testing each specimen received for:

- ❑ presence of **haemolysis**
- ❑ presence of **clots**
- ❑ **Inadequate specimen volume**
- ❑ **Age** of the specimen
- ❑ **Incorrect Storage Conditions**

Where specimens are found to be unsuitable on receipt at the Laboratory, the specimen will be rejected and a **second specimen** will be requested.

5.4.3 **General Collection and Transport Guidelines for microbiology specimens.**

- ❑ Where possible, collect specimen prior to the administration of antimicrobial therapy.
- ❑ If patient is on antibiotics, please identify which one on laboratory request form.
- ❑ Collect specimen with as little contamination from indigenous microbial flora as possible to ensure that the sample will be representative of the infective site. Collect specimen using sterile equipment and aseptic technique to prevent introduction of foreign micro-organisms.
- ❑ Collect an adequate amount of specimen. Inadequate amounts may yield false-negative results.
- ❑ Only swabs with transport medium should be used.
- ❑ Specimens should be transported as soon as possible.

5.4.4 **General Collection and Transport Guidelines for Other Specimens**.

<u>Specimen Collection</u>
All specimen collected by third-party entities (entities not being LABdeMED) shall adhere to priory approved collection procedures or the corresponding guidelines issued by the World Health organization (WHO).

<u>Authorized Physician and Application Requirements</u>
Each application of service received from third-party entities shall comply with the requirements set forth in Section2 5.1 and 5.3 of this manual, with the following additions:

- Authorized physician,
- Date and time of collection,
- When necessary, recording of date and time of received specimen.

<u>Transport of Specimen</u>
Specimens not collected by LABdeMED and destined to be tested by LABdeMED, must be

delivered to the laboratory at Rooi Catootje between the hours of 07:00 a.m. and 05:00 p.m., Monday through Friday.

During transport, the requestor (or third-party entity) shall assure a cooled mobile specimen storage environment not exceeding the range between 15-25 ^{o}C, or if test procedures require otherwise. Requestor will be responsible for recordkeeping so as to assure traceability of sample environment for integrity safeguarding. Requestor shall maintain records of all transporting times and durations

Requestor shall be solely responsible for transporting all materials in biohazard bags and according to biosafety regulations. Requestor remains responsible for any unauthorized disclosure of protected health information while the material is in transit.

Specimen Handling and Accountability

Prior and during transport, Requestor will assume all responsibilities for custody of the specimens. As custodian, Requestor shall have the authority and the corresponding duty to care for the personal, customer and other interests of the specimens.

Upon arrival of the specimens at the laboratory, the Requestor representative shall hand over the specimens at the Laboratory Specimen Collection Area (“Verdeelkamer”). With this exercise the custody of the specimens is transferred from the Requestor to the LABdeMED. The Requestor representative logs the transfer of custody on a “Transfer of Custody Form”. This form includes the following mandatory field:

- Time of arrival.
- Time of transfer to the Laboratory Specimen Collection Area (“Verdeelkamer”).
- Name of the LABdeMED representative receiving the specimen bags.
- Name of the Requestor representative delivering the specimens.
- Signature of the person receiving the samples, indicating transfer of custody.
- Sample box number.
- Temperature recorded inside the box.

None of the guidelines or requirements listed above shall relieve Requestor of its responsibilities for the care of its patients, including Requestor’s use of the test results or any other information provided to Requestor by LABdeMED.

5.5 Request Form and Specimen Labeling

The criteria for specimen acceptance, as described below, are strictly adhered to in order to comply with accreditation standards and in the interest of patient safety. Failure to provide the required data shall lead to rejection of the specimen and request form. Laboratory personnel are acting correctly when they take action to ensure that the minimum standards set out in this policy are met at all times.

Always perform the following steps in this order:

- ❑ Check the identity of the patient.
- ❑ Label the container – NAME, Accession Number, ID and DATE.
- ❑ Place the specimen in the labeled container.

5.5.1 It is essential that the following **patient identifiers** be recorded in a legible manner on all specimen bottles referred to the Laboratory:

1. Surname
2. First Name
3. Date of Birth
4. ID number

5.5.2 The following **specimen information** is required and should be documented in a legible manner on the specimen container:

1. Date of Specimen
2. Time Specimen was taken
3. Initials of person taking the specimen

All detailed requirements are documented in the following procedures:

- "Application and Intake"
- "Primary Samples Collection Manual" (This document)
- "Specimen Receiving and Collection"
- "Specimen Analysis"
- "Specimen Handling and Accountability"
- "Transport and Logistics"
- "Post Analytical Result Reporting"

5.6 Completion of Request Form

5.6.1 The request form must contain the following details, either on a printed label or clearly written:

- Surname and name patient
- Date of birth and Id.number
- Address
- Telephone number(s)
- Name of requester
- Insurance company

Specimens will be rejected if Patient Information Details (PID) are insufficient (see procedure "Application and Intake") or do not match details on form.

5.6.2 It is very helpful for LABdeMED to receive a brief set of clinical details on the request form.

5.6.3 Please note the specific requirements of individual lab tests mentioned in the Test Panel List (Chapter 8):

Biochemistry / Haematology: Analysis / Tests Required
Microbiology: Analysis / Tests required and specimen type

5.6.4 It is essential that the following **patient identifiers** be recorded in a legible manner on all request forms:

1. Surname
2. First Name
3. Date of Birth
4. ID
5. Patient Gender

5.6.5 The following **specimen information** is required for microbiological requests and should be documented in a legible manner on the request form:

1. Date of Specimen
2. Time Specimen was taken (timing in relation to antibiotic dose essential for Antibiotic Assays & for some Biochemistry tests)
3. Consultant, physician or specialist.
4. Patient's address.
5. Clinical details & relevant therapy (previous transfusion history, antibiotic treatment important for Microbiology)

5.6.6 The microbiology request should also include:

- The identification of the specimen source and/or specific site is important so that proper culture media will be selected during processing in the laboratory.

5.7 Exceptions for Labelling Requirements

5.7.1 Exceptions may be made for specimens not meeting the labelling requirements, with prior approval from a Supervisor or Management.

5.7.2 The Supervisor/Management or its designee should be consulted where uncertainty exists about the availability, appropriateness, or selection of tests, the nature of the specimen required, or the interpretation of results.

5.8 Incorrectly Labeled Specimens/Request Forms and Specimen Suitability

Where the requirements with respect to labeling of the specimen container or the request form or specimen suitability issues are not met, the following will apply.

Specimen Labeling:

Specimen	Action by Laboratory	Action Required by Clinician
No specimen received	Patient/client will be phoned informing of the event. This will be documented on the request form.	A second specimen must be collected with a new request form.
Specimen Unlabeled	Specimens will NOT be processed. This will be recorded on the request form, and an incident report will be filed. Request a new specimen.	A second specimen must be collected with a new request form
Absence of any of the mandatory patient identifiers on the specimen	Patient/client or physician will be phoned informing them of the event and requesting a second specimen. This will be documented on the request form and an incident report will be filed. Sample may be processed prior approval by a Supervisor	A second specimen must be collected with a new request form.
Mislabeled Specimens where there is a major conflict in any of the mandatory patient identifiers	Specimens will NOT be processed. This will be documented on the request form and an incident report will be filed.	A second specimen must be collected with a new request form.
Minor miscellaneous specimen labeling issues	Dealt with on a case by case basis	
Specimen collected but time of collection not indicated on either the request form or specimen bottle	The time of collection will not be entered into the LIS system. Certain tests eg ESR, APTT must be performed within specific time post phlebotomy, if no time of phlebotomy is supplied these tests will be rejected	In the event that a sample is procured from a patient more than once on a given day and the time of procurement is not noted, the chronological numbering sequence will not be ordered, in this case look at specimen number and chronological sequence i.e. earlier specimen will have an earlier number

Specimen Suitability

Specimen Suitability	Action by Laboratory	Action Required by Ward/ Clinician
Evidence of hemolysis Inadequate specimen volume Age of specimen Specimen integrity Miscellaneous quality Issues	The Laboratory will make a decision whether or not the specimen is suitable for testing.	A second specimen will be requested where appropriate.
Specimen container expired.	Specimen will not be processed	Second specimen will be requested

Request Form

Request Form	Action by Lab	Action Required by Ward/ Clinician
No request form provided with the specimen.	A second specimen will be requested. The original specimen will be discarded. In an acute emergency, the clinician responsible may complete a Specimen / Request Concession Form accepting responsibility for the amendments made to the inadequate/incorrect details.	A second specimen must be collected with a new request form. In an acute emergency, the clinician responsible may complete a Specimen / Request Concession Form accepting responsibility for the amendments made to the inadequate/incorrect details.
Inadequate or Incorrect Patient Details Recorded: □ Patient Surname (incomplete / incorrect spelling) □ Patient First Name (incomplete / incorrect spelling) □ Gender of Patient	The Laboratory will make a decision whether or not the specimen is suitable for testing. If deemed acceptable the incorrect spelling will be noted on the final report.	

