Criterion VIII- Nursing Part

8.1.5 Teaching hospital/ clinical laboratory

accredited by National Accrediting Agency

DVV FINDINGS

1. Provide policy documents
2. Provide NABL certificate

1. Provide policy documents

Sr. no	Policy document
1	Primary sample collection manual
2	Quality control manual
3	Safety manual

PRIMARY SAMPLE COLLECTION MANUAL

ISO 15189:2012

of

DEPARTMENT OF PATHOLOGY

LATA MANGESHKAR MEDICAL FOUNDATION'S

DEENANATH MANGESHKAR HOPSITAL &

RESEARCH CENTRE

Erandawane, Pune-411004

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RELEASE AUTHORISATION

The primary sample collection manual is released under the authority of Dr.Vijayshri Bhide, Consultant Pathologist and is the property of Deenanath Mangeshkar Hospital & Research Centre, Erandawane, Pune-411004.

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REVIEW SHEET

Sr. No.	Date	Comment	Signature of person Authorised for review	Signature of Quality Manager
1.	06.05.2020	Review done, changes done and details are available in amendment sheet	-Sd-	-Sd-
2.	06.05.2021	Review done, changes done and details are available in amendment sheet	-Sd-	-Sd-

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AMMENDMENT RECORD SHEET

S. No	Page No	Section/ Clause/ Para/Line	Date of amendment	Amendment made	Reasons of Amendment	Signature of person authorizing amendment	Signature of Quality Manager
1	34	5.4.7	27.04.2020	Changes done in pre-examination handling, preparation & storage	Added regarding storage of extracted DNA & RNA for infectious parameters	-Sd-	-Sd-
			27.04.2020	Test added in DOT	Test to be included in Scope of NABL Accreditation	-Sd-	-Sd-
2	Footer, release of authorisation	-	01.06.2020	Change in name of person authorized for issue of this document due to change of HOD	Hospital Policy	-Sd-	-Sd-

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ABBREVIATIONS

S. No	Abbreviations	Expansion
1	ANA	Anti nuclear antibody
2	BSL	Blood Sugar Level
3	Conc.	Concentrated
4	ELISA	Enzyme linked immuno sorbent assay
5	ESR	Erythrocyte Sedimentation Rate
6	FNAC	Fine needle aspiration cytology
7	GTT	Glucose tolerance test
8	HIV	Human Immunodeficiency Virus
9	HCL	Hydrochloric acid
10	Hb	Hemoglobin
11	HBsAg	Hepatitis B antigen
12	I.V.	Intra venous
13	ID	Identification
14	IPD	In Patient Department
15	LAB	Laboratory
16	MPW	Multi Purpose Worker
17	OT	Operation Theatre
18	OPD	Out Patient Department
19	OGCT	Oral glucose challenge test
20	PT	Prothrombin time
21	PTTK	Partial thromboplastin time with kaolin
22	PMC	Pune Municipal Corporation
23	T3	Triiodothyronine
24	T4	Thyroxine
25	Trop T	Troponin T
26	Trop I	Troponin I
27	TSH	Thyroid stimulating hormone
28	VDRL	Venereal Diseases Research Laboratory
29	VMA	Vanilyl mandelic acid

5.4 Pre-examination processes

5.4.1 General

The laboratory has documented procedures and information for pre-examination activities to ensure the validity of the results of examinations in primary sample collection manual.

5.4.2 Information for patients and users

The laboratory has information available for patients and users of the laboratory services. The information includes as appropriate:

b) The O.P.D for sample collection is located on ground floor 'B' Wing of old building and on the 1st floor in superspeciality building. The processing of all samples is done on the 1st floor of the new building. The department is open from 8.00 am to 8.00 pm. Processing of molecular and cytogenetic tests is done in the molecular diagnostic laboratory located in the A wing of the 6th floor in the Deenanath Mangeshkar Hospital Research Centre (DMHRC) building also called as the old building. The Molecular Diagnostics Department is open from 9.00 am to 6.30 pm. However, lab technicians are available in the superspeciality new building for blood collection during night for emergency cases.

c) All routine tests and few special tests are done in the laboratory. However, all rare special tests are sent to referral laboratories in Pune, Mumbai or all over India or even abroad. These tests are marked as *** (Outsourced tests)

d) The laboratory is open 24 hours x 7days. It is open throughout the day as well as night. It works even during public holidays.

e) The examinations offered by the laboratory are listed in Directory of Tests that gives information about test name, section, specimen, container, quantity, turnaround time, patient preparation and sent out test. Biological reference intervals and clinical decision values are included in the test report.

f) Request forms are accepted by the laboratory only when they are duly filled with respect to patient name, age, sex, MRD No, and clinical diagnosis. An electronic request is generated by the clinicians, in case of IPD patients and hard copy of the request is received, in case of OPD patients.

Relevant clinical data is retrieved from the software. (Refer to Annex E for test requisition forms)

g) Test instruction slips have been prepared in English and Marathi and are distributed to the patients in OPD. The patient preparation instructions for IPD patients have been included in the "Directory of tests" (DOT). (Refer to Annex C for test instruction slips)

h) Urine samples are collected by patients. Tests instructions are available for urine collection in DOT.

i) IPD/OPD samples are transported by pneumatic chute system and are received in the Accession room.

Samples that are not transported through pneumatic chute system are:

1. Histopathology samples
2. FNACs
3. Samples for culture
4. Bone marrow aspiration & biopsy samples
5. Body Fluids

Precious and emergency samples are transported by MPWs from wards and OPD laboratory. All samples have a standard transportation time of 15-30 minutes. For samples whose transportation is delayed due to some reasons, they are stored in a refrigerator at 2-8^{0}C, installed in OPD and Sample Accession Room. All emergency samples are transported to the laboratory immediately and the concerned lab personnel are duly informed. Amber colored containers are used when light affects the lab tests adversely for estimation of 24 hours urinary VMA. The sample taken for serum bilirubin is protected from direct sunlight and fluorescent light. **Some samples are to be sent to the laboratory immediately:**

1. Labile analytes (like plasma ammonia, lactate)
2. Prothrombin time
3. aPTT
4. D-dimer

5. Fibrinogen
6. Trop T
7. All microbiology samples

Paraffin embedded blocks processed and stored in outside laboratories, or in house blocks in patient's possession are received by the technical staff, in the molecular diagnostic department. Block ID and quantity is documented on the requisition slip, and countersigned by the patient or relative.

i) In case of bone marrow aspiration procedure, consent is taken in minor OT in the consent register. Informed consent is taken for HIV testing. Forms are also available for certain out sending genetic and molecular tests. The consent forms are available in both English as well as local language i.e. Marathi (Refer to Annex B for consent forms).

In emergency situations, consent might not be possible; under these circumstances necessary procedures are carried out, provided they are in the patient's best interest.

Consent is taken for following tests in the laboratory:

1. HIV
2. FNAC
3. Bone marrow aspiration & biopsy
4. Fetal autopsy
5. Molecular tests
6. Genetic tests
7. DNA banking

j) Sample rejection criteria:

1. Specimens with improperly filled requisition forms.
2. Specimens collected in improper containers
3. Insufficient quantity.
4. Specimen inappropriately labeled, unlabeled or with label discrepancies.
5. Specimens that are clotted, hemolysed or lipemic.
6. Grossly contaminated specimens.
7. Insufficient tumour cells in tumour blocks & insufficient cells on smears (for Molecular Diagnostics).

k) A list of factors known to significantly affect the performance of the examination and the interpretation of the results. Following are the factors that may affect performance

1. Time of collection is important in the following tests which may affect the performance of tests:

Sr.No	Test	Instructions for Sample collection timings
1	Blood sugar F & PP	Fasting & 2 hours after meal
2	Blood sugar F & PG	Fasting & 2 hours after glucose
3	G.T.T	Fasting, 1hr, 2hrs, 3hrs as per requirement
4	OGCT	Two hours after giving 75 gms of glucose
5	Lipid profile	12-14 hrs fasting
6	E.S.R	Fasting preferred
7	Prothrombin time	Before dose or minimum 6 hrs after dose
8	T3, T4, TSH	Fasting preferred
9	Serum Cortisol	At 8 am and 4 pm
10	Serum Digoxin	Before dose or 2 hours after therapy
11	d-xylose	Fasting
12	Urine Porphobilinogen (Quantitative)	Fresh Sample

2. Clinical history is important in following tests for interpretation of results.

Sr.No	Test	Instructions regarding Clinical information
1	Prothrombin time	Information is provided regarding dose and frequency of administration of warfarin/heparin orally/ injections.
2	Thyroid profile	History of medication, esp. thyroid drugs
3	Reproductive hormones	Clinical history, last menstrual period
4	Tumor markers	Sonography report and other clinical history
5	Cytology, Histopathology	Provide detail history

3. A few instructions for common tests have been mentioned below which affect the performance of examination and interpretation of the results:

Sr.No	Test	Instructions
1	Blood Sugar Fasting	Patient should be fasting; can drink only water
2	Blood Sugar Postprandial	Patient should come for blood collection two hours after lunch
3	Lipid Profile	12-14 hours fasting
4	24 hours urine sample	Collect all the urine of 24 hours in a container containing required preservative.
5	Tumor markers	Sonography report and other clinical history
6	Drug levels	Sample collected before taking dose
7	Thyroid Profile	Patient history of medication
8	Reproductive hormones	Last menstrual period Clinical history
9	Cortisol	8 am and 4 pm

4. Cytogenetic, Molecular: Provide detail clinical history & histopathology reports.

l) Laboratory ensures the provision of clinical advice with respect to the ordering of examinations, and on interpretation of examination results. This advice is offered by Consultant Pathologist/Microbiologist/Clinical Biochemists/Molecular Pathologist.

m) Policies have been established to protect patients from harm caused by loss or change of data, with system security and a backup. The data viewed in the wards on LAN cannot be changed by those in the ward.

n) The laboratory has a documented procedure for the management of complaints or other feedback received from clinicians, patients, laboratory staff or other parties. It is the policy of the laboratory to accept complaints, to investigate them completely and

to establish if any non-conformity has occurred and to take all corrective and preventive actions as necessary. Records of all complaints and their investigations and actions taken are maintained (DMH/QSP/MG-06/13). Feedbacks are taken from patients and clinicians regularly, they are reviewed and records are maintained. Complaints/Suggestion box is available in OPD laboratory. Lab Manager checks the suggestions box periodically and hands over the complaints/suggestions for necessary action to be taken by the lab. For IPD patients, feedback is taken at the time of discharge. If there is any suggestion or complaint it is directed to pathology department.

The Lab has information available for patients and users 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 is explained to the patient and user.

5.4.3 Request form information

An electronic request is generated by the clinicians, in case of IPD patients and hard copy of the request is received, in case of OPD patients. The laboratory uses a request form which contains sufficient information to uniquely identify each patient and the authorized requester. Relevant clinical data is retrieved from the software. The request form or an electronic equivalent is designed in such a way that it allows space for the inclusion of, but not limited to the following:

a) patient identification, including gender, date of birth, and the location/contact details of the patient, and a unique identifier in the form of MRD (Medical Record Document) Number.
b) name or other unique identifier of clinician, healthcare provider, or other person legally authorized to request examinations or use medical information, together with the destination for the report and contact details;
c) type of primary sample and, where relevant, the anatomic site of origin;
d) examinations requested;
e) clinically relevant information about the patient and the request, for examination performance and result interpretation purposes;
f) date and, where relevant, time of primary sample collection;
g) date and time of sample receipt.

The laboratory has a documented procedure concerning **verbal requests** for examinations that includes providing confirmation by request form (OPD)or electronic request(IPD) within a given time. (DMH/QSP/MG-06/25)

The laboratory takes all necessary efforts to cooperate with users or their representatives in clarifying the user's request.

5.4.4 Primary sample collection and handling

5.4.4.1 General

The laboratory has a documented procedure for proper collection and handling of primary samples.

Documented procedures are made available to those responsible for primary sample collection whether or not the collectors are laboratory staff. Specific instructions for proper sample collection and handling of primary samples are mentioned in the primary sample collection manual and a copy is kept in the OPD sample collection centre (old building) and OPD (new building).

Where the user requires deviations and exclusions from, or additions to, the documented collection procedure, these are recorded and included in all documents containing examination results and are communicated to the appropriate personnel.

Special procedures, including more invasive procedures, or those with an increased risk of complications to the procedure, are explained in detail as mentioned in primary sample collection manual and, in some cases, written consent is taken. Patient readily consents for phlebotomy, as the patient is counseled by the clinician, who hands over a requisition for performing laboratory investigations.

PRIMARY SAMPLE COLLECTION AND HANDLING

The primary sample collection procedures:

BLOOD COLLECTION PROCEDURE (PHLEBOTOMY)

- Phlebotomy is a process of venipuncture used to collect blood for various pathological tests to be carried out on blood. This is an important step in the pre-analytical phase of Quality Control.

Identification

The laboratory's instructions for collection activities include the following:

a) Patient after coming to the lab for collection is made comfortable first. Positive identification of primary sample is done by asking the patient his full name (first name, middle name and surname). If the patient is unconscious, too young (infant or child), mentally incompetent or does not speak the language of the phlebotomist, a relative is asked to identify the patient by full name before drawing the blood. All primary samples are properly identified by the laboratory technician by the name of the patient and MRD Number.

   In case of emergencies each patient is given a temporary but clear identification until a true ID can be generated. Samples lacking identification are not accepted. In case the samples are sent to the laboratory without proper identification, the samples are accepted if the primary sample is irreplaceable or critical and are processed. The results are telephonically communicated to the referring physician and printed reports are issued only after patient identification.

b) It is verified that the patient meets pre-examination requirements. For e.g. fasting status, medication status (time of last dose, cessation), sample collection at predetermined time or time intervals, etc.

c) Instructions for collection of primary blood and non-blood samples, with descriptions of the primary sample containers and any necessary additives are available in DOT.

d) In situations where the primary sample is collected as part of clinical practice, information and instructions regarding primary sample containers, any necessary

e) Additives and any necessary processing and sample transport conditions are determined and communicated to the appropriate clinical staff.

f) Identity of the person collecting the primary sample: collection date and collection time are also recorded in the software.

g) IPD/OPD samples are sent by pneumatic chute system and are received in Accession Room. Precious and emergency samples are transported by MPWs from ward and OPD laboratory.

Step 1: Generation of Barcode & Lab ID in Pathology Reception.