Request Form	Action by Lab	Action Required by Ward/ Clinician
Borderline examples: □ Clinical Information (not supplied) □ Incorrect test requested □ No test requested □ Address (absent/incorrect) □ Doctor or location (absent)	The laboratory will make a decision on whether or not the specimen is suitable for testing. Contact physician to confirm correct details. A second specimen may be requested. Details of information given by Clinician to be recorded on the request form.	

6. SPECIMEN DELIVERY, PACKAGING, STORAGE AND TRANSPORT REQUIREMENTS

6.1 General Information

Precautions

As a general rule, all blood and body fluids should be handled as potentially contaminated and, therefore, hazardous. Standard precautions are strictly observed. Infection control guidelines for dealing with biological spills should be followed in the event of a leakage or spillage of a specimen during transport or handling.

House visits

Blood and body fluid specimen are generally collected at the laboratory premises: Either at the main office or at one of the outreach locations. LABdeMED offers additional service in events or circumstances where specimen collection cannot be done at the lab location. Special visitation and transportation rounds are scheduled to visit customers who are unable to come to the phlebotomy locations. Applications can be submitted through verbal appointments made at the main contact phone number.

Transportation

The transport of specimens to the Laboratory must be done in such a way as to minimize the risk of infection to those who may come in contact with the specimens e.g. taxi drivers, postal workers, porters, laboratory staff etc.

Note: Routine specimens collected and delivered to the laboratory during non-office hours, the tests will be performed the following day.

6.2 Transport of Specimens by Courier

Specimens sent to the laboratory must be packaged correctly according to guidelines

for sending of specimens through the normal post. Alternatively, special transportation boxes may be used, which conform to the following guidelines (procedure “Transport and Logistics”):

- The transport box must be made of smooth impervious material such as plastic or metal, which can easily be disinfected or cleaned.
- The transport box must be secured with a secure lid.
- The box must retain liquid in the event of leakage of a specimen.
- The box must have clearly been labeled with the warning ‘Diagnostic Specimen-Fragile Handling with Care’. The label must clearly state that the box must not be opened or tampered with by unauthorized personnel.

6.3 Disposal of Waste Material Used In Specimen Collection

All materials used in the collection of specimens should be treated as potentially hazardous and discarded according to the procedures “Disposal of Specimens” and “Disposal of Expired Products”.

6.4 Storage of Examined Specimens for Archive and Look Back Purposes

6.4.1 Specimens are stored for a minimum period, as established and documented in the procedure “Disposal of Specimen”.

7. LABORATORY SERVICES

7.1 Provision of Service

Service Name	Service Description
Provision of Diagnostic Service	There is a wide range of Laboratory tests available. A general primary specimen collection manual is in place.
Clinical Chemistry	The clinical chemistry deals with the biochemical/immunochemical basis of disease and the use of biochemical tests for its diagnosis, prognosis, screening and management. The laboratory offers a diagnostic, analytical and interpretative service for a large range of analyses in body fluids. The Laboratory provides a reliable analytical service and advice on the management of patients with metabolic disturbances.

Service Name	Service Description
Hematology	A diagnostic hematology service is provided which provides the following Tests provided in routine Hematology include Full Blood Count, White Blood Cell Differential (Diff), Erythrocyte Sedimentation Rate (ESR), Reticulocyte count (Retic). Tests provided in routine coagulation include Prothrombin time (PT), International Normalized Ratio (INR), Activated Prothrombin time (APTT), Fibrinogen and D-Dimer.
Microbiology	The Microbiology Department offers a comprehensive range of diagnostic services in routine Bacteriology, Parasitology, Serology and Virology as well as consultation in Microbiology, infectious diseases and antibiotic utilization and provision of statistical and cumulative data for infectious disease monitoring.
Consultant Service	Consultant services are available in the following specialties: Clinical Chemistry, Clinical Immunology, and Clinical Microbiology.
Phlebotomy service	The phlebotomy department operates on a routine basis Monday to Friday to take blood specimens for diagnostic testing

7.2 Advisory Service Provided by the Laboratory

The Laboratory Medical and Scientific staff are able to provide an extensive advisory service. Laboratory scientific staff give advice in relation to timing of specimen collection, including repeat frequency of samples.

The Clinical Consultants advisory service includes the following:

- Examination of specimens, authorization, interpretation and reporting of the results obtained and communication with relevant clinicians.
- Ensuring that the service provided in the laboratory meets clinical needs.
- Attendance of regular quality meetings
- Review and sign off on external quality control schemes and non-conformances of medical significance
- Approval of clinical procedures, Quality Manual, Primary Sample User Manual, Validation plans and reviewing and approving reference ranges
- Participation in business planning, including the introduction and assessment of new methods, evaluation and organization of staff and equipment requirements.
- Participation in the education and training of Lab Analysis.

The Medical Microbiologists provides advisory service to other health care workers including doctors, nurses and hospital managers on the island and General Practitioners in the Caribbean; twenty-four hours a day, seven days a week, relating to diagnosis, management and prevention and control of infectious diseases. The microbiologist also liaises with public health physicians to ensure prompt reporting of communicable diseases to the government department of public health.

7.3 Laboratory Tests / Profile Description

The tests provided are listed in the Test Panel List (Chapter 8).

7.3.1 **TEST PROFILE DESCRIPTION**: This section outlines the tests that are available in the laboratory. Each Laboratory test will be described under the following headings:

- Test name
- Specimen type/site
- Specimen requirements
- Turnaround time

The test directory section is subject to change on a frequent basis, such as where the tests are carried out and the associated turnaround times or tests may be added to the directory. This change will not be reflected in the overall user manual and the current revision. Users will be notified of changes to the test directory through memos or highlighted in a specific location associated with this manual which will list any changes.

7.3.2 **TURNAROUND TIMES** is defined as the time from specimen receipt into the LIS system to the time results/services are available for issue. (See tests profiles for exceptions. Confirmation of some reactive specimens and specimens referred to external reference laboratories may have extended turnaround times.) If turnaround time is indicated in days, this is based on routine working days and excludes weekends and Public Holidays.

Non-compliance with the turnaround times

- Should there be a significant delay in the expected turnaround times, the requestor will be notified. In the instances where the delay could compromise patient care, the medical/ clinical personnel will be notified.
- The requestor must inform the laboratory of any change in the urgency of the test result/blood product required so that appropriate action can be taken.

7.4 Further Service Requests on the Primary Specimen

Subject to individual analyte stability, further tests on a specimen that is already in the laboratory can be requested by contacting the Laboratory and/or information provided to

the laboratory and the current guidelines**.** Contact the Laboratory as to whether or not a request form should accompany such a request.

7.5 Repeat Examination due to an Analytical Failure

In the event of an analytical failure, it is the policy of the laboratory:

- Repeat the test using the backup procedure OR
- Store the specimen in appropriate conditions until the cause of the analytical failure is identified and corrected and then repeat the test. The urgency of the outstanding specimen is reviewed by the Director or nominee.
- Where the primary specimen has been compromised due to an analytical failure, it may be necessary to request a replacement specimen for testing.
- It is the policy of the laboratory to pursue further investigation using the primary specimen, where possible.