Patient shows the test requisition slip to the Billing Assistant cum cashier. If the patient is already registered, at clinical OPDs, MRD Number. already exists. However, if patient comes for the first time directly to the lab, he is asked to fill the registration form and a unique MRD no. is generated. The billing Assistant cum cashier enters the tests to be done in the LIS. The patient pays the necessary amount and a receipt is generated. The patient is made to sit in the pathology reception for his/her turn. The patient's name is displayed on the T.V. Screen. He/she then goes to the Phlebotomy Room.

The lab technician views the tests menu on the computer and counter checks the tests entered by Billing Assistant cum cashier in the LIS with those written on request form. At this stage, lab number is generated on the Barcode.

Step 2: Identify & prepare the patient.

The process begins with the requisition slip (an electronic requisition or a hard copy) that a phlebotomist receives from the referring clinician. It mentions:

Patient demographics-

- The full name of the patient, age and sex – Patient identification.
- The investigations / tests that have to be done.
- Depending on the tests to be performed, the choice of vacutainers is made.

- One should make it a habit to ensure that the vacutainers with anti-coagulants do contain the anti-coagulant which may be in the form of a powder, mist or a liquid.
- The patient is asked to sit on the collection chair and is made comfortable. A few relevant questions are asked: Patient history

  For example: For BSL estimation – the patient is asked if he is a known case of diabetes, on oral anti diabetics or insulin injections.

  For PT / aPTT – whether the patient is on Warfarin: its dose and frequency.

  Patient identification is confirmed by asking patient to state his/her full name. Tests to be performed are informed and discussed with the patient & thus, a verbal consent is obtained.

  The patient is asked if he has phobias, allergies or has ever fainted during previous blood draws. If the patient is anxious or afraid, he is re-assured and made comfortable. The vacutainers are labeled with barcode.

Step 3: Perform hand hygiene and put on gloves

Perform hand hygiene; that is, hands are washed with soap and water and dried with single-use Paper towels.

7 steps of hand hygiene:

2 pumps of hand rub/liquid antiseptic soap solution is taken. Each of the below mentioned step is performed 6 times.

1) Palm to palm
2) Palm to back, fingers overfaced
3) Palm to palm, fingers interlaced

4) Fingers interlocked
5) Rotational rubbing of thumb in palm
6) Rotational rubbing of fingers in palm
7) Rubbing of each wrist

• After performing hand hygiene, alcohol based disinfectant is applied, well-fitting, non-sterile gloves are put on.

Step 4: Select the site for phlebotomy

1. The patient is asked to keep his hand extended over the arm rest straight at the elbow joint and is asked to clench his fist to make the vein prominent. A vein of good size that is visible, straight and clear is located. A tourniquet is applied on the arm 4 to 5 finger widths above puncture site that gives a pressure of 40 to 60 mm Hg.
2. Selection of vein is of utmost importance – Best sites for venipuncture are superficial veins of upper arm; a vein that is visible – superficial vein and is felt (as a bounce) is selected.

A) **Median cubital vein** is most commonly used because:

1) It is close to the surface of skin, lies between muscles and is most easy to puncture.
2) It is more stationary - vein does not slip during venepuncture.
3) It is not nested among nerves or arteries.
4) It is less painful to puncture.

The other veins that may be selected are:

B) Cephalic vein

C) Basilic vein

The sites that are inappropriate for venipuncture are:

- Arm on the side of mastectomy – It is difficult to find veins because of lymphedema.
- One should avoid the arm through which blood is being transfused, giving false high Hb value.

- Arm above the I.V. line or indwelling catheters causes dilution of blood, giving false low Hb value.
- Edematous areas
- Scarred areas
- Arms with cannulas, fistulas or vascular grafts.

The vacutainer assembly is made ready. It consists of the needle shield which has a white section and a colored section. The coloured section varies depending upon the number of the needle. We most preferably use a 22 number needle which has a black shield. 21 number needle is also used.The coloured section of the needle shield is twisted and the white section is removed. The colored shield is screwed onto the needle holder.

Step 5: Disinfect the entry site:

Venepuncture site is made sterile by cleaning the skin with alcohol swab consisting of 70% isoprohyl alcohol for 30 seconds. It is allowed to dry completely for 30 seconds. Alcohol is preferable to povidone iodine, because blood contaminated with povidone iodine may falsely increase levels of potassium, phosphorus or uric acid in laboratory test results.

Firm but gentle pressure is applied, starting from the centre of the venepuncture site and working downward and outwards to cover an area of 2 cm or more. Failure to allow enough contact time increases the risk of contamination.

The cleaned site is now not touched. If the site is touched with a finger to feel the vein, the process of disinfection is repeated.

Step 6: Perform venepuncture and take blood:

Patient is asked to form a fist so that the veins are more prominent.

The colored section of the needle shield is removed and venepuncture is made. The skin is first punctured and then the vein. The puncture is done ideally at an angle of 15^0, with a range from 15^0 to 30^0. At a higher angle, there are chances of cross – puncture and hematoma formation.

Step 7: Fill the vacutainers with blood:

As soon as blood flows into the hub of the needle, vacutainer tube is inserted into the holder. The diaphragm of the stopper gets punctured and blood flows into the tube and stops flowing, when vacuum is exhausted. The stopper is dis-engaged from the needle andthe vacutainer is removed from the holder.

Relevant vacutainers are inserted into the holder, as per the tests and blood is collected.

The tourniquet is released before withdrawing the needle.

The needle is withdrawn from the vein and patient is asked to keep the venepuncture site pressed with dry cotton swab, to prevent hematoma. A sticking is applied whenever required.

Vacutainers containing anticoagulant – additive vacutainers – are gently inverted 8 to 10 times, so that blood mixes well with the anticoagulant. They should not be vigorously mixed.

This can cause hemolysis. If mixing is not done, blood clots. This is a common cause of sample rejection in the laboratory.

Blood from plain vacutainer should not be mixed. The tubes are kept upright in the rack.

- The whole process of venepuncture is usually completed within 1 minute of Tourniquet application.
- One should remember that not everyone can draw blood from every patient. This applies even to the most experienced phlebotomist. After 2 failed attempts, somebody else should be asked to intervene. This is professionalism.

Step 8: Complete patient procedure:

The patient is informed that the procedure is over. He is also informed about the date and time for collection of report. The pateint is asked how he is feeling. The phlebotomy site is checked that it is not bleeding.

Step 9: Prepare samples for transportation:

The labels and forms are checked for accuracy. The sample is then sent to the laboratory as soon as possible for processing either through pneumatic chute system in canisters or in closed boxes by MPW, depending on the type of samples collected.[Refer to 5.4.2 (h),pg.2 for details]

All specimens are transported in closed plastic boxes within the hospital to avoid spillage and breakage. An ice pack is placed in the plastic box along with the sample though not in close proximity with the sample so that the sample temperature is maintained. The boxes are latched and bear a biohazard label.

Whenever any serum sample is transported it is ensured that transportation is done keeping in mind that all samples are biohazardous. If samples are seropositive for HIV/HBsAg, they are transported in suitably labeled containers with biohazard stickers, sealed well so that there is no risk to the transporters. If any culture sample has to be transported, it is sent in sterile, screw capped, leak proof container.

The Types of vacutainers used are as follows:

Colour of the cap of Vacutainer	Vacutainer Anticoagulant	Indications for Use
Lavender	EDTA	Hemogram, platelet, Optimal test for malaria, Glycosylated Hb, etc.
Blue	Sodium citric acid	PT, PTTK, D-dimer, Thrombin time, Factor assays, Coagulation tests, etc.
Green	Sodium Heparin	TropT, bicarbonate, Ammonia, osmotic fragility test, etc.
Green microtainers	Lithium Heparin	Biochemistry tests in neonates, especially serum Bilirubin
Gray	Sodium fluoride	Blood Sugar-Random, Fasting, Post Prandial, GTT, etc.
Yellow (with gel)	Plain Vacutainer- No Anticoagulant	For all tests done on serum: Renal function tests, Liver function tests, Cardiac enzymes, Lipid profile, Serological tests like HIV, HBsAg, etc.
Red (without gel)		For body fluids like ascitic fluid, pleural fluid, etc.

Step 10: Procedure to be followed for subsequent phlebotomies

With subsequent phlebotomies, If hands are not visibly contaminated, they are cleaned with alcohol rub – 3 ml of alcohol rub is poured on the palm of the hand, and rubbed into fingertips, back of hands and all over the hands until dry.

Gloves are not changed with each phlebotomy, unless they are soiled.

Order of draw is as per WHO Guidelines 2010

Order of use	Type of tube/ usual colour	Additives	Mode of action	Uses
1	Blood culture bottle	Broth mixture	Preserves viability of microorganisms	Microbiology –aerobes, anaerobes, fungi
2	Non-additive tube	-	-	-
3	Coagulation tube (light blue top)	Sodium citrate	Forms calcium salts to remove calcium	Coagulation tests (prothrombin time & aPTT)
4	Clot activator (red top)	Clot activator	Blood clots, and the serum is separated by centrifugation	Chemistries, immunology and serology
5	Sodium heparin (dark green top)	Sodium heparin	Inactivates thrombin and thromboplastin	For lithium level and for ammonia
6	EDTA (purple top)	EDTA	Forms calcium salts to remove calcium	Haematology
7	Blood tube (pale yellow top)	Acid-citrate-dextrose	Complement inactivation	HLA tissue typing, DNA studies
8	Oxalate/fluoride (light grey top)	Sodium fluoride and potassium oxalate	Anti-glycolytic agent preserves glucose.	Glucose

Procedure for Scalp Vein Collection of Blood:

All vacutainers required for tests ordered are kept on the table. The child is made to lie down on bed. Hands and feet of the child are held tightly by the MPW. The vein of the child is felt. The vein is pricked with the needle of scalp vein. The number of needle is 23 gauge. Once blood starts flowing into the tubing, a syringe is attached to the tubing. Another technician pulls the syringe to collect required volume of blood. The scalp vein is then removed by the technician. The needle is punctured into the cap of the vacutainer (without opening the cap) and vacutainers are filled with adequate amount of blood. The puncture site is pressed with dry cotton and the child is made comfortable.

Precautions taken to prevent hematoma:

1) Use major veins.
2) Puncture only the uppermost wall of the vein.
3) Do not make partial penetration with needle.
4) Remove the tourniquet before removing the needle.
5) Apply a small amount of pressure to the area with cotton after blood collection.

If patient feels uneasy or faints, following steps are taken:

1) The collection procedure is stopped.
2) The patient's feet are elevated with head low position.
3) Fan is started for fresh air.
4) Patient is given glucose sarbat to drink (if he is not a known case of diabetes).
5) If the patient does not recover following above procedures, he is referred to casualty for further management.

Blood Collection for indwelling lines/central lines

1) Aseptic technique must be utilized for all aspects of central line care. Appropriate hand washing immediately before accessing any central line is mandatory.
2) Explain procedure to the patient. Assess all medications and infusions before selecting a port for sampling.
3) Wear gloves.
4) Clamp the catheter and disconnect the infusion from the entering port that is being sampled.
5) If drawing from a multi-lumen central line, it is recommended to temporarily (≥ 1 minute) stop all other infusions until blood drawing has been completed.
6) Using vigorous friction for at least 15-30 seconds, prepare the injection site with chlorhexidine gluconate swab, if accessing a central line. Let dry thoroughly. (Antiseptic maximum effectiveness is only achieved if antiseptic is allowed to air dry thoroughly)
7) If obtaining specimens from an indwelling line, which may contain heparin, using a 10 or 12 ml syringe first flush the line with 10 ml of normal saline using a pulsatile push-stop-push-stop motion.
8) Remove the syringe and clamp the catheter.
9) Attach a new syringe and withdraw the first 5 ml of blood or 6-times the line volume (dead space volume of the catheter), and discard.
10) With a new syringe, withdraw volume of blood equal to the total amount of blood you need for all blood samples. If a blood culture is being obtained, use a separate syringe for blood culture and a different syringe for other labs.
11) Using a 10 or 12 ml syringe, flush the catheter with normal saline using a pulsatile push-stop-push-stop motion. Always withdraw before flushing to ensure that air bubbles will not be infused.
12) In the inpatient setting, it is appropriate to collect blood through a cannula that is being inserted for long-term fluid infusions at the time of first insertion to prevent a

second stick. An arm containing a cannula or arteriovenous fistula should not be used without consent of the patient's physician.

13) If fluid is being infused intravenously into limb, the fluid should be shut off for 3 minutes before a specimen is obtained and a suitable note made in the patient's chart. The first 5 to 10 ml of blood collected should be discarded and not used for testing because of possible contamination with the infused fluid.

14) Specimens obtained from the opposite arm or below the infusion site in the same arm are satisfactory for most tests because retrograde blood flow does not occur in the veins and the fluid that is infused must first circulate through the heart and return before it reaches the sampling site.

COLLECTION OF URINE SPECIMEN IN CATHETERIZED PATIENTS

Urinalysis is not routinely performed on all long-term catheterized patients, as virtually all patients will have bacteria present in their urine.

Indications

Urinalysis / catheter specimen of urine (CSU) should be undertaken when:

1) Patient is systemically unwell
2) Patient has a high temperature
3) Following lack of response to treatment
4) Admitted/transferred to hospital to ascertain the presence of HAI or CAI (hospital or community acquired infection).

Urine samples from a catheter are obtained under aseptic technique from the needle free sampling port by syringe aspiration. The sampling port has been specially designed to re-seal after aspiration of the urine sample. Obtain large volumes of urine for special analyses (not culture) aseptically from the drainage bag. If the indwelling catheter has been in place for more than 7 days, the catheter should be changed, and the urine should be collected from the new catheter so the sample is representative of the microorganisms really present in the bladder and not the microorganisms that have adhered to the interior wall of the catheter.

Procedure

If there is no urine visible in the catheter tubing then clamp may be placed a few centimeters distal to the sampling port. Once there is sufficient urine visible in the drainage tube above the clamp, then wipe the sampling port with an alcohol swab and allow to dry. Insert a sterile syringe into the needle-free sampling port. Aspirate the required amount of urine. Remove the syringe and transfer specimen into sterile specimen pot. Wipe the sampling port with an alcohol swab and allow to dry. Unclamp the drainage tubing.

Collection of urine specimen for culture sensitivity

Type of specimen: First voided midstream urine

Container for urine collection: Clean, sterile wide mouthed plastic containers, with screw-cap tops.

Instructions given to the patients:

1) Void directly into the container. During the collection the initial portion of the urine stream is allowed to escape while the midstream portion is collected in the container.
2) Specimens from infants and young children can be collected in a clean bedpan and transferred into the bottle. Care must taken to avoid faecal contamination.
3) Specimen if collected at home should be submitted to the laboratory within an hour or two. Urine is stored at 2-8^{0}C in a refrigerator, if sample is to be stored for longer than one hour before analysis.

24 hours urine collection

Pass the urine in the toilet at a particular timing (8 am). There after collect all the urine in the container provided. The container contains the necessary preservative according to the tests, required to prevent the deterioration of elements to be measured. Next day collection should be stopped at the same timing at which the first urine was passed (8 am). Please note that each and every urine specimen passed in 24 hours should be collected in the container provided. Errors in total volume can lead to erroneous final results.

Creatinine clearance test

1) Collect 24 hrs urine using toluene as preservative.
2) Measure the volume and process.
3) Collect 3ml of blood in plain bulb. Load serum and diluted urine (1:10) for creatinine.
4) Principle of procedure for calculating results:

$$\text{Creatinine clearance (ml/min)} = \frac{\text{Urinary creatinine}}{\text{Serum Creatinine}} \times \frac{\text{Total Volume}}{1440}$$

Procedure for urea clearance test

1) Collect 24 hrs urine using toluene as preservative.
2) Measure the volume and process
3) Collect 3ml of blood in plain bulb. Load serum and diluted urine (1:10) for Urea.
4) Principle of procedure for calculating results:

$$\text{Urea clearance (ml/min)} = \frac{\text{Urinary Urea}}{\text{Serum Urea}} \times \frac{\text{Total Volume}}{1440}$$

Preservatives

S.No	Test	Preservative	Quantity
1	Urea Clearance	Toluene	10ml
2	Creatinine Clearence	Toluene	10ml
3	Protein	Toluene	10ml
4	Osmolarity	Toluene	10ml
5	Calcium	Thymol Crystals	Few
6	Phosphorus	Thymol Crystals	Few
7	VMA	Conc.HCL	10ml
8	Copper	Conc.HNO3	Few drops
9	BJ Protein	Toluene	10ml
10	17 ketosteroids	Conc. HCL	10ml
11	Metanephrine	Conc. Glacial acetic acid	10ml
12	HIAA	Conc. HCL	10ml
13	Uric acid	Thymol Crystals	Few
14	Electrolytes	Thymol Crystals	Few
15	Cortisol	Thymol Crystals	Few

Urine Pregnancy test (UPT)

1) Wait for minimum 7 days after the missed period for a pregnancy test.
2) First voided mid-stream urine is preferred.
3) Collect urine in a clean sterile container directly.
4) The lab technician notes down the date of the last menstrual period on the requisition form.

Collection of faeces (stool)

1) Collect sufficient quantity in a wide mouth plastic container with a tightly fixing cap.
2) Specimen is labeled, indicating identification no, name and date/time.
3) Specimen should not be left uncovered (to prevent drying)
4) Specimen should be examined within one hour.

PRIMARY SAMPLE COLLECTION AND HANDLING

Sputum Collection

1) Collect early morning specimen.
2) Brush teeth and rinse the mouth thoroughly with water.
3) Cough up for some time (Approximately for 2-5 minutes)
4) Sputum should be collected (not saliva) by coughing it up from lungs or brochi.
5) Collect in wide mouth bottle, with tightly fixing cap.
6) Avoid smearing it outside the container.

Oral Glucose Tolerance Test

Oral glucose tolerance test is performed to diagnose diabetes mellitus or to characterize diabetes.

Instructions

The test should be done in the morning after an overnight fast (no calorie intake for last 8 hours). The subjects should remain seated and should not smoke throughout the test.

Procedure:

A. GTT with 75 grams

1) Fasting (overnight) blood is collected in fluoride bulb along with urine.
2) 75 grams of glucose powder is dissolved in 300 ml of water and is given to drink within 5 minutes and noted the time.
3) Blood and urine samples are collected after every one hour interval, for 2 hours.

B. GTT with 100 grams

2) Fasting (overnight) blood is collected in fluoride bulb along with urine.
3) 100 grams of glucose powder is dissolved in 300 ml of water.
4) Blood and urine samples are collected after every one hour interval, for 3 hours.

- Collection procedures for tests in microbiology are documented in "Microbiology Collection procedures". (Refer to Annex D)
- Collection procedures for tests in serology are documented in "Directory of tests". (Refer to Annex A)

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PRIMARY SAMPLE COLLECTION AND HANDLING

- **Collection procedures for Histopathology**

The laboratory technician checks the requisition form online/written for patient demographics, the type of specimen-biopsy/resection specimen, site of biopsy, referring doctors name/hospital name etc. A printout of the online requisition form is taken out.

The specimen is checked for appropriate fixative in10% formalin or Bouin's fluid. If the specimen is not sent in formalin, then the requisition form is rechecked to ensure that the specimen is not meant for frozen section/microbiologic studies. If not, 10% formalin solution is added immediately by the receiving lab technician. If it is a large resection specimen, then the on call doctor/resident doctor is informed regarding the fixative and formalin is added.

- **Collection procedures for Cytopathology**

The following material should be ready at hand before performing fine-needle aspiration cytology (FNAC); 22/23G no. needle, two 5 cc syringe, cotton, spirit, slides and a fixative.

Fixative may be either a spray fixative or a mixture of ether-alcohol in a Coplin jar. Written informed consent has to be taken before the procedure. The material obtained is taken on a slide. Smears are prepared by spreading the material on the slide by the attending lab technician or Resident doctor, wearing gloves. Majority of the smears are immediately wet fixed in a Coplin jar containing cytofixative solution provided by the laboratory. If FNAC is from a lymph node or thyroid, then a few smears are air dried and then fixed (which may be used for Leishman's stain, MGG stain, ZN stain, etc.).

The slides are then properly labeled and sent to the histopathology section for further processing and staining. Vaginal cytology is done by Thin Prep, which is a semi - automated method. It has an advantage of HPV testing.

- **Collection procedure for Genetics (Molecular Diagnostics)**

The laboratory technician checks the online/ written requisition & the clinician's requisition for test, patients demographic details, type of specimen/ paraffin block received, and corresponding histopathology and IHC report. The number of blocks, HE slides or specimen received is documented on the requisition form and signature of the patient is taken for the same. In case of specimen, it is checked for appropriate fixative in 10% formalin. Sample for genetic tests is received directly in the molecular diagnostic lab by the technician. In case, if patient comes with outside blocks, after 6.30 pm, OPD technician receives the same and hands it over to accession room technician. He/she receives the same and keep blocks in Molecular diagnostic lab sample box. Next day blocks are transported to the laboratory by MPW.

5.4.4.2 Instructions for pre-collection activities

The laboratory's instructions for pre-collection activities include the following:

a) completion of request form (OPD) or electronic request (IPD);
b) preparation of the patient (e.g. instructions to caregivers, phlebotomists, sample collectors and patients);
c) type and amount of the primary sample to be collected with descriptions of the primary sample containers and any necessary additives;
d) special timing of collection, where needed
e) Clinical information relevant to or affecting sample collection, examination performance or result interpretation (e.g. history of administration of drugs).

5.4.4.3 Instructions for collection activities

The laboratory's instructions for collection activities include the following:

Patient after coming to the lab for collection is made comfortable first. Positive identification of primary sample is done by asking the patient his full name (first name, middle name and surname). If the patient is unconscious, too young (infant child), mentally incompetent or does not speak the language of the phlebotomist, a relative is asked to identify the patient by full name before drawing the blood. All primary samples are properly identified by the laboratory technician by the name of the patient and MRD Number. MRD number is generated by the HIS that is unique to a particular patient. It does not change with subsequent visits. However, sample ID generated is different for each sample. In case of emergencies each patient is given a temporary but clear identification until a true ID can be made. Samples lacking identification are not accepted. In case the samples are sent to the laboratory without proper identification, the samples are accepted if the primary sample is irreplaceable or critical and are processed. The results are telephonically communicated to the referring physician and printed reports are issued only after patient identification.

a) It is verified that the patient meets pre-examination requirements [e.g. fasting status, medication status (time of last dose, cessation), sample collection at predetermined time or time intervals, etc.];

b) Instructions for collection of primary blood and non-blood samples, with descriptions of the primary sample containers and any necessary additives are available in DOT.

c) In situations where the primary sample is collected as part of clinical practice, information and instructions regarding primary sample containers, any necessary additives and any necessary processing and sample transport conditions are determined and communicated to the appropriate clinical staff.

d) Instructions for labeling of primary samples are in place in a manner that provides an unequivocal link with the patients from whom they are collected. A primary sample is labeled with barcode with unique MRD number. The sample ID Number on barcode is different for each section of lab e.g. Sample ID generated is like 0001BI130101; 0001-sample number, BI-Biochemistry, year, month and date. CP for clinical pathology, HM for hematology, HS for histopathology, MI for microbiology, S for serology, OS for outsending, SS for special serology, MD for molecular diagnostics, CT for cytology.

The primary sample is identified by a unique MRD Number and sample ID that is generated by the software of the Hospital.

OPD patients/Outside sample collection: Once patient comes to the hospital, the billing officer generates unique patient number/ MRD No. MRD number remains the same for all OPD visits, only Sample ID differs. Technicians generate the test order, then computer gives the sample ID with respect to department and printout of barcode is taken from barcode printer. Patient with receipt comes to the Phlebotomy room. After asking the patient to be seated, requisition form is filled if required, printout of barcode is taken, sample collection tubes (vacutainers) or containers are labeled with barcode, which contains name of patient, age, sex, MRD No, Visit No and sample ID.

IPD patients: When a patient is admitted for the first time in the hospital, a patient number (MRD) and sample ID is generated, in ward after generating the test order. Barcode is then affixed on vacutainer or containers; sample is collected and sent to pathology department. Before accepting the samples, lab technician checks for its suitability. The samples are processed with the same MRD number in each section of the laboratory.

e) Identity of the person collecting the primary sample, collection date and collection time are also recorded in the software.

f) All samples have a standard transportation time of 15 to 30 minutes. For samples whose transportation is delayed due to some reasons, they are stored in a refrigerator at 2-8^{0}C, installed in OPD and Sample Accession Room. All emergency samples are transported to the laboratory immediately and the concerned lab personnel are duly informed.

Amber colored containers are used when light affects the lab tests adversely for estimation of 24 hours urinary VMA. The sample taken for serum bilirubin is protected from direct sunlight and fluorescent light

g) Safe disposal of material used in the collection

LABORATORY WASTE DISPOSAL

Color code of Bag/Bin	Category of Waste	Particulars of Waste
Yellow	Infectious Waste	Soiled alcohol swabs, cotton balls and tissue paper. Used Syringes, Used Tourniquets, Vacutainers with blood samples and body fluids, Surgical specimens received in histopathology, stool samples along with stool containers, Microbiology cultures and syringes, used loops, Thermocol rack used for keeping samples, used droppers and UPT Cards, Cuvettes, cartridges, blood vacutainers
Red	Infectious Plastic Waste	Urine samples are discarded in drain connected to STP. Emptied plastic containers are rinsed in water and discarded in red bin. Broken unused syringes, ESR tubes, expired culture swabs, plastic folders, Expired Vacutainers, Needle covers and Syringes without patient's samples. All plastic and latex gloves
Black	Non Infectious General Waste	Alcohol swab wrappers, barcode stickers, plastic wrappers of syringes, paper, empty kit boxes, Refill, markers.
White puncture proof containers	Infectious/Non Infectious sharps	Needles used during phlebotomy, scalp vein needles, TT injection needles, scalpel blades used for grossing in histopathology
Puncture proof can with blue label	Infectious/Non Infectious glass	Glass bottles.Wet slides are soaked in a bowl filled with 0.1% Sodium Hypochlorite, contents are drained in basin connected to STP and sent to housekeeping in puncture proof cans labeled with blue colour coded sticker. Dry/broken slides are kept in a bowl and sent to housekeeping in puncture proof cans labeled with blue colour coded sticker.

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DEPARTMENT OF PATHOLOGY

INSTRUCTIONS FOR COLLECTION ACTIVITIES

Special Instructions:

1. All waste collected in Microbiology lab is autoclaved in yellow bag and then sent to PASSCO (CBMWTF) for further disposal through housekeeping.
2. Bowls at workstation are separate for glass and plastic
3. Sharps: The needle along with the guard is discarded in the puncture-resistant sharps container. After the box is filled 3/4th, it is sealed and sent to PASSCO (CBMWTF) for disposal through housekeeping. Needles are never re-capped.
4. Gloves are discarded in red bags and are cut before they are sent to PASSCO (CBMWTF).
5. All Biomedical waste is handed over to PASSCO Environment solutions for further disposal.
6. All hazardous chemical materials including those used in histopathology section like formalin, xylene and Iso propylalcohol (IPA) are drained off in running water in sluice which is connected to the sewage treatment plant (STP) of the hospital.
7. All urine, Liquid chemical waste like Sodium hypochlorite ultimately goes to the central Sewage treatment plant (STP) of the hospital.
8. Effluent from STP is regularly checked for its environmental safety.
9. All plastic and latex gloves are discarded in a separate red bin.

Reference:

Guidelines for management of health care waste as per biomedical waste management rules 2016, Amended in 2018.

5.4.5 Sample transportation

The laboratory's instructions for post-collection activities include packaging of samples for transportation. The laboratory has a documented procedure for monitoring the transportations of samples to ensure they are transported:

a) within a time frame appropriate to the nature of the requested examinations and the laboratory discipline concerned;

b) within a temperature interval specified for sample collection and handling and with the designated preservatives to ensure the integrity of samples;

c) in a manner that ensures the integrity of the sample and the safety for the carrier, the general public and the receiving laboratory, in compliance with established requirements.

All samples from OPD or IPD are transported through pneumatic chute system except precious samples-body fluids, culture sensitivity, biopsies and surgically resected specimens of Histopathology (DMH/QSP/MG-06/40). Only when the chute system is out of order, they are transported by MPWs in closed plastic boxes. All specimens are transported in closed plastic boxes within the hospital to avoid spillage and breakage. An ice pack is placed in the plastic box along with the sample though not in close proximity with the sample so that the sample temperature is maintained. The boxes are latched and bear a biohazard label.