Additional internal requirements are documented in procedures to define the responsibility for authorization of the resumption of examinations after nonconformities are identified and/or resolved.

7.6 Tests Not Listed

If a diagnostic test that is not listed in Chapter 8 is needed, contact LABdeMED such that arrangements can be made for outsourcing.

7.7 Specimen Referral to an External Laboratory

Where further testing is relevant to the investigation or diagnosis of the conditions of symptoms which gave rise to the original test request then it is the policy of LABdeMED to pursue a diagnosis by performance of additional tests using the primary specimen.

Tests not done on-site are sent to reference laboratories for analysis. Tests to which are under the scope of accreditation are only sent offsite to other accredited laboratories when testing on site is not possible. Information on most of these tests is included in the test directory. In addition, the department arranges for less usual tests to be performed by outside collaborating laboratories.

7.8 Emergency out of Hours Service

Tests provided out of hours are shown in the table below. If any other test is required, the person requesting the test should contact the relevant laboratory medical consultants or Director to request the test.

8. TEST PANEL LIST

This chapter provides information for patients and users to enable informed consent.

8.1 The STAT Testing Package

A “STAT Specimen” is any lab examination to be performed on a specimen, which is ranked of high priority because of a potentially immediate impact on patient health care. “STAT” is an abbreviation from the Latin word “*statim*", meaning “immediately". High priority is translated in work processes that allow for operational preferences so that a turnaround time (TAT) of four (4) hours is achieved. The STAT testing packages includes the following tests:

Clinical Chemistry		
Alkaline phosphatase	Chloride	LDH
Amylase	CPK	Magnesium
ASAT	CRP	Natrium (Sodium)
ALAT	Cortisol (especially in the newborn)	HIV screen (pre-op)
Albumin	Digoxin	Gentamycin
Bilirubin	FT4	Total Protein
Glucose	Gamma-GT	Troponin (high-sensitivity)
Blood gas	Potassium	TSH
NT-proBNP	Creatinine	Urea
b-HCG (quant.)	Lactate	Uric Acid
Calcium		

Hematologie		
APTT	Leucocytes diff: special indications	Malaria
CBC	Liquor CSF (cells, TE, gluc.)	
Blood group/Rhesus	PT of INR-test	
D-Dimer	Sickle cell (screening)	

Urine		
Amylase	Potassium	Urea/BUN
Chloride	Creatinine	Urinalysis screen (multistix)
Protein (UPRO)	Sodium	Urine sediment (after positive stix)
Protein/Creat Ratio		Pregnancy Test (qualitative)

NOTE: The quantitative CRP determination has greatly replaced the ESR test which has become more or less obsolete in an EMERGENCY setting and there is certainly no urgent indication for this test. Moreover, ESR also takes more time.

8.2 Directory of Tests

The following directory list provides an overview of the tests provided at LABdeMED, in alphabetical order. The maximum Turn Around Time (TAT) for each test is established to be 24 hours, unless indicated otherwise:

Test	Tube type	Location	Frequency	ml	Remarks
CLINICAL CHEMISTRY AND SPECIAL CHEMISTRY					
ALAT	Serum	Clinical chemistry	Daily	5	
ASAT	Serum	Clinical chemistry	Daily	5	
Albumin	Serum	Clinical chemistry	Daily	5	
Alfa-fetoprotein	Serum	Clinical chemistry	Weekly	5	Send out
Alkalic phosphatase	Serum	Clinical chemistry	Daily	5	
Amylase	Serum	Clinical chemistry	Daily	5	
Anti-HBs	Serum	Clinical chemistry	Daily	5	
ANCA/GBM	Serum	Clinical chemistry	Daily	5	MPO, PR3 and anti GBM antibodies using line blot methodology
Anti-CCP	Serum	Clinical chemistry	Daily	5	
Anti-EBV (IgG/IgM)	Serum	Clinical chemistry	Daily	5	
Anti -HCV	Serum	Clinical chemistry	Daily	5	
ASO	Serum	Clinical chemistry	Daily	5	
Beta-HCG	Serum	Clinical chemistry	Daily	5	May be requested STAT
Bicarbonate (serum)	Serum	Clinical chemistry	Daily	5	Sample has limited stability once the tube is exposed to air.

Bilirubin	Serum	Clinical chemistry	Daily	5	
Calcium	Serum	Clinical chemistry	Daily	5	
Cannabinoid	Urine	Clinical chemistry	Daily		
CA 125	Serum	Clinical chemistry	Daily	5	
CA 15-3	Serum	Clinical chemistry	Daily	5	
CA 19.9	Serum	Clinical chemistry	Daily	5	

Test	Tube type	Location	Frequency	ml	Remarks
C.E.A.	Serum	Clinical chemistry	Daily	5	
Chloride	Serum	Clinical chemistry	Daily	5	
Chikungunya IgG/IgM	Serum	Clinical chemistry	Daily	5	
Cholesterol	Serum	Clinical chemistry	Daily	5	Fasting sample
Cocaine	Urine	Clinical chemistry	Daily		
Cortisol	Serum	Clinical chemistry	Daily	5	Values depend of the time of draw
CMV IgG	Serum	Clinical chemistry	Daily	5	
CMV IgM	Serum	Clinical chemistry	Daily	5	
C-Peptide	Serum	Clinical chemistry	Daily	5	
C.P.K.	Serum	Clinical chemistry	Daily	5	
C.R.P.	Serum	Clinical chemistry	Daily	5	
C.R.P. hs	Serum	Clinical chemistry	Daily	5	
Depakine (Valproine)	Serum	Clinical chemistry	Daily	5	
Dengue IgG/IgM	Serum	Clinical chemistry	Daily	5	Day of onset symptoms is

Test	Tube type	Location	Frequency	ml	Remarks
					critical to interpret the result.
Dengue NS1 antigen	Serum	Clinical chemistry	Daily	5	
DHEA-S	Serum	Clinical chemistry	Daily	5	
Dilantin (phenytoin)	Serum	Clinical chemistry	Daily	5	Time of draw is relevant.
Digoxin	Serum	Clinical chemistry	Daily	5	Has a narrow therapeutic range.
Estimated eGFR (ckd-epi)	Serum	Clinical chemistry	Daily	5	CKD-epi Estimated GFR is reported together with the creatinine test. Only applicable for ages 18 and up.
HDL-cholesterol	Serum	Clinical chemistry	Daily	5	
LDL-cholesterol	Serum	Clinical chemistry	Daily	5	
HDL/ Chol ratio	Serum	Clinical chemistry	Daily	5	
Estradiol	Serum	Clinical chemistry	Daily	5	Values depend on menstrual cycle.
Ferritin	Serum	Clinical chemistry	Daily	5	
Fe saturation	Serum	Clinical chemistry	Daily	5	
Folic Acid	Serum	Clinical chemistry	Daily	5	
Gamma-GT	Serum	Clinical chemistry	Daily	5	
Glucose fasting	Sodium fluoride plasma	Clinical chemistry	Daily	2	
Growth hormone	Serum	Clinical chemistry	Daily	5	
Gentamycin	Serum no gel	Clinical chemistry	Daily	5	Send out

Test	Tube type	Location	Frequency	ml	Remarks
HbA1c	EDTA	Clinical chemistry	Daily	4	Performed by capillary electrophoresis
Hb-profile	EDTA	Clinical chemistry	1x week		Performed by capillary electrophoresis. Not applicable for ages < 6 months.
Haptoglobin	Serum	Clinical chemistry	Daily	5	
HbsAg	Serum	Clinical chemistry	Daily	5	
Hepatitis A (Tot Ab.)	Serum	Clinical chemistry	Daily	5	
Hepatitis A IgM Ab.	Serum	Clinical chemistry	Daily	5	
Hepatitis C Ab Total	Serum	Clinical chemistry	Daily	5	
HCV	Serum	Clinical chemistry	Daily	5	
Hepatitis B panel	Serum	Clinical chemistry	Daily	5	
HIV Ag and Ab screen	Serum	Clinical chemistry	Daily	5	4th generation HIV ag/ab test. Reactive samples will be confirmed same day. Only from primary tube!!
Creatinine	Serum	Clinical chemistry	Daily	5	
Creatinine clearance	Serum	Clinical chemistry	Daily	5	
HIV Confirmation	Serum	Clinical chemistry	Daily	5	Only from primary tube!!
HSV IgG/IgM	Serum	Clinical chemistry	Daily	5	
Hs-Troponin I	Serum	Clinical chemistry	Daily	5	Cut-off represents 99Th