Whenever any serum sample is transported it is ensured that transportation is done keeping in mind that all samples are bio-hazardous. If samples are seropositive for HIV/HBsAg, they are transported in suitably labeled containers with biohazard stickers, sealed well so that there is no risk to the transporters. If any culture sample has to be transported, it is sent in sterile, screw capped, leak proof container.

5.4.6 Sample reception

All samples sent from OPD (old building, new building) and from IPD are received in the Accession room. They are checked for suitability and are received in the electronic form. The time of reception along with the date is available in LIS.

The laboratory's procedure for sample reception ensures that the following conditions are met.

a) Samples are unequivocally traceable, by request and labelling, to an identified patient or site.

b) Laboratory-developed and documented criteria for acceptance or rejection of samples are applied.

c) Where there are problems with patient or sample identification, sample instability due to delay in transport or inappropriate container(s), insufficient sample volume, or when the sample is clinically critical or irreplaceable and the laboratory chooses to process the sample, the final report indicates the nature of the problem and, where applicable, that caution is required when interpreting the result.

d) All samples received are recorded in the computer. The date and time of receipt and/or registration of samples is recorded. The identity of the person receiving the sample is also recorded.

e) Authorized personnel evaluate received samples to ensure that they meet the acceptance criteria relevant for the requested examination(s).

f) Where relevant, there are instructions for the receipt, labelling, processing and reporting of samples specifically marked as urgent. The instructions include details of any special labelling of the request form and sample, the mechanism of transfer of the sample to the examination area of the laboratory, any rapid processing mode to be used, and any special reporting criteria to be followed. (DMH/QSP/MG-06/25)

All portions of the primary sample are unequivocally traceable to the original primary sample by the patient name and the patient MRD Number.

5.4.7 Pre-examination handling, preparation and storage

The laboratory has necessary procedures and appropriate facilities for securing patient samples and avoiding deterioration, loss or damage during pre-examination activities and during handling, preparation and storage.

Laboratory procedures include time limits for requesting additional examinations or further examinations on the same primary sample. All samples are stored under conditions appropriate to their stability and to enable reproducibility of results when either repeats testing is done or additional examinations are asked for. A list of stability periods is maintained in primary sample collection manual as per NABL 112 guidelines or as per hospital policy.

1) **Storage of examined samples**:

The examined samples are stored for a minimum period as specified below:

Clinical biochemistry: 1 day at 2-8^{0}C

Hematology:

Complete blood counts: 24 hours at 2-8^{0}C

Coagulation screening test: 6-8 hours at 2-8^{0}C

Bone Marrow slides: 5 years

Serology: 3 days at 2-8^{0}C

Blood samples for HIV Testing: 7 days (NACO Guidelines)

Histopathology & Cytopathology:

Specimens-1 month

Slides/Blocks-10 years

Clinical Pathology:

Routine urine samples-24 hours at 2-8^{0}C

Fluids- 24 hours at 2-8^{0}C

Fluids for TB PCR are stored for one month.

Cytotek Slides-10 years, if positive for malignancy

Cytotek Slides, if Negative for malignancy are discarded after 1 month.

Genetics (Molecular Diagnostics):

Extracted DNA – 5 years at -20^0 C

Extracted RNA – 5 years at -70^0 C

Two Years for infectious parameters

Molecular diagnostic gel pictures – 5 years

2) Time limit for requesting additional examinations: varies with the sample and tests requested.

Clinical biochemistry tests: 1 day

Hematology:

Complete blood counts: 24 hours

Coagulation screening test: 6-8 hours

ESR: 24 hours

Serology: 3 days at 2-8^{0}C

Clinical Pathology:

Routine urine examination-24 hours

Fluids- 24 hours

A requisition is sent by the clinician for any additional examination requested.

SECTION WISE TURN AROUND TIME

1) Clinical Biochemistry:

TAT : On working days- 7 am to 3 pm: 8 hrs

After 3 pm to 7 am - 20 hrs.

Saturday 3 pm to Monday 7 am : TAT 48 hr.

2) Clinical Pathology:

TAT : On working days- 7 am to 3 pm: 8 hrs

After 3 pm to 7 am - 20 hrs.

Saturday 2 pm to Monday 7 am : TAT 46 hr.

3) Hematology:

TAT :On working days – 7 am to 2 pm : 12 hrs

2 pm to 7 am : 24 hrs.

Saturday 2 pm to Monday 7 am : TAT 48 hr.

4) Serology:

TAT : On working days- 7 am to 3 pm: 13 hrs

After 3 pm to 7 am:30 hrs.

Saturday 3 pm to Monday 7 am : TAT 48 hr.

POLICY REGARDING

QUALITY CONTROL

QUALITY CONTROL

The laboratory has developed an internal quality control system by performing various quality control measures followed daily to verify the reliability and accuracy of results generated. All control systems used have standard stated ranges so that it becomes easy for the senior technician/pathologists to make technical and medical decisions.

Clinical Biochemistry

Sr.No	Parameter/Test	IQC	EQAS/ ILC	Split Sample/ Replicate sample
1	Glucose	Two Levels Controls Run Daily **Level I and Level II :** Between 9-10am: Two level controls (Normal & Abnormal Control) **Level I :** Between 5-6 pm: One level of control (Normal Control) **Level II :** Between 1-2 am: One level of control (Abnormal Control)	**Biorad** Once in a Month	-
2	Urea			
3	Blood urea nitrogen (BUN)			
4	Creatinine			
5	Total Billirubin			
6	Direct Billirubin			
7	Alanine amino transeferase (ALT)			
8	Aspartate amino transferase (AST)			
9	Alkaline phosphatase			
10	Protein			
11	Albumin			
12	Calcium			
13	Phosphorus			
14	Uric Acid			
15	Electolyte (Na, K, Cl)			
16	Cholesterol	Two Levels Controls Run Daily **Level I and Level II :** Between 9-10am: Two level controls (Normal & Abnormal Control)	**Biorad** Once in a Month	
17	Triglyceride			
18	HDL Cholesterol			
19	Creatinine phosphokinase (CPK)			
20	Gamma GT			
21	Amylase			
22	Lipase			
23	Magnesium			
24	Lactate dehydrogenase (LDH)			
25	Iron			
26	Unsaturated iron binding capacity (UIBC)			
27	Microalbumin	Two Levels Controls Run Daily	**CMC Vellore** Once in a Month	-

28	HbA1c	Two Levels Controls Run Daily	**CMC Vellore** Once in a Month	-
29	Blood Ammonia	Three level controls-One Level QC Run daily	-	Once in a Month
30	CK-MB	Three level controls-One Level QC Run daily	**ILC:** Once in 6 Months	Once in a Month
31	Osmolarity	Two Levels Controls Run Daily	**Biorad** Once in a Month	-
32	Adenosine Deaminase (ADA)	One Level QC Run daily	**ILC:** Once in 6 Months	Replicate Sample
33	Xylose absorption test	One Level QC Run daily	**ILC:** Once in 6 Months	-
34	24 hrs Urinary Protein	Two Levels Controls Run Daily	**ILC:** Once in 6 Months	Replicate Sample
35	24 hrs urinary creatinine Clearance	Two Levels Controls Run Daily	**CMC Vellore** Once in a Month	-
36	24 hrs Urinary urea clearance	Two Levels Controls Run Daily	**CMC Vellore** Once in a Month	-
37	24 hrs urinary creatinine, Uric acid, Phosphorus, calcium	Two Levels Controls Run Daily	**CMC Vellore** Once in a Month	-
38	24 hrs urinary Electrolyte	Two Levels Controls Run Daily	**CMC Vellore** Once in a Month	-
39	Protein Electrophoresis	Two levels controls- one Level control is run with every batch	**ILC:** Once in 6 Months	Once in a Month
40	Triiodothyronine (T3)	**Level I and Level II** run on Alternate Days	**Randox** Once in a Month	-
41	Thyroxine (T4)			
42	Thyroid stimulating hormone (TSH)			
43	Free T3			
44	Free T4			
45	Follicle stimulating hormone (FSH)			

46	Leutinizing hormone (LH)	**Level I and Level II** run on Alternate Days	**Randox** Once in a Month	
47	Prolactin (PRL)			
48	Beta HCG			
49	Cortisol			
50	Progesterone			
51	Testosterone			
52	Ferritin			
53	Alpha Feto Protein			
54	Prostate Specific Antigen (PSA)			
55	Ca 125			
56	Ca 19-9			
57	Carcino embryonic antigen (CEA)			
58	Estradiol			
59	Vit D			
60	Folate			
61	Insulin			
62	Vitamin B12			
63	Homocysteine		**ILC:** Once in 6 Months	-
64	Direct LDL	Two Levels Controls Run Daily **Level I and Level II :** Between 9-10am: Two level controls (Normal & Abnormal Control)	**Biorad** Once in a Month	-

We have Architect Ci4100 instrument for measuring Routine biochemistry tests, Urine Chemistry and Immunoassay. There are two standby instruments; Architect C4000 for Routine Biochemistry & Urine Chemistry and Architect i1000 for Immunoassay.

Control data are displayed on Levey Jennings charts. Repeated measurements characterize the precision of the methods. Routine Westgard rules are followed for interpretation of LJ Charts. The frequency of controls used are tabulated and used accordingly.

Control data are displayed on Levey Jennings charts. Repeated measurements characterize the imprecision of the methods. The frequency of controls used are tabulated and used accordingly.

Routine Biochemistry:

a) Between 9-10 am: Two level controls (Normal & Abnormal Control)

b) Between 5-6 pm: One level of control (Normal Control)

c) Between 1-2 am: One level of control (Abnormal Control)

Immunoassay: Controls are run whenever test is carried, with frequency of one level of control per day.

Control chart is prepared for each analyte with concentration on y-axis and time on x-axis. Horizontal lines display mean and standard deviation. Westgard rules are used for acceptance criteria. The test run is accepted when none of the rules indicates a lack of statistical control and then patient results are released. Following Westgard rules are used:

When two level QC are used:

a) Acceptable: when lie within 2SD

b) Warning: if Either QC value is outside 2 SD (1_{2S}).

c) Reject test run: if Either QC value is outside 3 SD (1_{3S}), Both QC values are outside 2 SD on the same side, but within 3SD (2_{2S}), 10 consecutive values of the same level QC are above or below the mean, but within 2 SD (10x)

When one level QC is used:

a) Acceptable: when lie within 2SD

b) Reject test run if following errors occur:

- If value lie outside 2SD
- Value is outside 3 SD (1_{3S})
- 10 consecutive values of the same level QC are above or below the mean, but within 2 SD (10x)

When the analytical method shows warning

a) Repeat QC from fresh vial.

When the analytical method is out of control

a) Repeat QC from the same vial/fresh vial taken out from the freezer/from a freshly reconstituted QC lot.

b) Check QC/Calibrator/Reagent-storage conditions, Check QC/Calibrator/Reagent-expiry date, and if required Recalibrate and reanalyzed controls.

c) Type of error is determined

(i) Random errors (affect precision)-Usually 1_{3s} error

(ii) Systematic errors (affect accuracy)-Usually 2_{2s}, and 10x errors

d) Trouble shooting guide is referred.

e) Follow manufacturer's trouble shooting instructions and if necessary call Equipment engineer.

6. Rare parameters (CK-MB, ADA)

a) Replicate test of specimen by different person.

b) Clinical Correlation of test results with other parameters

References:-

1.Tietz Fundamentals of Clinical Chemistry, edited by Carl A Burtis,Edward R Ashwood,David E.Burns,Sixth edition,2008.

2.Guidelines for Good Clinical Laboratory Practices(GCLP) Indian Council Of Medical Research,New Delhi 2008.

Hematology

Sr. No.	Parameters/Test	IQC	EQAS/ILC
1	Hemoglobin	1. Three level commercial controls- Sysmex XN check- once a day each L1: 8 am L2 : 4 pm L3 : 12 midnight 2. Retained patient sample and inter instrument comparison once a day.	AIIMS : New Delhi EQAP: Once in 3 months.
2	Total WBC Count		
3	WBC differential count		
4	Absolute count		
5	RBC count		
6	Platelet Count		
7	RBC indices		
8	Packed well volume		
9	Peripheral Blood smear	Reviewed by two Pathologists– once a month	AIIMS : New Delhi EQAP: Once in 3 months.
10	Rapid malaria Antigen test	Inbuilt control with every test	ILC- Once a month
11	Reticulocyte Count	3 level commercial controls- Sysmex XN check- once a day each L1: 8 am L2 : 4 pm L3 : 12 midnight	AIIMS : New Delhi : Once in 3 months.
12	Bone marrow aspiration	Reviewed by two Pathologists- once a month.	ILC- once in 3 months
13	APTT	Control plasma N twice a day: 8 am & 7 pm. Commercial abnormal level 2 control – Citrol 2 – once a day 8 am.	CMC Vellore EQAS- once in 4 months.
14	PT		

Westgard rules have been formulated and are as follows:

- 1:2s-Warning when one value of control exceeds ± 2SD limit but within 3SD.
- 10:x-Warning when 10 consecutive control values fall on one side of the mean, but within 2 SD (10x).
- 2:2s-Reject when 2 consecutive values of control are outside 2SD on the same side but within 3SD.
- R:4s-Reject when difference between any two level QC values is >4SD i.e. One level QC is >2SD and other level QC is <2SD.

Clinical Pathology

Quality control for urine chemistry			
Parameters/Test	**Internal quality control**	**Inter laboratory comparison**	**Split and Replicate testing (As EQAS not done)**
pH, Protein, Glucose, Ketone, Bilirubin, Urobilinogen, Specific gravity.Color, Turbidity	Commercial control Level 1, Level 2. (Twice a day) Cross check dipstick with manual method every 6 months	Every 6 months	Split sample testing every 3 months. Replicate sample testing every month.
Blood	Commercial control Level 1, Level 2. (Twice a day)	Every 6 months	Split sample testing every 3 months. Replicate sample testing every month
Nitrite, Leucocyte	Commercial control Level 1, Level 2. (Twice a day)	Every 6 months	Split sample testing every 3 months. Replicate sample testing every month
Ascorbic acid	Not available	-	Split sample testing every 3 months. Replicate sample testing every month

Quality Control for Urine Microscopic Examination			
Parameters/Test	**Internal quality control**	**Inter laboratory comparison**	**Split and Replicate testing**

			(As EQAS not done)
Pus cells, Red blood cells	Commercial control Level 1, Level 2. (Twice a day) Interobserver pathologist report.(Every 3 months)	Every 6 months	Split sample testing every 3 months. Replicate sample testing every month.
Pus cells clumps, Dysmorphic RBC, Non squamous epithelial cells, Squamous epithelial cells,Crystals, Calcium oxalate crystals,Triple phosphate crystals, Uric acid crystals, Calcium phosphate crystals,Amorphous urate crystals,Hyaline casts,Pathological casts,Granular casts, RBC casts,WBC casts,Bacteria, Bacteria rods, Bacteria cocci, Yeast,Trichomonas, Parasites, Schistosoma Haematobium, Mucus,Spermatozoa, Artifacts	Interobserver pathologist report.(Every 3 months)	Every 6 months	Split sample testing every 3 months. Replicate sample testing every month.