Test	Tube type	Location	Frequency	ml	Remarks
					percentile of normal.
Insulin	Serum	Clinical chemistry	Daily	5	
IGF-1	Serum	Clinical chemistry	Daily	5	
Helicobacter P. antibody	Serum	Clinical chemistry	Daily	5	
LDH	Serum	Clinical chemistry	Daily	5	
LDL	Serum	Clinical chemistry	Daily	5	Fried Ewald formula is only applicable when triglyceride <400 mg/dl
L.D.L measured	Serum	Clinical chemistry	Daily	5	
L.H./F.S.H. Follicular mid-cycle Menopause male	Serum	Clinical chemistry	Daily	5	Gender, menstrual cycle dependent values
Lipase	Serum	Clinical chemistry	Daily	5	
Magnesium	Serum	Clinical chemistry	Daily	5	Result is dependent on albumin concentration.
Sodium (Natrium)	Serum	Clinical chemistry	Daily	5	
Nicotine	Serum	Clinical chemistry	Daily	5	
NT-proBNP	Heparin plasma	Clinical chemistry	Daily	5	
Phosphate	Serum	Clinical chemistry	Daily	5	
Potassium	Serum	Clinical chemistry	Daily	5	

Test	Tube type	Location	Frequency	ml	Remarks
PTH	Serum	Clinical chemistry	Daily	5	
Progesterone	Serum	Clinical chemistry	Daily	5	
Prolactin	Serum	Clinical chemistry	Daily	5	
P.S.A.	Serum	Clinical chemistry	Daily	5	
P.S.A. free	Serum	Clinical chemistry	Daily	5	Reflex test when PSA is between 4 and 10 ng/ml
Rheum factor (RF)	Serum	Clinical chemistry	Daily	5	
RPR	Serum	Clinical chemistry	Daily	5	
RPR-titer	Serum	Clinical chemistry	Daily	5	
Rubella IgM	Serum	Clinical chemistry	Daily	5	
Rubella IgG	Serum	Clinical chemistry	Daily	5	
Serum Iron (Fe)	Serum	Clinical chemistry	Daily	5	
SHBG	Serum	Clinical chemistry	Daily	Daily	
Sodium	Serum	Clinical chemistry	Daily	Daily	
T.I.B.C.	Serum	Clinical chemistry	Daily	Daily	Calculated through transferrin test result.
Total protein	Serum	Clinical chemistry	Daily	Daily	
Toxoplasma IgG	Serum	Clinical chemistry	Daily	Daily	
Toxoplasma IgM	Serum	Clinical chemistry	Daily	Daily	
T4	Serum	Clinical chemistry	Daily	Daily	
T4 free (FT4)	Serum	Clinical chemistry	Daily	Daily	
Treponema Screen	Serum	Clinical chemistry	Daily	Daily	

Test	Tube type	Location	Frequency	ml	Remarks
T.S.H.	Serum	Clinical chemistry	Daily	Daily	
Tegretol (Carbamazepine)	Serum	Clinical chemistry	Daily	Daily	
Testosterone	Serum	Clinical chemistry	Daily	Daily	
Transferrin	Serum	Clinical chemistry	Daily	Daily	
Triglyceride	Serum	Clinical chemistry	Daily	Daily	Fasting sample
Troponin I (high-sensitive)	Serum	Clinical chemistry	Daily	Daily	
Urea	Serum	Clinical chemistry	Daily	Daily	
Uric Acid	Serum	Clinical chemistry	Daily	Daily	
Vitamin B12	Serum	Clinical chemistry	Daily	Daily	
Vitamin D 25-OH	Serum	Clinical chemistry	Daily	Daily	
Zika	Serum	Clinical chemistry	Daily	Daily	
Hematology					
ESR	EDTA	Hematology	Daily	4	Sample must be analyzed within 4 hrs after draw.
Blood group and Rhesus	EDTA	Hematology	Daily	4	Store at 2-8°C up to 3 days.
Coombs Test: Direct	EDTA	Hematology	Daily	4	Store at 2-8°C up to 3 days.
Coombs Test: Indirect	EDTA	Hematology	Daily		Store at 2-8°C up to 3 days
Erythrocytes	EDTA	Hematology	Daily	4	CBC: sample should be <8 hrs old to perform a manual differential
Hematocrit	EDTA	Hematology	Daily	4	
Hemoglobin	EDTA	Hematology	Daily	4	
Hemoglobin Profile	EDTA	Hematology	Daily	2	
White blood Cells (WBC).	EDTA	Hematology	Daily	4	Manual cell count is performed according to

Test	Tube type	Location	Frequency	ml	Remarks
					laboratory criteria.
WBC differentiation	EDTA	Hematology	Daily	4	
M.C.H.	EDTA	Hematology	Daily	4	
M.C.H.C.	EDTA	Hematology	Daily	4	
M.C.V.	EDTA	Hematology	Daily	4	
Reticulocytes	EDTA	Hematology	Daily	4	
Sickle cell screening	EDTA	Hematology	Daily	4	
Thrombocytes (PLT)	EDTA	Hematology	Daily	4	Patient should be in febrile state for maximum sensitivity.
Malaria	EDTA	Hematology	Daily	4	
Coagulation					
APTT	Citrate plasma	Hematology	Daily	2.7	Sample is stable for 4 hrs at RT (20-25°C) or 2 weeks at -20°C
D-Dimer	Citrate plasma	Hematology	Daily	2.7	Sample is stable for 6 hrs at RT (20-25°C) or 2 weeks at -20°C
Prothrombin time (PT)	Citrate plasma	Hematology	Daily	2.7	Sample is 24 hrs stables at RT (20°C-25°C) or 2 weeks at -20°C
INR test Non-therapeutic Therapeutic Heart valve/ embolism	Citrate plasma	Hematology	Daily	2.7	Sample is 24 hr stables at RT (20°C-25°C)
Allergy					
IgE	Serum	Clinical chemistry	Daily	5	
Individual allergens	Serum	Clinical chemistry	3x week	5	
All allergens	Serum	Clinical chemistry	3x week	5	
Immunology					
Anti-TG	Serum	Clinical chemistry	Daily	4	

Test	Tube type	Location	Frequency	ml	Remarks
Anti TPO	Serum	Clinical chemistry	Daily	4	
Anti dsDNA	Serum	Clinical chemistry	Daily	4	
ANF screen	Serum	Clinical chemistry	Daily	4	
Anti SSA	Serum	Clinical chemistry	Daily	4	
Anti SSB	Serum	Clinical chemistry	Daily	4	
Anti Sm	Serum	Clinical chemistry	Daily	4	
Anti RNP	Serum	Clinical chemistry	Daily	4	
Anti Jo1	Serum	Clinical chemistry	Daily	4	
Anca Screen	Serum	Clinical chemistry	Daily	4	
Anti PR3	Serum	Clinical chemistry	Daily	4	
Anti MPO	Serum	Clinical chemistry	Daily	4	
Anti-Insulin	Serum	Clinical chemistry	Daily	4	
Anti-parietal cells	Serum	Clinical chemistry	Daily	4	
Anti-Gliadin IgA/IgG	Serum	Clinical chemistry	Daily	4	
Anti tTG	Serum	Clinical chemistry	Daily	4	
Anti-Intrinsic factor	Serum	Clinical chemistry	Daily	4	
Urine (quantitative)					
Amylase	Urine	Clinical chemistry	Daily	2	
Cortisol	Urine	Clinical chemistry	Daily	2	
Protein	Urine	Clinical chemistry	Daily	2	
Phosphate		Urine	Daily	2	
Potassium	Urine	Clinical chemistry	Daily	2	