Quality Control for Body fluids

Pleural Fluid, Ascitic fluid, Pericardial fluid, Synovial fluid, Cerebrospinal fluid, CAPD fluid (Microscopy only)

Parameters/Test	Internal quality control	Inter laboratory comparison	Split and Replicate testing (As EQAS not done)
Physical Examination : Colour, Appearance,Cobweb, Coagulum	Interobserver pathologist report.(Every 3 months)	Every 6 months	Split sample testing every 3 months. Replicate sample testing every month.
Chemical Examination :Protein, Sugar	Commercial control Level 1, Level 2. (Everyday)	Every 6 months	Split sample testing every 3 months. Replicate sample testing every month.
Microscopic Examination : Nucleated cells, RBC, Polymorphs, Lymphocytes, Macrophages, Mesothelial cells,	Commercial control Level 1/2/3. (Everyday) Interobserver pathologist report.(Every 3 months) Manual Count by Neubauer Chamber every month.	Every 6 months	Split sample testing every 3 months. Replicate sample testing every month.

Quality control for special tests.

Parameters/Test	Internal quality control	Inter laboratory comparison	Split and Replicate testing (As EQAS not done)
UPT	With known positive serum of pregnant woman (whenever a new kit is opened)	-	Split sample testing every 3 months. Replicate sample testing every month.
Urine Porphobilinogen (Qualitative)	-	Every 6 months	Split sample testing every 3 months. Replicate sample testing every month.
Urine Myoglobinuria Hemoglobinuria	(Positive control using Hemolysate)	Every 6 months	Split sample testing every 3 months. Replicate sample testing every month.
Urine Bence Jones Protein	-	Every 6 months	Split sample testing every 3 months. Replicate sample testing every month.
Urine Haemosiderin	(Positive control using known slide of bone marrow with increased iron stores)	Every 6 months .	Split sample testing every 3 months. Replicate sample testing every month.
Urine Multidrug of abuse profile (12 drugs) (Qualitative)	Commercial control positive or negative (whenever a new kit is opened.)	Every 6 months	Split sample testing every 3 months. Replicate sample testing every month.
Stool Fat (Qualitative)	-	Every 6 months	Split sample testing every 3 months. Replicate sample testing every month.
Stool routine	-	Every 6 months	Split sample testing every 3 months. Replicate sample testing every month.
Stool occult Blood	In built control 2% RBC suspension as positive control whenever the test is ordered (whenever a new kit is opened)	Every 6 months	Split sample testing every 3 months. Replicate sample testing every month.
Lugols iodine	Starch (Whenever a new bottle is opened and once every week)	-	-

- QC with commercial control level 1 & 2 is performed twice for chemical & microscopic examination. Cross check of dipstick with manual method is done every six month.
- Commercial control for chemical analysis for urine does not include ascorbic acid parameter.
- Internal QC for urine pregnancy test is done whenever a new lot is received with a known positive serum of pregnant women.
- Internal QC for urine Myoglobinuria and Hemoglobinuria is done by using hemolysate as positive control.
- Internal QC for urine hemosiderin is done by using a known bone marrow slide with increased iron stores as positive control.
- Internal QC for stool occult blood is done by using 2% RBC suspension as positive control and an in built control is also used, whenever the new kit is opened.
- Lugol's iodine: Internal QC for Lugol's iodine is done by using starch which turns blue on adding lugols iodine. The control is run every week and also whenever new bottle is opened.
- CSF Protein: Internal QC for CSF protein is done by using commercial control Level1 & Level 2.
- Split and replicate testing of urine, stool and fluid samples is done every three months and one month respectively as EQAS is not performed.
- Internal lab comparison (ILQA) is done every six months for routine tests, special tests and fluid analysis. In case of special tests which are infrequent ILQA is done whenever test is ordered every 6 months.
- Internal QC for fluid cell count is done every day by using commercial control level 1,2 & 3.
- Westgard rules have been formulated and are as follows:

a) Acceptable: when lie within 2SD

b) Warning: if Either QC value is outside 2 SD (1_{2S}) but within 3SD.

c) Reject test run if following errors occur:
   - If any one value of control is outside 3 SD (1_{3S})
   - If two consecutive values of control are outside 2 SD on the same side, but within 3SD (2_{2S})
   - 10 consecutive values of the same level QC are above or below the mean, but within 2 SD (10x)

Microbiology and Serology

Tests	Internal Quality Control	EQAS	ILC	Split Samples
Blood Culture	• Media QC & sterility check of BD Bactec blood culture bottles • IQC of ID and AST panels and antibiotics discs, MH agar with ATCC strain E. Coli 25922 Pseudomonas aeruginosa ,27853 Staphylococcus aureus 25923 • Quality control of Gram stain with ATCC E.Coli & ATCC Staphylococcus aureus	• 3 smears for microscopy , 3 lyophilised culture for identification and sensitivity done quarterly with CMC Vellore under IAMM. • ID & sensitivity done by Phoenix 50, Vitek 30 & Kirby Bauers method	Identification and sensitivity done twice a year.	Done with every 3 months
Sputum/Bronchial lavage/ Endotracheal aspirate Pus Swab/ Aspirate, Urine, Tissue, Body Fluids	Sterility check of collection container. Media QC and sterility of solid media (MacConkey's agar, blood agar, sheep blood agar)with ATCC strain . E. Coli 25922 Pseudomonas auroginosa 27853 Staphylococcus aureus 25923. Quality control of Gram stain with ATCC E.Coli 25922 & ATCC Staphylococcus aureus 25923. IQC of ID and AST panels and antibiotics,discs, MH agar with ATCC strain E. Coli 25922 Pseudomonas auroginosa 27853 Staphylococcus aureus 25923.	• 3 smears for microscopy , 3 lyophilised culture for identification and sensitivity done quarterly with CMC Vellore under IAMM. • ID & sensitivity done by Phoenix 50, Vitek 30 & Kirby Bauers method	Identification and sensitivity done once a year.	Done with every 3 months
Gram Stain	• Quality control of Gram stain with ATCC E.Coli 25923& ATCC Staphylococcus aureus 25923 every day.	3 Gram stains for microscopy done quarterly with IAMM EQAS- CMC Vellore	Not Applicable	Not applicable
ZN Stain	• Quality control of ZN stain with ATCC H37 RV daily & ATCC E.Coli 25922 every day.	Not Available	Once a year.	Not applicable

Stool Modified ZN	• Quality control of ZN stain with 3% acid alcohol and 1 % H2So4 done with retained positive slide with new stain /decolorizer prepared .	Not available	Once a year.	Not applicable
Skin Clip	• Quality control of ZN stain with 5% H2So4 done with retained positive slide with new stain / decolorizer	Not available	Not done	Not applicable
CSF for Cryptococcus neoformans	• Quality control check of India ink done with retained culture of Cryptococcus neoformans	Not available	Twice a year.	Not applicable
Fungal Culture	• Sterility check and quality check with ATCC Candida albicans 90028 of Sabouraud's dextrose agar. • Performanance check of germtube test with ATCC Candida albicans • Performanance check of Candida yeast AST. Panels done with ATCC Candida albicans for every new lot procured.	Not done	Twice a year.	Twice a year
AFB Culture & antibiotic sensitivity : Sputum & other respiratory sample, Pus, Urine, Body fluids, Bone marrow, Blood	Quality check of every new batch of MGIT 7 ml tubes with ATCC H37 RV strain. For Quality check of all the reagents prepared in house, eg.NAOH NALC, PBS a negative control should be run along with the clinical specimen on every new reagent batch. Sterility check of every new lot of 7 ml MGIT tube is done by incubating in the MGIT machine to demonstrate no growth at the end of 6 weeks. Every new lot of 7 ml MGIT tubes is tested for lot verification with the isolate of retained positive sample processed previous batch of media. Quality control of drug susceptibility testing (all first line, 2nd line and 3rd line drug for every new lot) is	Not available	Twice a year.	Twice a year

	done by using M.tuberculosis ATCC H37 RV 27294 and a known INH/RIF resistant strain.			
RPR	• Kit positive and negative control is run whenever a new kit is opened. • Kit positive and negative control is run every week.	Test done with Neu- QAP Banglore , quaterly .	Once in Two months.	Not applicable
Widal	• Negative control run for every test. • Inhouse positive control run whenever a new kit is opened.	Test done with Neu- QAP Banglore , quaterly .	Not done	Once a year
ASO	• Positive & negative control provided in the kit and inhouse positive control run whenever a new kit is opened. • Kit positive control run with every test.	Not Available	Once in Two months.	Not applicable
CRP	• Calibration done on change of reagent / change of machine. • Inhouse positive and negative control run every day. Known Randox controls (level 1/leve3) are run every day.	CMC Vellore quaterly	Once a month.	-
RA Factor	• Positive & negative control (Randox) run everyday. In house negative control (retained sample) run everyday. In house positive control run whenever a new kit is opened.	CMC Vellore quaterly	Once in Two months.	-
HIVI,II , HbsAGg, HCV Rapid	• Inhouse positive and negative controls run with every new kit opened. • Control band in the card verified with every test.	Test done with Neu- QAP Banglore , quaterly .	Not done	Not applicable
HIV I,II, HbsAg, HCV CMIA	• Positive & negative control provided in the kit run everyday. • Positive control & negative control from the kit with a known positive and negative inhouse control	Test done with Neu- QAP Banglore , quaterly , Biorad monthly	Not done	-

	run with every new kit opened. • VIROTROL Control run everyday			
HIV I,II ELISA	• Positive and negative control provided in the kit and blank run with every batch of tests performed. • Inhouse positive and negative control run with the kit controls whenever a new kit is opened.	Test done with Neu- QAP Banglore , quaterly	Not done	Once a year
Dengue IgM,Ig G	• Kit positive and negative control run with every batch of test. .	Test done with Neu- QAP Banglore , quaterly .	Twice a year.	Once a year
Dengue NS1	• Kit positive & negative control run with every batch of test – Panbio ELISA • Known inhouse positive & negative control run with every batch of test- i Quant Fluorescence Immunoassay.	Not Available	Once a year.	Once a year
Procalcitonin	• Kit positive controls, high , medium, low and calibrators run whenever a new kit is opened. • Kit control (medium) run everyday.	Not Available	Once a year.	-
HEV IgM	• Positive & negative control provided in the kit run with every batch of tests performed. • Inhouse positive and negative control run with the kit controls whenever a new kit is opened.	Test done with Neu- QAP Banglore ,Once a year	Not done	Once a year

Histopathology & Cytopathology

Sr. No.	Parameters/ Tests	IQC	Frequency of IQC	EQAS/ILC	Frequency of EQAS
1	Histopathology	HP slide making/H&E staining 1. Evaluation of slide quality-for fixation, proper processing, embedding, cutting of sections & quality of staining-Routine H&E staining 2. Frozen section Temperature of cryostat is recorded. The FS report is correlated with the final report of paraffin section 3. Squash Smear cytopathology The Squash Smear report is correlated with final report of paraffin section	Daily Daily With every sample With every sample	1. Anand diagnostic laboratory (Neu QAP, Banglore-4 cycles One tissue ius sent for preanalytical assessment with four virtual slides viewing (online) for diagnosis 2. Tata Memorial hospital, Mumbai (NCG EQAS)- 3 cycles (preanalytical + Analytical assessment) 3. MAPCON (Maharashatra Chapter of IAPM)	Every 3 months Every 4 months Once a year
2	Cytopathology	1. Evaluation of quality of PAP staining (for FNAC as well as Gynec Pap, Fluid cytology) 2. Histopathology & cytology correlation 3. Assessment of ASCUS-SIL Ratio for Gynec PAP 3. Vaginal cytology reporting	Daily Whenever FNAC is followed by biopsy Yearly Ratio should be as per expected standard range	Tata Memorial hospital, Mumbai- 2 cycles (Included Adequacy, staining quality, stained slides of 5 cases are received which include Gynaec PAP, fluid cytology, sputum, urine & FNAC slides)	Every 6 months

Sr. No.	Parameters/ Tests	IQC	Frequency of IQC	EQAS/ILC	Frequency of EQAS
3	Immunohistochemistry(IHC)	Validation is done for every new antibody ER, PR & Her-2 positive & negative controls All other IHC markers- positive & negative controls	- With every test & every batch With every test & every batch	1. Ruby Hall clinic, Pune- 4 cycles (5 IHC markers per cycle) 2. Tata Memorial hospital, Mumbai (NCG EQAS)- 5 Cycles (ER, PR,Her2/neu, Lymphoma, Carcinoma & Sarcoma panel)	Every 3 months Every 2.5 months
4	Special stains	Evaluation of special stains (PAS, GMS, Reticulin, Masson's trichrome stain, Mucicarmine, Giemsa. Orcein, Congo red, Alcian Blue, PAS & ZN stain)	Whenever special stain is done, control is also stained.	1. Ruby Hall clinic, Pune - 4 cycles (5 cases per cycle)	Every 3 months

Molecular Diagnostics (Genetics)

Sr. No	Parameter	IQC procedure done	IQC frequency	EQC procedure done	EQC frequency
1	HER2 Neu FISH	In built internal control	Every test	Interlaboratory Comparison	Once in a year
		Negative / Positive control	With every batch/every lot		
		Split sample testing	Once in a year		
2	HLA A-B-DR DNA TYPING- low resolution	Internal control	In every well	Interlaboratory Comparison	Once in a year
		Negative Control	With every sample		
		Split sample testing	Once per year.		
		DNA concentration checked	For every sample		
3	EGFR Mutation analysis	Colour control	in every strip	Interlaboratory Comparison	Once in a year
		Negative Control	in every strip	-	-
		Positive control	in every strip	-	-
		Split sample testing	Once per year.	-	-
		Gel electrophoresis to check amplicons	For every PCR	-	-
		DNA concentration	For every sample		
		Real time PCR confirmation	In case of faint bands	-	-
4	ANA by IF	Negative / Positive control	With every batch	EQAS programme- EUROIMMUN (Auto antibodies against cell neuclei scheme)	Once in a year
		Split sample testing	Once in a year	-	-
5	HIV viral load (GenXpert)	Internal quantitative high & low standards (IQS-H & IQS- L) integrated in each cartridge. Probe check control for each reaction.	With each test	Interlaboratory comparison	Once in a year
		Split sample testing	Once in a year	-	-
6	HIV-1 Quantitative Real time PCR (Rotorgene Q)	Internal control added during extraction. 2 standards and NTC. All 4 standards and NTC is run with to plot standard curve	In each sample. With every batch when new kit is opened.	Interlaboratory comparison	Once in a year
		Split sample testing	Once in a year	-	-

SAFETY MANUAL

of

DEPARTMENT OF PATHOLOGY

LATA MANGESHKAR MEDICAL FOUNDATION'S

DEENANATH MANGESHKAR HOSPITAL AND RESEARCH CENTRE

Erandawane, Pune-411004

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This Safety Manual is released under the authority of Dr. Dattatreya Phadke, Consultant Pathologist and is the property of Deenanath Mangeshkar Hospital & Research Centre, Erandawane, Pune-411004.

Dr. Dattatreya Phadke
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DEENANATH MANGESHKAR HOSPITAL
AND RESEARCH CENTRE, PUNE
DEPARTMENT OF PATHOLOGY

REVIEW SHEET

Sr. No.	Date	Comment	Signature of person Authorised for review	Signature of Safety Officer
1.	06.05.2020	Review done, changes done and details are available in amendment sheet	-Sd-	-Sd-
2.	06.05.2021	Review done, changes done and details are available in amendment sheet	-Sd-	-Sd-

DEENANATH MANGESHKAR HOSPITAL
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DEPARTMENT OF PATHOLOGY

AMMENDMENT RECORD SHEET

S.No	Page No	Section/ Clause/ Para/Line	Date of amendment	Amendment made	Reasons of Amendment	Signature of person authorizing amendment	Signature of Safety Officer
1	32	-	27.04.2020	Changes in preparation of Sodium Hypochlorite	Hospital Policy	-Sd-	-Sd-
2	Footer, release of authorisation	-	01.06.2020	Change in name of person authorized for issue and release of this document due to change of HOD	Hospital Policy	-Sd-	-Sd-

DEENANATH MANGESHKAR HOSPITAL
AND RESEARCH CENTRE, PUNE
DEPARTMENT OF PATHOLOGY

TABLE OF CONTENT

Sr. No.	Abbreviation	Expansion
1.	DMH	Deenanath Mangeshkar Hospital
2.	ISO	International Organization for Standardization
3	QM	Quality Manager
4	HOD	Head of Department
5	SOP	Standard Operating Procedure
6	HIS	Hospital Information System
7	LIS	Laboratory Information System
8	MPW	Multi-Purpose Workers
9	NC	Non-Conformance
10	ATCC	American Type Culture Collection
11	ID	Identification
12	IPD	In Patient Department
13	OPD	Out Patient Department
14	QC	Quality Control
15	AMC	Annual Maintenance Contract
16	LJ Chart	Levy-Jennings Charts
17	PAP Stain	Papanicolaou stain
18	WHO	World Health Organization
19	JDR	Job Description Record
20	MHR	Machine History Record
21	ECR	Equipment Calibration Record
22	HCG	Human Chorionic Gonadotropin
23	UPS	Uninterrupted Power Supply
24	HR	Human Resources
25	TLR	Temperature Log Register
26	ISH	International society of Haematology
27	IFCC	International Federation of Clinical Chemistry and Laboratory Medicine
28	IUMS	International Union of Microbiological Societies
29	LAN	Local Area Network
30	LM	Lab Manager
31	UPT	Urine Pregnancy Test
32	JPMT	Jnana Probodhini Medical Trust
33	CMO	Casualty Medical Officer
34	lab	laboratory
35	PPE	Personal Protection equipment
36	WHO	World health organization
37	AIIMS	All Indian Institute of Medical Sciences
38	IUPAC	International Union of Pure and Applied Chemistry
39	ELISA	Enzyme linked immunosorbant assay
40	STP	Sewage Treatment Plant

Introduction

The Pathology Department of **Deenanath Mangeshkar Hospital and Research Center** is committed to the safety of its employees and to the safety of the working environment. Safe practices and working conditions are the responsibility of both the employer and the employee. The overall responsibility of Laboratory Safety Practices lies with the Safety Officer.

Policies in this manual are in accordance with:

- Occupational Health and Safety Act
- Hospital Corporate Policy
- Infection Control Policies

The Laboratory Safety Manual is intended to address universal safety measures for achieving a safe and healthy working environment. It describes good laboratory practices that must be understood and observed by all individuals involved in the laboratory. It describes control measures essential for protecting all laboratory occupants from potential biological, chemical and physical hazards. These controls consist of, but are not limited to, policies, guidelines, training requirements, standard operating procedures, personal protective equipment, laboratory inspections, hazard evaluations, and engineering controls. Aspects of a safety program addressed in this guideline include maintenance and inspection, personal safety, and warning signs and labels. In addition, the guideline addresses fire prevention, electrical safety, and other potential laboratory hazards.

Definitions

Major spill – A spill that spreads rapidly, presents an inhalation hazard, endangers people or the environment, and/or involves personal injury or rescue and should be handled as an emergency.

Standard precautions – Set of precautions applied to all patients designed to reduce risk of transmission of microorganisms in the healthcare setting; **NOTE:** All blood, tissue, body fluids, secretions, and excretions (except sweat) are considered potentially infectious.

Universal precautions – Set of precautions designed to reduce risk of transmission of HIV, hepatitis B virus, and other blood-borne pathogens in the healthcare setting; **NOTES:**

a) All human blood, other body fluids containing visible blood, semen, vaginal secretions, tissue, and the following fluids (cerebrospinal, synovial, pleural, peritoneal, pericardial, and amniotic) are considered potentially infectious under standard precautions;

b) Universal precautions do not apply to feces, nasal secretions, saliva(except in a dental setting), sputum, sweat, tears, urine, and vomitus unless they contain visible blood.

1. Visitor Safety

Visitors are prohibited from entering the various sections of the laboratory. Children are not allowed in laboratory premises. Signages indicating “Entry only for authorized staff” have been put up at the entrances.

2. Body Substance Precautions

Procedure:

1. Handle all specimens as if they are potentially infectious. Biological safety cabinets (ClassII) are used to process all microbiology specimens.

2. Wash your hands thoroughly:

Before:

- Beginning work
- Direct patient contact
- Leaving the laboratory at the end of the day
- Having food

After:

- Contact with biological material
- Removal of gloves
- Direct patient contact
- Going to the washroom
- Covering your mouth or nose due to cough or sneeze

3. It is the responsibility of the Head of Department to ensure that hand wash sinks are available, accessible and properly equipped at all times with liquid soaps and sterillium wherever necessary.

4. Wear disposable gloves when handling specimens. Remove them and wash hands before leaving the laboratory. All used gloves are disposed of in red biohazard bin after cutting. Do not touch your face/hair or clean areas with gloves on.

5. If there is potential for splashing/aerosolization with body fluids, use additional personal protective equipment such as aprons, goggles or perform procedures in a biological safety cabinet. Keep biological safety cabinets clear of clutter.

6. To remove caps on blood specimens, gently loosen the cap and release tube in a direction away from the technologist.

7. Change protective clothing when necessary to ensure cleanliness or when contaminated with hazardous material. If a laboratory coat becomes grossly soiled with

biological material, remove it immediately and hand it over to linen department of the hospital for washing.

3. Disposal of Biological Waste

Color code of Bag/Bin	Category of Waste	Particulars of Waste
Yellow	Infectious Waste	Soiled alcohol swabs, cotton balls and tissue paper. Used Syringes, Used Tourniquets, Vacutainers with blood samples and body fluids, Surgical specimens received in histopathology, stool samples along with stool containers, Microbiology cultures and syringes, used loops, Thermocol rack used for keeping samples, used droppers and UPT Cards, Cuvettes, cartridges
Red	Infectious Plastic Waste	Urine samples are discarded in drain connected to STP. Emptied plastic containers are rinsed in water and discarded in red bin. Broken unused syringes, ESR tubes, expired culture swabs, plastic folders, Expired Vacutainers, Needle covers and Syringes without patient's samples. All plastic and latex gloves
Black	Non Infectious General Waste	Alcohol swab wrappers, barcode stickers, plastic wrappers of syringes, paper, empty kit boxes, Refill, markers.
White puncture proof containers	Infectious/Non Infectious sharps	Needles used during phlebotomy, scalp vein needles, TT injection needles, scalpel blades used for grossing in histopathology
Puncture proof can with blue label	Infectious/Non Infectious glass	Glass bottles. Wet slides are soaked in a bowl filled with 0.1% Sodium Hypochlorite, contents are drained in basin connected to STP and sent to housekeeping in puncture proof cans labeled with blue colour coded sticker. Dry/broken slides are kept in a bowl and sent to housekeeping in puncture proof cans labeled with blue colour coded sticker.

Special Instructions:

1. All waste collected in Microbiology lab is autoclaved in yellow bag and then sent to PASSCO (CBMWTF) for further disposal through housekeeping.
2. Bowls at workstation are separate for glass and plastic
3. Sharps: The needle along with the guard is discarded in the puncture-resistant sharps container. After the box is filled 3/4th, it is sealed and sent to PASSCO (CBMWTF) for disposal through housekeeping. Needles are never re-capped.
4. Gloves are discarded in red bags and are cut before they are sent to PASSCO (CBMWTF).
5. All Biomedical waste is handed over to PASSCO Environment solutions for further disposal.
6. All hazardous chemical materials including those used in histopathology section like formalin, xylene and Iso propylalcohol (IPA) are drained off in running water in sluice which is connected to the sewage treatment plant (STP) of the hospital.
7. All urine, Liquid chemical waste like Sodium hypochlorite ultimately goes to the central Sewage treatment plant (STP) of the hospital.
8. Effluent from STP is regularly checked for its environmental safety.
9. All plastic and latex gloves are discarded in a separate red bin.

Reference:

Guidelines for management of health care waste as per biomedical waste management rules 2016, Amended in 2018.

4. General Chemical Safety

Personal practices

- Do not eat, drink, smoke, chew gum, apply cosmetics or wear contact lenses in the laboratory.
- Do not store food items or cosmetics in areas where laboratory chemicals are used or stored.
- Confine long hair and loose clothing when working with chemicals.
- Wear shoes with closed toes and closed heels
- Wear appropriate personal protection equipment including lab coat, gloves and eye protection.
- Do not smell or taste chemicals.
- Do not use mouth suction for pipetting or starting a siphon.
- Always wash hands and other exposed skin after chemical use.

5. Potential hazards of Chemicals:

Storage of Chemicals:

Arrangement for the storage of chemicals depends on the quantities of chemicals needed and the nature or type of chemicals. Proper storage is essential in the prevention as well as the control of laboratory fires and accidents. The chemicals are segregated according to the category and are stored preferably in the lower compartment of shelves

The laboratory chemicals are classified into five categories:

1. Flammable/Combustible Chemicals:

Flammable and combustible liquids, which are used in numerous routine procedures, are among the most hazardous materials in the clinical chemistry laboratory because of possible fire or explosion. For example: Ether, Methanol etc.

I. Sub-divisions

Combustible and flammable materials include the following sub-divisions;

- B1 Flammable gases
- B2 Flammable liquids
- B3 Combustible liquids
- B4 Flammable solids
- B5 Flammable aerosols
- B6 Reactive flammable materials

Flammables or combustibles are materials that under standard conditions can generate sufficient vapor to cause a fire in the presence of an ignition source.

2. Corrosive Chemicals:

Corrosive chemicals are injurious to the skin or eyes by direct contact or to the tissues off the respiratory and gastrointestinal tract if inhaled or ingested. e.g. acid and bases.

For example. Hydrochloric acid, Potassium permanganate etc.

General precautions for use of corrosive materials in the lab

- Wear appropriate Personal Protection equipment (PPE), laboratory coat, goggles and gloves.
- Limit the amount of corrosive chemicals at the bench to the amount required for testing.
- Keep containers tightly closed.
- Always add acid to water (never the reverse), and do so slowly, to avoid a violent reaction and splattering.
- In case of eye splash the eyes are washed thoroughly with water and tear plus is dropped into the eyes. He/She is directed to the staff clinic for further ophthalmologic management.

3. Poisonous/Carcinogenic Chemicals:

Carcinogenic chemicals are known to cause cancers. Hence they should not used in the laboratory e.g. Benzidine powder is carcinogenic. Hence is no longer being used for stool occult blood

4. Toxic chemicals:

These chemicals are harmful when ingested or inhaled. For example, Glutaraldehyde, Sodium thiosulphate etc.

5. Non-hazardous:

These chemicals are not harmful.

Categorization of Laboratory Chemicals:

1. Molecular Diagnostics

Flammable: Acetone, Methanol, Ethanol, Isopropanol

Corrosive: HCL, Glacial acetic acid

Toxic: Phenol chloroform isoamyl alcohol

Irritable: 2-Mercaptoethanol,Tri sodium citrate, Ammonium chloride, Ethylene diaminetetra acetic acid

Non-hazardous: Qualigen tris (hydroxy methyl) methamine, Pot. dihydrogen phosphate, Pot. dihydrogen phosphate

2. Clinical Biochemistry

Corrosive: Hydoxymethyl Methylamine, Hexadecyltrimethylammonium bromide**,** Brilliant Blue, 4-Bromoaniline 98%, Sodium Nitroprusside, Perchloric Acid 70%, Liquid Ammonia, Orthophosphoric Acid, Glacial Acidic Acid, Nitric Acid, Hydrochloric Acid, Sulphuric Acid, Sodium hydoxide pellets

Flammable: Toluene, Ethyl Acetate, Metanol

Toxic: Potasium Ferricyanide, Tris Buffer

Non Hazardous: Potassium Carbonate, Potassium Sodium Tartate, Sodium Carbonate, Ferric Chloride, Potassium Iodide, Sodium Dihydrogen Orthophospate, Zinc Sulphate, Ammonium Chloride, Sodium Nitrate, Ethylene Diamine Tetra Acetic Acid (EDTA)**,** Potassium Hydrogen Carbonate Pure, 2-Amino-2-Methyl-1-Propanol Hydrochloride, Cupric Sulphate, Lithium Lactate Extrapure, Glycine, 1-Nitroso 2-Napthol, Toluidine Blue, Sodium Benzoate, Thymol Crystal, Sodium Chloride, Thiourea, Sodium Fluoride, Di-Sodium Hydrogen Orthophosphate Dihydrate, Sodium Acetate.