Test	Tube type	Location	Frequency	ml	Remarks
Creatinine	Urine	Clinical chemistry	Daily	2	
Micro-albumin	Urine	Clinical chemistry	Daily	2	
mAlb/creatinine ratio	Urine	Clinical chemistry	Daily	2	
Natrium (Sodium)	Urine	Clinical chemistry	Daily	2	
Pregnancy test (screen)	Urine	Clinical chemistry	Daily	2	
Urine (qualitative)					
Bilirubin*	Urine	Clinical chemistry	Daily	4	
Blood*	Urine	Clinical chemistry	Daily	4	
Glucose*	Urine	Clinical chemistry	Daily	4	
Ketone*	Urine	Clinical chemistry	Daily	4	
Leukocytes*	Urine	Clinical chemistry	Daily	4	
Nitrates*	Urine	Clinical chemistry	Daily	4	
pH*	Urine	Clinical chemistry	Daily	4	
Protein*	Urine	Clinical chemistry	Daily	4	
S.G.*	Urine	Clinical chemistry	Daily	4	
Uric bilirubin*	Urine	Clinical chemistry	Daily	4	
Medical Microbiology Direct exam procedures					
Test	**Tube type**	**Location**	**Frequency**	**ml**	**Remarks**
Occult blood	Feces	Microbiology	Daily		Antigen detection
H. Pylori	Feces	Microbiology	Daily		Antigen detection
E. coli 0157:H7	Feces	Microbiology	Daily		Antigen detection
Campylobacter	Feces discharge swab	Microbiology	Daily		Antigen detection

Test	Tube type	Location	Frequency	ml	Remarks
Trichomonas vaginalis Ag	Vaginal	Microbiology	Daily		Antigen detection
Bacterial vaginosis	Vaginal discharge swab	Microbiology	Daily		
Parasitology					
Amoeba/Cyst/Worm eggs	Feces	Microbiology	Daily		Feces
Cryptosporidium/ Giardia Lamblia	Feces/swab	Microbiology	Daily		Antigen detection
Culture bacteriology Urine culture					
Salmonella	Feces/swab	Microbiology	Daily		
Shigella	Feces/swab	Microbiology	Daily		
MRSA	All types	Microbiology	Daily		
Mycology Candida albicans					
Candida non-albicans	Urine/vaginal swab	Microbiology	Daily		
Candida species	Feces	Microbiology	Daily		
POCT					
PH	Syringe	HLQC	Daily	3	
PCO2	Syringe	HLQC	Daily	3	
PO2	Syringe	HLQC	Daily	3	
BE (base excess)	Syringe	HLQC	Daily	3	
HCO3	Syringe	HLQC	Daily	3	
TCO2	Syringe	HLQC	Daily	3	
O2 Saturation	Syringe	HLQC	Daily	3	

Chemistry/Hematology/Special Chemistry

8.3 Reference Values and Their Origin

Use of reference ranges and values:
Reference values are determined in a reference population. This is done in various ways:

- In samples that have been taken in a well-defined group of donors.
- Some reference values are taken from literature since these are derived from international guidelines.
- In addition, there are a number of reference values that are determined in our laboratory.

These reference areas represent the so-called 95% interval for a representative population. In other words, 5% of the values found in a laboratory test are "increased or decreased" values. These do not necessarily have to indicate a pathology but may be a static phenomenon possible. This also emphasizes the need sparingly to deal with laboratory test requests since the non-indicated applications testing can lead to abnormal results which may cause unnecessary unrest/anxiety in the patient.

TEST	REFERENCE RANGE + ORIGIN (SEE FOOTNOTE) *	REMARKS
CLINICAL CHEMISTRY AND SPECIAL CHEMISTRY		
ALAT	9- 44 U/l (2)	
ASAT	12-40 U/l (1)	
Albumin	3.- 5.1 g% (1)	Minimize stasis
Alfa-fetoprotein	≤10 ng/ml (2)	Sent out, Non-pregnant patients
Alkaline phosphatase	30-90 U/l (1)	
Amylase	25-125 U/l (2)	
Anti-HBs	Neg (5)	
ANCA/GBM	neg (2)	Line blot assay
Anti-CCP	< 20 U/ml (2)	Use in combination with RF test
Anti-EBV (IgG/IgM)	Neg (2)	
Anti -HCV	Neg (2)	
ASO	0 – 125 IU/ml (2)	
Beta-HCG	≤ 30 U/l (neg. pregnancy) (2) ≥ 30 U/l (pos. pregnancy) (2)	
Bilirubin	indir. 0.2 0.7 IU/l (2) totaal 1.01 – 1.99 IU/l (2) direct <2.0 IU/l (2)	
Bicarbonate	22.0-29.0 mmol/l	
Calcium	2.1 - 2.6 mmol/l (2)	
Cannabinoid	Neg (2)	
CA 125	<35 U/ml (2)	
CA 15-3	<58.0 U/ml (2)	
CA 19.9	< 37 U/ml (2)	
C.E.A.	< 5.0 ng/ml (2)	99ste percentile
Chloride	102 - 112 mmol/l (1)	Indirect ISE
Chikungunya IgG/IgM	Negative (5)	Send out
Cholesterol	120 - 200 mg/dl (3)	
Cocaine	Neg (2)	

TEST	REFERENCE RANGE + ORIGIN (SEE FOOTNOTE) *	REMARKS
HDL-cholesterol	35 – 65 mg/dl	
LDL-cholesterol	< 100 mg/dl (6)	Friedewald equation. If triglyceride > 400 mg /dl, LDL calculated.
HDL/ Chol ratio	20 – 26 %	
Cortisol	5- 25 µg% (2)	
CMV IgG	Neg (2)	
CMV IgM	Neg (2)	
C-Peptide	1.1 – 5.0 ng/ml	
C.P.K.	26 - 190 U/l (1)	
C.R.P.	<0.8 mg/dl (2)	
C.R.P. hs	< 11 mg/l (2)	
Depakine (Valproine)	50-100 µg/ml (2)	Trough values
Dengue IgG/IgM	Negative (5)	
Dengue NS1 antigen	Negative (5)	Offered as a panel together with dengue Ab
DHEAS	< 640 ug/dl (2)	Sex and age-dependent
Dilantin (phenytoin)	10-20 µg/ml (2)	
Digoxin	0.8-2.0 ng/ml (2)	Send out
Estimated eGFR	> 60	Calculated using MDRD-4 formula
Estradiol	Follicular 12-160 pg/ml (2) Mid-cycl. 34-400 pg/ml (2) Luteal phase 27 – 246 pg/ml Menopauze 12-30 pg/ml (2) Males < 45 pg/ml (2)	
Ferritin	Male 15-280 ng/ml (1) Female 10-160 ng/ml (1)	
Fe saturation	14 45 %	
Folic Acid	2.8- 16.9 ng/ml (2)	
Gamma-GT	10 – 55 U/L (2)	
Glucose fasting	82-115 mg/dl (4)	
Growth hormone	Male 0.01 – 1.00 ng/ml (2) Female < 10.00 ng/ml	
HbA1c	4.0 – 6.2 % (4) 20- 41mmol/mol	Capilair electroforese
Haptoglobin	> 30 mg/dl	Send out