3. Microbiology & Serology

Flammable: Methanol, Ethanol, Butanol, Link solvent, RAL Stainer

Corrosive: Potassium hydroxide, benzoic acid, Sodium Hypochlorite

Toxic: Chromagar candida, Selenite F Broth (A,B), Hydrosen Ag, Potassium nitrate, Sulfuric acid,

4. Hematology

Toxic: Brilliant cresyl blue, 2% potassium ferrocyanide, Methyl violet, Giemsa Stain, Benzidine powder, Field stain A & B, Ferric chloride, Eosin, Myeloperoxidase, Leishman stain, Sodium acetate powder, Zinc sulphate powder, sodium metabisulphite powder, Hydrogen peroxide

Flammable: Methanol, Absolute alcohol, xylene.

Corrosive: N/10 HCL, Formalin (Pure), Hydrogen peroxide

Non-hazardous: Barium sulphate powder, Urea

5. Histopathology & Cytopathology

Toxic: potassium ferrocyanide, mercuric oxide, hexamethylene tetramine, Glutaraldehyde, sodium thiosulphate, oxalic acid

Flammable: Ether, Ethanol, methanol

Corrosive: sodium hydroxide, chromium trioxide, potassium permanganate, Hydrochloric acid, liquour ammonia, Hydrogen peroxide

Irritant: aluminium hydroxide gel, borax powder

Non-hazardous: sodium chloride, Tris (hydroxymethyl aminomethane), congo red (stain), aluminium ammonium sulphate, lithium carbonate, sodium bisulphite, Glycerol, aluminium chloride, trisodium citrate, dipotassium hydrogen orthophosphate.

6. Clinical Pathology

Toxic: Acetone Detection A&B, Barium Chloride, Erlich's reagent, Benedict reagent, Fouchet solution, OB powder, Para-toluene sulphonic acid, Seliwanoff reagent, Sudan III,

Flammable: Chloroform, Methanol

Corrosive: Acetic acid, Glacial acetic acid, Sodium saturated acetate, Liquor ammonia, Lugols iodine, Sulphosalicyic acid, Sulphuric acid, Tincture iodine, N/10 HCL, 7N Acetic acid, Sodium acetate, con HCL, Hydrogen peroxiode

Non-hazardous: Normal saline, filter pad, pH paper

Disposal of Chemical Waste:

Usually all the chemicals are utilized before their expiry dates. If, for some reason they need to be discarded, they are diluted with water and drained in running tap water in the basin that is connected to the sewage treatment plant.

6 Equipment Safety

Procedure:

General Principles of Equipment Safety

1. Reasonable efforts should be made to ensure that all equipment has appropriate safety features and that such features are properly utilized.
2. A program of preventive maintenance including function and safety checks should be developed and monitored as appropriate for all equipment.
3. The choice of location for an item of equipment should consider also its environmental implications (noise, fume / vapour generation etc.).
4. Equipment, which can be left unattended, should be monitored by occasional inspection to determine any significant malfunctions.
5. Consider safety, cleaning and maintenance requirements prior to purchase.
6. Review and follow manufacturers' instructions to ensure proper set-up.
7. Establish and maintain preventive maintenance schedules as per manufacturers' recommendations
8. Keep complete and detailed service records for each piece of equipment.
9. Decontaminate all equipment appropriately prior to servicing.

SPECIFIC EQUIPMENT

Centrifuges

- Use only centrifuges with sealed centrifuge buckets / compartment / rotors.
- Use only centrifuges with interlocks.
- Do not operate centrifuges in a biological safety cabinet because the motor may produce strong air currents and turbulence, which may disrupt the laminar air flow.

Procedure for handling a broken tube:

- Remove unbroken tubes and wipe exterior with 1.0% hypochlorite. Remove broken glass with forceps and discard into sharps container.
- Soak bucket / rotor in non-corrosive disinfectant (e.g. glutarldehyde 2%). Disinfect centrifuge parts with a non-corrosive disinfectant. (Bacillol Spray)

Water baths

- Unplug before filling or emptying.
- Clean on a regular basis and document
- Take steps to minimize generation of aerosols

Pipeting devices

- Take steps to minimize generation of aerosols (expel liquids down the side of the tube, perform in biological safety cabinet)
- Clean and disinfect pipettes and pipetting aids when contaminated and on a regular basis.
- Use appropriate pipetting aids and use in the correct manner

Microscopes

- Wipe the stage and focus adjustment controls except optics with soft cloth/tissue and an appropriate disinfectant in the event of spills or contamination.
- Inspect cords, plugs, etc., regularly.

Automated equipment

- Ensure that waste line discharges meet municipal regulations
- Clean spill trays regularly

- Disinfect lines on a regular basis as recommended by the manufacturer

Microtomes

- Use safety guards
- Always lock the handwheel when microtome is not attended
- Remove blades or knives when microtome is not attended.

Electrophoresis

- Check continuity of the ground on a regular basis and document
- Post warning sign regarding voltage.

Equipment with flames

- Ensure tubing connected to gas cylinder and instrument is secure
- Inspect hose connections regularly

Examples: Bunsen burners

Refrigerators

- Do not store flammable or combustible liquids in a domestic refrigerator.

Autoclaves

- To be effective the steam must penetrate the wrapping. The length of time required for sterilization of biological material is determined by the quantity of the load, the volume of liquid in the load and the density of the material.
- Read the operating manual carefully
- Post the operation procedures near the autoclave
- After the pressure has been released, open the door only slightly to allow steam to escape before unloading
- Wear insulated gloves when unloading the material
- Monitor all autoclaves routinely for efficacy and maintain records

7. Potential hazards of Electrical appliances:

Precautions required when working with electrical equipment.

1. Ensure that hands and work surfaces are dry before touching electrical equipment or connecting cords.
2. Examine all wiring, plugs, and extension cords for any signs of exposed wires, fraying or deteriorating insulation. Replace if necessary.
3. Check all electrical outlets for current, grounding and polarity at least annually.
4. Ensure there are a sufficient amount of electrical outlets to avoid multi plug adaptor use. In the event of a shock (even if minor) or emission of smoke or a burning smell, immediately tag the equipment "out of order" and remove it for servicing.
5. Do not over-ride fuses, circuit breakers or interlock switches.
6. Remove cords from receptacles by grasping and pulling the plug, not the cord.
7. Ensure that extension cords consist of three separate insulated wires and 3-pronged connectors in good condition and that they are of the appropriate amperage for the purpose for which they are being used.
8. Do not use extension cords through walls, doorways, ceilings and floors as they are not substitutes for permanent wiring.
9. Ensure that all cords are kept off walkway floors where they can become tripping hazards or be damaged; protect cords by running them along perimeter walls or enclosing them in protective covers.

Most individuals are aware of the potential hazards associated with the use of electrical appliances and equipments. Hazards of electrical energy can be direct and result in shock and/or burns or indirect and result in fire and/or explosion. There are, therefore, many precautionary procedures to follow when operating or working around electrical equipments.

1. Be particularly careful when operating high-voltage equipment.
2. Use only properly grounded equipment (3-prong plug).
3. Check for "frayed" electrical cords.
4. Report any malfunctioning or equipment producing a prompt for repair.

5. Do not work on "live" electrical equipment.
6. Never operate electrical equipment with wet hands.
7. Know the exact location of the electrical control panel for the electricity to your work area.
8. Use only approved extension cords and do not overload circuits.
9. Avoid storing highly flammable liquids near electric equipment.
10. Have periodic preventive maintenance performed on equipment.
11. In case of electrical shocks turn off power at the source or separate the victim from the source with a nonconductor, like wood.
12. If fire results, turn off the electricity at the source.

8. Transportation of Specimens

1. All specimens must be placed into leak-proof non-breakable containers.
2. Assure that specimen containers are securely closed and clean on the outside (if not, wipe with alcohol).
3. Personnel must be trained in the safe handling practices and decontamination of spills
4. Specimens are transported as per guidelines given in 'Guidance on regulations for transport of infectious substances WHO/CDS/EPR/2007.2, 2007-2008'. Specimens, in their leak proof containers, must be placed into a sealable secondary container, with absorbent material in between which will contain the specimen if the primary container breaks in transit.
5. Laboratory requisitions must be protected from contamination. If necessary, put in to a separate bag or container. Do not place requisition in same bag as specimen.

Receiving of Transported Specimens

1. Appropriate gloves must be worn when handling all specimens. Gloves should be discarded before answering phone or opening doors.
2. Personnel must be trained in the safe handling practices and decontamination of spills.
3. 1% Sodium hypochlorite must be used to wipe contaminated tubes.
4. Visibly contaminated laboratory requisitions must be discarded and replaced.
5. Tubes must be stoppered while centrifuged.

9. Fire Safety

Fire may be due to combustible solid material like paper, plastic and fabric or due to inflammable liquids or electrical equipments or could be due to combustible/reactive metals.

Depending on the nature of the combustible material they are classified as

- Class A - combustible solid materials such as paper, plastic and fabric.
- Class B - flammable liquids
- Class C - electrical equipment
- Class D - combustible/reactive metals such as magnesium, sodium and potassium

Extinguisher used in case of fire is dry powder chemical extinguisher.

FIRE FIGHTING SYSTEM PROVIDED:

1. The building is provided by fire service inlet in the courtyard to connect fire tankers to the wet grid. The hospital has emergency exits in case of fire accidents.
2. Firefighting equipment like fire extinguishers have been placed in each wing of the hospital.
3. CO_2 cylinders have been placed in the laboratory at easily accessible locations. It is maintained by maintenance section. It is provided on each floor which is maintained by maintenance section periodically.

FIRE DETECTION SYSTEM PROVIDED:

1. The entire laboratory is covered with fire detection system. It has been covered by smoke detectors and the entire floor is covered by the detection system.
2. The entire system is monitored from one single fire control room situated on ground floor round the clock.
3. Training for fire safety is conducted yearly or whenever required by the maintenance department. Records are available in employee training record file.

10. First Aid

Procedure:

First aid boxes are available in OPD (old building) and in OPD (New Building). They are also available at hand in Hematology, Microbiology & Serology and Histopathology sections of the laboratory.

Contents of the first aid box

- Bandage
- Normal saline
- Hydrogen peroxide
- Povidone iodine solution
- Helex plus(aerosol spray dressing)
- Tears plus
- Chlorhexidine cream
- Bandaids
- Cotton
- Gloves
- scissors

In case of any accidents first aid is given and the staff is directed to staff clinic for further management

11. Classification of Biological Agents According to Risk

RISK GROUP 1 AGENTS: REQUIRING CONTAINMENT LEVEL 1

Risk Group 1 (low individual and community risk)

This group includes those microorganisms, bacteria, fungi, viruses and parasites, which are unlikely to cause disease in healthy workers or animals.

RISK GROUP 2 AGENTS: REQUIRING CONTAINMENT LEVEL 2

Risk Group 2 (moderate individual risk, limited community risk)

A pathogen that can cause human or animal disease but under normal circumstances, is unlikely to be a serious hazard to healthy laboratory workers, the community, livestock, or the environment. Laboratory exposures rarely cause infection leading to serious disease; effective treatment and preventive measures are available and the risk of spread is limited.

Risk Group 2 (Bacteria, Chlamydia, Mycoplasma)

Actinobacillus - all species

Actinomyces pyogenes (C. pyogenes)

Bacillus cereus

Bartonella bacilliformis, B. henselae, B. quintana, B. elizabethae

Bordetella pertussis, B. parapertussis and B. bronchiseptica

Borrelia recurrentis and B. burgdorferi

Campylobacter spp. *(C. coli, C . fetus, C. jejuni)*

Chlamydia pneumoniae, *C. psittaci* (non-avian strians), *C. trachomatis*,

Clostridium botulinum, Cl. chauvoei, Cl. difficile, Cl. haemolyticum,

Cl. histolyticum, Cl. novyi, Cl. perfringens, Cl. septicum,

Cl. sordellii, Cl. tetani

Corynebacterium diphtheriae, C. haemolyticum,

C. *pseudotuberculosis, C. pyogenes (A. pyogenes)*

Edwardsiella tarda

Erysipelothrix rusiopathae (insidiosa)

Escherichia coli enterotoxigenic/invasive/hemorrhagic strains

Francisella tularensis Type B, (biovar palaearctica), *F. novocida*

Fusobacterium necrophorum

Haemophilus influenzae, H. ducreyi

Helicobacter pylori

Legionella spp.

Leptospira interrogans - all serovars

Listeria monocytogenes

Mycobacteria - all species (except *M. tuberculosis,* and *M. bovis* (non-BCG strain), which are in Risk Group 3)

Mycoplasma pneumoniae, M. hominis Neisseria gonorrhoeae, N. meningitid is

Nocardia asteroides, N. brasiliensis

Pasteurella, all species (except *P. multocida* type B in Level 3)

Pseudomonas aeruginosa

Salmonella enterica (S. choleraesuis)

Salmonella enterica serovar arizonae *(Arizona hinshawii)*

Salmonella enterica ser. gallinarum-pullorum *(S. gallinarum-pullorum)*

Salmonella enterica ser. meleagridis *(S. meleagridis)*

Salmonella enterica ser. paratyphi B *(S. paratyphi B)* (Schottmulleri)

Salmonella enterica ser. typhi *(S. typhi)*

Salmonella enterica ser. typhimurium *(S. typhimurium)*

Shigella boydii, S. dysenteriae, S. flexneri, S. sonnei

Staphylococcus aureus

Streptobacillus moniliformis

Streptococcus spp. (Lancefield Groups A, B, C, D, G)

Treponema carateum, T. pallidum (including *pertenue*), *T. vincentii*

Ureaplasma urealyticum

Vibrio cholerae (incl. El Tor), V. parahaemolyticus, V. vulnificus

Yersinia enterocolitica, Y. pseudotuberculosis

Risk Group 2 -Fungi

Cryptococcaceae

Candida albicans

Cryptococcus neoformans

Moniliaceae

Aspergillus flavus

Aspergillus fumigatus

Epidermophyton floccosum

Microsporum spp.