TEST	REFERENCE RANGE + ORIGIN (SEE FOOTNOTE) *	REMARKS
HbsAg	Negative (2)	
Hepatitis A (Tot Ab.)	Negative	Send out
Hepatitis A IgM Ab.	negative	Send out
Hepatitis C Ab Total	negative	Send out
HCV	Negative (2)	
Hepatitis B panel	negative	
HIV Ag and Ab screen	Negative (2)	
HIV Confirmation	negative	Red Cross send out
HSV IgG/IgM	Negative (2)	
Insulin	6 -27 (2)	
Irregular antibody screening (IRAS)	Absent for irregular antibody (5)	IRAS result is only valid for a maximum of 72 hrs.
IGF-1	163 – 424 ng/ml	
Helicobacter P. antibody	IgA <20.0 U/ml neg (2) >20.0 U/ml pos (2) IgG <20.0 U/ml neg (2) >20.0 U/ml pos (2)	
Creatinine	0.6 – 1.2 mg/dl (1)	Age and gender dependent
Creatinine clearance	46 – 84 ml/min/1.73m^2	Serum and 24-hr urine paired samples
LDH	135 - 225 U/l (2)	
L.D. L	< 100 mg/dl (6)	
L.D.L measured	< 100 mg/dl (6)	
L.H./F.S.H. **Follicular** **mid-cycl** **Menopause** **male**	L.H. F.S.H. mIU/ml (2) 2-15 3-11 mIU/ml (2) 10-80 6-21 mIU/ml (2) 10-60 22-153 mIU/ml (2) 2-10 1-9 mIU/ml (2)	Gender, menstrual cycle dependent values
Lipase	10 – 60 IU/l (2)	
Magnesium	0.65- 1.05 mmol/l (2)	Depends on Albumin concentration and Age
Natrium (Sodium)	138-145 mmol/l (1)	Indirect ISE
Nicotine	<25 (2)	
NT-proBNP	< 300 pg/ml Heart failure unlikely 300 500 pg/ml grey zone >500 pg/ml Heart failure is likely	Age-dependent cut-off
Phosphate	0.70-1.60 mmol/l (1)	Age dependent!

TEST	REFERENCE RANGE + ORIGIN (SEE FOOTNOTE) *	REMARKS
Potassium	3.5- 5.1 mmol/l (2)	
PTH	11- 62 pg/ml (2)	
Progesterone	fol. Fase 32-200 ng/dl lut. fase 119 – 2160 ng% **Adult females:** Post-menopausal <100 ng/dl Oral contraceptives: 34-92 ng/dl ***Pregnancy stage:*** 1e trim 930– 3320 ng% 2e trim 2950– 5000 ng% 3e trim 8310-16000 ng% Males < 20 ng%	
Prolactin	Males 1 - 25 ng/ml (2) Females 1 – 20 ng/ml (2)	
P.S.A.	<4 ng/ml (2)	Basal PSA values increase with age
P.S.A. free	0.05 – 0.25 ng/ml	
Rheumatoid factor (RF)	< 20 IU/ml (2)	Combine with anti-CCP for increased specificity
RPR	Neg (5)	
RPR-titer	neg. (5)	>1:256 is indicative for a primary infect. In case of congenital syphilis suspicion, draw sample from both mother and child and calculate titer ratio!
Rubella IgM	>10	send out
Rubella IgG	Non-reactive <10 Reactive <10	
Serum Iron (Fe)	41 – 132 µg% (2)	Concentration is affected by time of draw
SHBG	Male 13 – 71 nmol/l (2) Female 18 – 114 nmol/l	
T.I.B.C.	100 – 400 µg/dl	Calculated from transferrin concentration. Age dependent
Total protein	6.0 – 8.6 g/dl (2)	
Toxoplasma IgG	Neg (5)	
Toxoplasma IgM	Neg (5)	

TEST	REFERENCE RANGE + ORIGIN (SEE FOOTNOTE) *	REMARKS
T4	7.4-13.0 ug/dl (2)	
T4 free (FT4)	0.7-1.8 ng% (2)	Method not validated for newborn samples
Treponema Screen	Negative (5)	ELISA
T.S.H.	0.4 - 4.0 µIU/ml (2)	Higher in newborns
Tegretol (Carbamazep)	4.0-12 µg/ml (2)	THROUGH VALUE!
Testosterone	Male 166- 811 ng% (2) Female 13- 108 ng% (2)	
Transferrin	198 – 337 mg% (2)	
Triglycerides	39-176 mg% (3)	Should be a fasting sample for adequate interpretation
Troponin I (high-sensitive)	Male < 25 ng/l Female <11ng/l	99th percentile cut-off
Urea	16 - 39 mg/dl (1)	
Uric Acid	3.6 -7.2 m/dl (1)	
Vitamin B12	220 - 1000 pg/ml (2)	
Vitamin D 25-OH	>20 (2)	
Zika	Neg (5)	
HEMATOLOGY		
ESR	1 – 9 mm (1)	Age-dependent
Blood group and Rhesus	Not applicable	
Coombstest: **direct** **indirect**	 neg (5) neg. (5)	If coombs indirect is positive, an antibody identification panel (11-cel) is requested
Erythrocytes	3.8-4.8 10*12/l (1)	Age - dependent
Hematocrit	Male 43 - 52% (1) Female 38 – 47% (1)	
Hemoglobin	Man 14-17 g% (1) Vrouw 12-15 g% (1)	Age-dependent
Hemoglobin Profile	HbAA is normal adult profile	Capillaries electrophoresis
White blood Cells (WBC).	4.5 - 10.5 x 10*9/l (1)	Age – and race dependent
WBC differentiation	In adults (1) % Granulocytes: 40 – 75 % Lymphocytes: 20 - 45 % Monocytes: 2 - 18 % Eosinophils: 0 - 6	Age dependent. Manual differentiation will be performed in analyzer flags or extremes in the different parameters are found.

TEST	REFERENCE RANGE + ORIGIN (SEE FOOTNOTE) *	REMARKS
	% Basophils: 0 - 2	
Malaria	Neg (5)	Alarm value: should be communicated directly
M.C.H.	26 – 33 pg (1)	
M.C.H.C	30 - 35 % (1)	
M.C.V.	81 - 94 fl (1)	
Reticulocytes	0.5- 1.5 % (10)	
Sikkelcel screening	Neg (5)	Only applicable for samples from babies > 6 months
Thrombocytes (PLT)	150- 400 x 10*9/l (1)	Adjust calculation if PLT count is done in citrate-anticoagulated blood.
COAGULATION		
APTT	21- 34 sec (2)	Range depends on the reagent/analyzer combination
D-Dimer	≤ 0.5 ug/ml (2)	Mini vidas
Prothrombin time (PT)	10.7 – 12.6 sec (2)	
INR test **Non therapeutic** **Therapeutic** **Heart valve/ embolism**	(9) 1.0 – 1.7 1.7 – 3.1 3.1 – 7.0	Therapeutic ranges for OAC therapy
ALLERGY TESTING		
IgE total	0 - 328 IU/ml (2)	
Individual allergens		
All allergens	<0.35 kUA/l neg (2)	
Immunology		
Anti-TG	Neg (2)	
Anti TPO	Neg (2)	
Anti dsDNA	Neg (2)	
ANF screen	Neg (2)	
Anti SSA	Neg (2)	
Anti SSB	Neg (2)	
Anti Sm	Neg (2)	
Anti RNP	Neg (2)	
Anti Jo1	Neg (2)	
Anca Screen	Neg (2)	
Anti PR3	Neg (2)	

TEST	REFERENCE RANGE + ORIGIN (SEE FOOTNOTE) *	REMARKS
Anti MPO	Neg (2)	
Anti-Insulin	Neg (2)	
Anti-parietal cells	Neg (2)	
Anti-Gliadin IgA/IgG	Neg (2)	
Anti tTG	Neg (2)	
Anti-Intrinsic factor	Neg (2)	
URINE (quantitative)		
Sample is a 24-hour collection unless stated otherwise		
Amylase	≤480 U/l (2)	Urine portion
Cortisol	40- 350 µg	24-hrs
Protein	< 0.3 g (2)	24-hrs
Protein concentration	≤ 0.2 g/l (2)	Random sample
Phosphate	12.9 – 42.0 mmol/24hr	
Potassium	30-100 mmol (2)	
Creatinine	Male 0.8 - 2.0 g (2) Female 0.6 – 1.8 g/24hrs	24-hr output
Micro-albumin	< 20 mg/l (2)	1st morning void
mAlb/creatinine ratio	< 30 mg/g creatinine (2)	Random sample. Gender dependent
Natrium (Sodium)	40 - 220 mmol (2)	
Pregnancy test (screen)	Negative (2)	Do not use gross hemolytic sample
URINE (qualitative)		
Bilirubin	**Neg**	
Blood	**Neg**	
Glucose	**Neg**	
Ketone	**Neg**	
Leukocytes	**Neg**	
Nitrates	**Neg**	
pH	**4.7-8.0**	
Protein	**Neg**	
S.G.	**1.010 – 1.030**	
Urobilirubine	**Normal**	
Medical microbiology		
Occult blood	Neg. (5)	Sample in a closed container
H. Pylori	Neg	
E. coli 0157:H7	Neg (5)	Sample in a closed container

TEST	REFERENCE RANGE + ORIGIN (SEE FOOTNOTE) *	REMARKS
Campylobacter	Neg	
Trichomonas vaginalis Ag	Neg	
Bacterial vaginosis	Neg	
Parasitology		
Amoeba/Cyst/Worm eggs	Neg	
Cryptosporidium/ Giardia Lamblia	Neg	
Culture bacteriology Urine culture		
Salmonella	**(Neg)**	
Shigella	**(Neg)**	
MRSA	**(Neg)**	
Mycology candida albicans		
Candidanon non-albicans	**(neg)**	
Candida species	**(neg)**	
POCT		
	BLOODGAS	
	Arterial/Capilair (7) pH: 7.31 – 7.41 PCO2: 41–51 mmHg PO2: 22-26 mmol/l BE (Base Excess): -2- -3 HCO3: 23 - 28 TCO2: 24 - 29 O2 Saturation: 95-98%	

*Origin of Reference values:
1. Method comparison/reference range verification
2. Derived from the Instructions for use
3. NECP (National Educational Cholesterol Program, USA)
4. American Diabetes Association (ADA) guideline
5. Norm/by convention
6. Tietz textbook of Clinical Chemistry, 4th Edition, Burtis Eds.
7. I-stat poit of care abbott: https://www.pointofcare.abbott/us/en/offerings/istat/istat-test-cartridges/G3
9 www.fnt.nl (federatie Nederlandse trombosediensten)
10. Essential Haematology, Hoffbrand and Pettit, 3e editie, 1997

8.4 Explanation of Clinical Procedures

This section of the manual includes explanation of the most important or most frequently used clinical procedures being performed. This information is provided to enable informed consent for patients and users.

Test or Clinical Procedure (Dutch) i	Test or Clinical Procedure (English)	Explanation
Clinical Chemistry		
Glucose	Glucose	Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, idiopathic hypoglycemia, and pancreatic islet cell carcinoma.
HbA1C	HbA1C	Electrophoresis is a well-established technique routinely used in clinical laboratories for measuring components from body fluids. The essential principle applied is to separate these components first. A principle of capillary electrophoresis in free solution is commonly used. With this technique, charged molecules are separated by their electrophoretic mobility in an alkaline buffer with a specific pH. Separation also occurs according to the electrolyte pH and electroosmotic flow.
Cholesterol	Cholesterol	Cholesterol measurements are used in the diagnosis and treatment of atherosclerotic coronary artery disease. Cholesterol measurements are also used in the diagnosis of metabolic disorders involving lipids and lipoproteins. Total serum cholesterol concentrations depend on many factors including age, gender, diet, physical activity, liver disease, and other metabolic disorders.
Triglyceriden	Triglycerides	Triglycerides are a form of fat and a major source of energy for the body. This test measures the amount of triglycerides in the blood. Most triglycerides are found in fat (adipose) tissue, but some triglycerides circulate in the blood to provide fuel for muscles to work. After a person eats, an increased level of triglycerides is found in the blood as the body converts the energy not needed right away into fat. Triglycerides move via the blood from the gut to adipose tissue for storage. High levels of triglycerides in the blood are associated with an increased risk of developing cardiovascular disease (CVD).
SGOT/ASAT	AST	AST reagent is intended for the quantitative determination of aspartate aminotransferase activity in human serum or plasma. Aspartate aminotransferase measurements are used in the diagnosis and treatment of certain types of liver and heart disease.
SGPT/ALAT	ALT	ALT reagent is intended for the quantitative determination of alanine aminotransferase activity in human serum or plasma. Alanine aminotransferase measurements are used in the diagnosis and treatment of certain liver diseases (e.g., viral hepatitis and cirrhosis) and heart diseases.
Alk. Fosf.	ALP	This is a quantitative determination of alkaline phosphatase activity in human serum or plasma. Alkaline phosphatase measurements are used in the diagnosis and treatment of liver, bone, parathyroid, and intestinal diseases.
LDH	LD	Lactate dehydrogenase measurements are used in the diagnosis and treatment of liver diseases such as acute viral hepatitis, cirrhosis, and metastatic carcinoma of the liver, cardiac diseases such as myocardial infarction, and tumors of the lung or kidneys.

i As mentioned in Dutch on the Laboratory Test Application Form

Test or Clinical Procedure (Dutch) i	Test or Clinical Procedure (English)	Explanation
CPK	CK	A quantitative determination of creatine kinase activity in human serum or plasma. Measurements of creatine kinase and its isoenzymes are used in the diagnosis and treatment of myocardial infarction and muscle diseases such as progressive, Duchenne-type muscular dystrophy.
Kreatinine	Creatinine	Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.
Ureum	Urea	Urea nitrogen measurements are used in the diagnosis and treatment of certain renal and metabolic diseases.
Urinezuur	Uric	Uric acid measurements are used in the diagnosis and treatment of numerous renal and metabolic disorders, including renal failure, gout, leukemia, psoriasis, starvation or other wasting conditions, and of patients receiving cytotoxic drugs.
Natrium	Sodium	Sodium measurements are used in the diagnosis and treatment of aldosteronism (excessive secretion of hormonealdosterone), diabetes insipidus, adrenal hypertension, Addison's disease, dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance.
Kalium	Potassium	Potassium measurements are used in the diagnosis and treatment of hypokalemia (metabolic alkalosis, metabolic acidosis or the absence of acid-base disturbances), hyperkalemia (over-administration of potassium, acidosis, or crush injuries), renal failure, Addison's disease or other diseases involving electrolyte imbalance.
Chloor	Chloride	Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.
Tot. eiwit.	TP	Total protein measurements are used in the diagnosis and treatment of diseases involving the liver, kidney or bone marrow, as well as other metabolic or nutritional disorders.
URINE		
Volledig onderzoek	Urinalysis	This is an assortment of tests grouped to ease application and intake. These tests are performed un urine samples to detect the presence of normal or abnormal metabolism, cells, fragments of cells and bacteria. Urine is produced by the kidneys, two fist-sized organs located on either side of the spine at the bottom of the ribcage. The kidneys filter wastes out of the blood, help regulate the amount of water in the body, and conserve proteins, electrolytes, and other compounds that the body can reuse. Anything that is not needed is eliminated in the urine, traveling from the kidneys through ureters to the bladder and then through the urethra and out of the body. Urine is generally yellow and relatively clear, but each time a person urinates, the color, quantity, concentration, and content of the urine will be slightly different because of varying constituents.
HEMATOLOGY		
Voll. Bloedbeeld		The Complete Blood Count (CBC) includes: Hemoglobin, Hematocrit, Platelet Count, Red Cell Count, Red Cell Indices (MCV, MCH, MCHC), RDW, White Cell Count, WBC Auto Differential.
BSE	ESR	ESR measures how fast the red blood cells descend in a blood tube. Perform this test to detect the presence of inflammation caused by one or more conditions such as infections, tumors or autoimmune diseases.
Bloedgroep +Rh	Blood Type and Rhesus Factor	All blood contains the same basic components (red cells, white cells, platelets, and plasma), not everyone has the same types of markers on the surface of their red blood cells. These markers (also called antigens) are proteins and sugars that our bodies use to identify the blood cells as belonging in our own system.

Test or Clinical Procedure (Dutch) i	Test or Clinical Procedure (English)	Explanation
		Blood cell markers are microscopic. But they can make the difference between blood being accepted or rejected after a transfusion. So medical experts group blood into types based on the different markers.
Trombotest	CL4	Thrombocytes are the platelets that provide the first phase of blood clotting during bleeding. At the site of the bleeding, these platelets collect and are also activated there. In this way they clump together (aggregation) and form a blood clot that closes the site of bleeding. The platelets are smaller than the red and white blood cells. A reduced measured value can have various causes and is actually only a problem with bleeding. An increased value is found among other things in infections.
APTT	APTT	Activated partial thromboplastin time. The APTT is also called cephalin time. The APTT is a measure of the coagulability of blood taken from sodium citrate after the addition of calcium, phospholipids and an activator. The result says something about the activity of a number of coagulation factors.
PTT	PTT	Prothrombin time. The PTT is expressed in seconds and is a measure of blood clotting. In this test, which does not have to be carried out in the fasting state, the clotting time of blood taken from sodium citrate is measured after the addition of thromboplastin. Thromboplastin is a mixture of phospholipids and tissue factor, in contrast to the APTT test in which only phospholipids are used. In the PT test (PTT), the activity of those coagulation factors, whose activity depends on vitamin K and functional disorders of the liver, is measured. An extended time indicates delayed clotting and may fit with a vitamin K deficiency, for example as a result of a disturbed uptake in the gut or a shortage of gout. Bile salts are required for the absorption of, among other things, the fat-soluble vitamins through the small intestine. For the coagulation, in addition to vitamin K, a number of substances produced by the liver are also required. This test is also used to determine the degree of inflammation or blood thinning in patients who are taking medicines - oral anti-coagulation therapy - and are under the supervision of the Thrombosis Service. In rare cases, there may be a deficiency of a certain coagulation factor, possibly hereditary. This can be, for example, the so-called Factor VII which, in addition to many other coagulation factors, is produced in the liver.
HORMONES		
T4	T4	Tetraiodothyronine or thyroxine. The secretion of T4 is stimulated by the TSH hormone from the anterior pituitary of the pituitary gland and, like T3, is a hormone of the thyroid gland. For their production, iodine is required, as is also evident here from the name. In the blood, the majority of T4 is bound to proteins with a transport function. A small percentage of T4 occurs in free form, this is FT4 or free T4. The metabolism or basal metabolism in the body is also influenced by T4.
TSH	TSH	The thyroid stimulating hormone or thyrotropin (thyreotropin) comes from the anterior pituitary of the pituitary gland. The thyroid gland fulfills a central role in our metabolism. In case of a deficiency of thyroid hormone (free T4), all kinds of processes in the body are slower which is often accompanied by symptoms such as fatigue, slowness, lethargy, weight gain and constipation. A too fast thyroid gland leads to acceleration of many processes with consequences such as excitement, slimming, palpitations and diarrhea. In case of a thyroid gland that is too fast or too slow, the amount of thyroid hormone will be too high or too low. In addition, the value of the TSH hormone that stimulates the thyroid gland goes up or down. Changes in the TSH values indicate whether the thyroid gland works too quickly or too slowly. See also T4.
IMMUNOLOGY		

Test or Clinical Procedure (Dutch) i	Test or Clinical Procedure (English)	Explanation
Lues screening	Syphilis	This test is used to screen for or diagnose an infection with the bacterium Treponema pallidum, which causes the sexually transmitted disease syphilis. The most common route of transmission is through contact with an infected person's sore during sexual activity. The bacteria enter the body through minor cuts or abrasions in the skin or mucous membranes. Syphilis is contagious during its primary and secondary stages, and sometimes in the early latent period.
Anti-HIV	Anti-HIV	AIDS (Acquired Immunodeficiency Syndrome) is characterized by changes in the population of T-cell lymphocytes. In an infected individual, the virus causes depletion of CD4 helper T-cells, which leaves the person susceptible to opportunistic infections and some malignancies. The virus that causes AIDS exists as two related types known as HIV-1 and HIV-2. The multiplication of the HIV in the effected cells leads to cell rupture and thus the release of HIV virus particles, which are first detected in the form of HIV RNA and next in the form of HIV antigen.
H.Pylori Ag	H.Pylori Ag	H. Pylori is a small, spiral-shaped bacterium that lives in the surface of the stomach and duodenum. It is implicated in the etiology of a variety of gastrointestinal diseases, including duodenal and gastric ulcer, non-ulcer dyspepsia and active and chronic gastritis. Both invasive and non-invasive methods are used to diagnose H. pylori infection in patients with symptoms of gastrointestinal disease. Specimen-dependent and costly invasive diagnostic methods include gastric or duodenal biopsy followed by urease testing (presumptive), culture, and/or histologic staining. A very common approach to the diagnosis of H. pylori infection is the serological identification of specific antibodies in infection patients.
MICROBIOLOGY		
Urine kweek		The urinary tract consists of the organs that produce urine and the organs through which urine is discharged, which is the kidney, the renal pelvis and the ureters as the higher urinary tract, and the bladder and the urethra as the lower urinary tract. A UTI (Urinary Tract Infection) is the collective name for all the infections that could affect the urinary tract. Bacterial urinary tract infection can affect patients of all ages and both sexes. The determination of a UTI is based on the count of colony-forming units (CFU) per milliliter of urine and the identification of the causative agent, on the basis of isolation of micro-organisms together with relevant susceptibility test.
ACW	ACW	ACW stands for Amoeben Cysten Wormeieren. The ACW test is a parasitology test to verify if an infection has a parasite as its cause with excessive diarrhea as a consequence. There are several other types which are occasionally seen in the feces as cysts, usually not considered pathogenic.
Occult blood	FOBT	The fecal occult blood test (FOBT) is a test used to check stool samples for hidden (occult) blood. Occult blood in the stool may indicate colon cancer or polyps in the colon or rectum — though not all cancers or polyps bleed. Typically, occult blood is passed in such small amounts that it can be detected only through the chemicals used in a fecal occult blood test. If blood is detected through a fecal occult blood test, additional tests may be needed to determine the source of the bleeding. The fecal occult blood test can only detect the presence or absence of blood — it doesn't indicate potential sources of bleeding.

9. REPORTING OF TEST RESULTS

9.1 Reporting Results

9.1.1 All results once released, are available on the LABdeMED computer system with restricted access.

9.1.2 Reports are printed with reference ranges and/or suitable comments wherever appropriate, to aid interpretation of results. Reports will only be given to the requesting doctor. Private individuals may receive a copy of the reports, provided they present an acceptable identification document.

9.1.3 Where an preliminary report is issued, a final report will follow.

9.1.4 Where a test is delayed the requestor will be notified. It is LABdeMED's policy to immediately notify the referring physician when there are indications that the results may be delayed. A verbal report will be given as progress of the test becomes available, if required.

9.1.5 Printed reports are delivered by the Secretarial Staff/messenger every afternoon. Results for Generals Practitioners are printed and posted daily. Emergency, critical and urgent reports are phoned/faxed directly to the physician and/or requesting doctor.

9.2 Telephoned Results

9.2.1 It is LABdeMED policy to issue hard copy reports. In urgent circumstances, LABdeMED will provide telephoned results to the patient's physician/or designated clinical personnel, prior approval from the Supervisor.

9.2.2 When requesting a verbal report, the patient's personal identifiers, i.e. patient's name and ID must be confirmed to the laboratory Operational Coordinator. LABdeMED will also require the details of the requestor i.e. their own name and designated responsibility, for example from a clinician or nurse. All details will be documented in a Log book (STAT Registry Form) or as a comment on the patient's results on the LIS. A hard copy of the report will follow.

10. REVIEW & ASSESSEMENT OF CUSTOMER SATISFACTION

Customer satisfaction is assessed through regular survey of users and the processing of complaints and through feedback received at meetings with physicians and specialists.

10.1 Customer Complaints

LABdeMED operates within its Quality Management System incorporating services complaint procedures.

The objectives of our complaints handling system require:

- ❑ All complaints are rapidly and effectively handled and fully investigated.
- ❑ Customer and/or patient difficulties are alleviated promptly.
- ❑ Appropriate corrective and preventive actions are taken to reduce the risk of repeated errors
- ❑ Customer confidence is maintained in our service.
- ❑ Relevant information is recorded and reported to the Out-Reach Supervisor or the Quality Officer of LABdeMED.

END OF DOCUMENT