Sporothrix schenckii

Trichophyton spp.

Risk Group 2 -Parasites

Infective stages of the following parasites have caused laboratory infections by ingestion, skin or mucosal penetration or accidental injection. Preparations of these parasites known to be free of infective stages do not require this level of containment.

Protozoa

Babesia microti

Babesia divergens

Balantidium coli

Cryptosporidium spp.

Entamoeba histolytica

Giardia spp. (mammalian)

Leishmania spp. (mammalian)

Naegleria fowleri

Plasmodium spp. (human or simian)

Pneumocystis carinii

Toxoplasma gondii

Trypanosoma brucei, T. cruzi

Helminths Nematodes -

Ancylostoma duodenale

Angiostrongylus spp.

Ascaris spp.

Brugia spp.

Loa loa

Necator americanus

Onchocerca volvulus

Strongyloides spp.

Toxocara canis

Trichinella spp.

Trichuris trichiura

Wuchereria bancrofti

Cestodes

Echinococcus (gravid segments)

Hymenolepis diminuta

Hymenolepis nana (human origin)

Taenia saginata

Taenia solium

Trematodes

Clonorchis sinensis

Fasciola hepatica

Opisthorchis spp.

Paragonimus westermani

Schistosoma haematobium

Schistosoma japonicum

Schistosoma mansoni

RISK GROUP 3 AGENTS: REQUIRING CONTAINMENT LEVEL 3

Risk Group 3 (high individual risk, low community risk)

A pathogen that usually causes serious human or animal disease, or which can result in serious economic consequences but does not ordinarily spread by casual contact from one individual to another, or that can be treated by antimicrobial or antiparasitic agents.

Risk Group 3 (Bacteria, Chlamydia, Rickettsia)

Bacillus anthracis

Brucella - all species

Burkolderia (Pseudomonas) mallei; B. pseudomallei

Chlamydia psittaci - avian strains only

Coxiella burnetii

Francisella tularensis, type A (biovar tularensis)

Mycobacterium tuberculosis; M. bovis (non-BCG strains)

Pasteurella multocida, type B

Rickettsia - all species (also see Table 1)

Yersinia pestis

12. Biological Safety

There are 4 Biosafety levels which Correspond to the 4 risk groups of infectious agents. Biosafety level 2 is the practice level at which the Microbiology lab must operate. Most pathogens that the lab isolates are from Risk Group 2. *Mycobacterium tuberculosis* is a Risk Group 3 pathogen.

Biological safety cabinets are the most accepted primary containment devices. The appropriate cabinet for Biosafety level 2 is a Class II cabinet.

Biosafety Level Practices and Techniques/ Safety Equipment Facilities

1. Standard microbiological practices

None: primary containment provided by adherence to standard laboratory practices during open bench operations.

2. Level 1 practices:

Laboratory coats; decontamination of all infectious wastes; limited access; protective gloves and biohazard warning signs as indicated. Partial containment equipment (i.e., Class I /II Biological Safety Cabinets) used to conduct mechanical manipulative procedures that have high aerosol potential that may increase the risk of exposure to personnel.

3. Level 2 practices:

Special laboratory clothing; controlled access. Partial containment equipment (Biosafety Cabinet IIa) used for all manipulations of infectious material.

Procedure :

1. All specimens are to be in solid, leak resistant containers contained in a secondary container (plastic bag) that is securely closed. The plastic bag should have a pouch for the requisition.

2. Do not use dry ice, freezer pads etc. used for transportation of specimens for any other purpose as they are potentially contaminated.

3. Perform procedures that have the potential to generate aerosols or droplets in a biological safety cabinet or behind a protective shield. Keep biological safety cabinets clear of clutter.

4. Consider all quality control materials as potentially infectious.

5. Keyboards and telephones in non-laboratory areas should not generally be accessible to individuals handling specimens or engaged in laboratory work. In the event that such a worker needs to use these keyboards or telephone, they must remove their gloves and wash their hands before doing so.

6. Service personnel must use gloves prior to use of such keyboards

Wash your hands thoroughly upon leaving the laboratory. Always change gloves if they have become grossly contaminated with blood or body fluids.

7. Do not operate centrifuges in a biological safety cabinet since the motor may produce strong air currents and turbulence which may disrupt the laminar air flow.

8. Perform vortexing using sealed tubes or secondary containers in an open laboratory. Do not use Parafilm as a primary closure.

9. Procedures for cleaning, disinfection and sterilization of laboratory equipment, supplies, and environmental surfaces are available.

10. Clean and disinfect equipment (water baths, test tube racks, etc.) at least once a month or after contamination with any biological material.

11. Clean and disinfect the exterior of the pipetting devices with an appropriate disinfectant if it becomes contaminated with specimen. If the pipetter is contaminated internally, the entire unit must be disassembled and decontaminated.

12. Clean and disinfect any equipment to be repaired prior to repair.

13. When using a syringe for inoculating bottles, do not hold the bottle by hand when puncturing the top and do not force blood or any body substance into the bottle.

13 Reporting Work Related Incidents

Whenever there is a an untoward incident in the laboratory it is recorded in the format enclosed

ACCIDENT REPORTING

Name of the employee:

ID NO. :

Date & Time of accident:

Sequence of events leading to accident:

Emergency measures taken :

Steps taken to prevent the recurrence of such accidents :

Date.....

Signature of HOD.....

Place.....

Designation.....

14. PERSONAL PROTECTIVE EQUIPMENT

DMH provides appropriate personal protective equipment (PPE) to all its employees when contact with body substances/chemicals is deemed likely. All human blood or body fluids are capable of harbouring infectious pathogens. Employ proper personal hygiene. Frequent hand washing is the single most important measure to reduce the risks of transmitting organisms. Wash your hands whenever you leave the laboratory and remove laboratory coats/gowns before entering other nonlaboratory facilities or areas which are considered to be clean.

PERSONAL PROTECTION EQUIPMENT (PPE) PROCEDURE PRECAUTIONS

- Clothing Laboratory coat/apron and gloves.
- Wear laboratory coat at all times when working in the laboratory.
- Use PPE if there is potential for splashing / aerosolization with body fluids
- Remove the lab coat worn in the laboratory prior to exiting the work area or entering office areas.

Hand protection

Disposable gloves

- Staff trained in appropriate use/treatment of gloves
- Wear disposable gloves when handling biological specimens.
- Remove before leaving the laboratory
- Wash hands after removing gloves
- Provide a protective barrier
- Prevent gross contamination of hands to blood or body fluids.

Other gloves

- Purpose of gloves varies - to protect against chemical burns; abrasions, cuts, punctures; temperature extremes in the work environment (e.g., autoclave, - 80^0C freezer)
- Gloves are discarded in red bags.
- Do not touch your face/hair or clean areas with gloves on.

15. Decontamination

Definition:

Decontamination is a procedure involving cleaning and disinfection of equipments, done to remove infective material and microorganisms and render them noninfectious.

Methods of Decontamination:

1. Physical-UV decontamination
2. Chemical-The following disinfectants are used
    1. 0.1 % Sodium Hypochlorite.
    2. Bacillocid

Frequency of decontamination:

All instruments that are directly exposed to infective material and the sample processing areas are decontaminated everyday with bacillocid.

In case of spillage of infective material:

1 % Na hypochlorite is poured over the spillage material and kept for 30 minutes. An absorbent (tissue paper/newspaper) is kept on the infective spillage material. This material is then discarded and the processing area is again wiped with 0.1 % Na Hypochlorite.

Preparation of Sodium hypochlorite:

1% and 0.1 % Sodium Hypochlorite is prepared and provided by the house keeping department. Dilution is done by the housekeeping department using auto dilution machines.

Decontamination of equipments:

Decontamination of Equipments in Histopathology & Cytopathology:

Since the surgical specimens (biopsies/excised specimens) are received in 10 % formalin, decontamination is not indicated for tissue processors, tissue embedding systems and microtome.

Decontamination is done for Cryostat that is directly exposed to fresh tissue received in normal saline for frozen section.

1) U.V. disinfection:

The cryostat is disinfected with U.V disinfection after every frozen section and at the end of the day. The disinfection cycle is started by pressing UVC key. Disinfection is carried out for 30 minutes on routine tissue. Whenever frozen section is carried out on known HIV positive patient, the cryostat is exposed to U.V. disinfection for 180 minutes. In both cases, care is taken to keep the sliding window completely closed.

2) Spray disinfection:

Ready to use spray is used for disinfection after every frozen section.

Decontamination of equipments in Hematology:

Tube decontamination is done daily with Cell Clean solution of Sysmex analyzer.

Decontamination of equipments in Clinical Biochemistry:

Tube decontamination for Architect is done with tube decontamination solution respectively. For Erba Chem-7, Erba Wash solution is used daily for tube decontamination.

Decontamination of equipments in Clinical Pathology:

Tube decontamination of LabUmate2 & Urised2 is done by using 1% hypochlorite. Disinfection of Labureader plus2, LabUmate2 & Urised2.is done by using Bacillocid.

16. SPILLAGE HANDLING

In case of infective material spillage

1. 1 % Na hypochlorite is poured over the spillage material and kept for 30 minutes. An absorbent (tissue paper / newspaper) is kept on the infected spillage area. This material is picked up using a dust pan and is then discarded in the yellow bin for biomedical waste. The area is again wiped using clean mop and dried.

2. Personal protective devices like rubber gloves, plastic apron and mask should be used while clearing the spills. All these materials are available in the spill management kit.

3. The contents of spill management kit are as follows :-
    1. 1 % Sodium Hypochlorite.
    2. Absorbent papers
    3. Rubber gloves
    4. Plastic apron
    5. Mask
    6. Sand
    7. Sodium bicarbonate
    8. Dust pan and mop
    9. Yellow bag

4. Spill kits are available in OPD Pathology (old building), Accession Room (New building), Microbiology and hematology section of the laboratory.

In case of chemical spillage

1. For acid spills, the area is covered with Sodium bicarbonate.
2. For alkaline spills the area is covered with sand. The area is then cleaned using dust pan and mop.

HANDLING AND STORAGE OF FORMALDEHYDE (FORMALIN)

FORMALDEHYDE SAFE USE PRACTICES

1. Preparation of formaldehyde solutions is performed in a chemical fume hood.
2. Formalin is available as 40% formalin. 10 parts of formalin is poured in a plastic can to which 90 parts of tap water is added to make 10% formalin. These cans are stored separately beneath the grossing table in a closed compartment. It is prepared by MPWs using PPE.
2. Formalin is stored and transported in labeled, leak/spill-proof, no breakable containers.
3. Formalin is a hazardous chemical materials, hence is drained off in running water in dedicated sluice which is connected to the sewage treatment plant (STP) of the hospital.

CONTENTS OF FORMALDEHYDE (FORMALIN) SPILLAGE KIT:

1. Board-Wet floor sign
2. Nitrile Gloves
3. Disposable gown
4. Mask
5. Protective eye wear: goggles
6. Absorbent paper
7. Yellow bin/bag
8. Tweezers
9. Brush / Small broom/Dustpan
10. Plastic Can/beaker for water

FORMALIN SPILL

Formalin spills are cleaned up immediately by properly protected personnel who are not sensitive to formalin using PPE (lab coat, safety goggles, nitrile gloves & shoe covers). If it is a major spill, all other persons are told to leave the area. Clean up spills using absorbent paper. The paper is discarded in yellow bag. The area is wiped with detergent and water. Remove gloves and discard in red bin. Wash hands with soap and water upon completion of tasks.

Follow the steps below for any exposures to formalin:

- Inhalation exposure: Move out of contaminated area. Get medical help
- Sharps injury (needlestick and subcutaneous exposure): Scrub exposed area thoroughly for 15 minutes using warm water and soap.
- Skin exposure: Use the nearest safety shower for 15 minutes.
- Eye exposure: Use the eyewash for 15 minutes while holding eyelids open.

Monitoring of formalin vapors:

Permissible exposure limit (PEL); This air borne concentration of 0.75 ppm to which lab personnel are permissible to be exposed to formalin vapors during a 40 hour work week for a working lifetime without adverse effects. This being monitored by formalin indicator. The residents grossing surgical specimens work in a chemical fume hood fitted to the grossing table to minimize risk of exposure to formalin.

Mercury spillage

INTRODUCTION:

Elemental mercury is a potent neurotoxin that can cause adverse effects in very small amounts. Mercury is a heavy, liquid metal and a breakage usually results in the mercury spreading over a wide area, in many small globules. It is important to prevent people walking through the spillage area, spreading the mercury further.

Equipments that contain mercury are

1. Thermometers
2. Sphygmomanometers
3. Dental amalgam.

Mercury spill or exposure to mercury in hospital occurs due to breakage or release of mercury dust or liquid or vapor.

This may be either due to

1. Breakage of equipment
2. Leak from the instrument

HEALTH HAZARDS OF MERCURY SPILLAGE:

1. Central nervous system: Vertigo, anxiety, depression, emotional instability.
2. Lung: edema
3. Kidney damage
4. Eyes: discoloration of lens, irritation and burning of eyes.
5. Digestive system: severe and permanent damage.
6. Skin: Allergic reactions, irritation and burns.

CONTENTS OF MERCURY SPILLAGE KIT:

1. Nitrile gloves
2. Disposable gown
3. Mask
4. Protective eye wear: goggles
5. Absorbent powder
6. Paper towel
7. Brush / Small broom/Dustpan
8. Caution Sign
9. Yellow bin/bag

PROCEDURE FOR HANDLING MERCURY SPILLAGE:

1. Place a sign of wet floor where there is a spillage.
2. Bring mercury spillage kit. (MPW)
3. Wear mask, gown, goggles, and gloves before beginning the procedures.
4. Remove all glass or sharp objects on a paper towel and place in a bag.
5. Locate all mercury beads. Use cardboard to gather all mercury beads.
6. Use absorbent powder to cover the spill.
7. Use brush or small broom to remove the powder and discard in yellow bag and label it as " Mercury Hazardous waste".
8. Wipe the entire spillage area with soap and water and let it dry.

9. Remove all PPE and discard in appropriately in another bag.
10. Perform hand hygiene.
11. Remove the wet floor sign.
12. Record the incident in a spillage register.

PRECAUTIONS TO BE TAKEN DURING CLEANING OF MERCURY:

- Never walk around the area contaminated with mercury
- Never use an ordinary vacuum cleaner to clean up the mercury.
- Never use broom to clean up mercury as it can break it into small pieces.
- Never pour mercury down the drain.
- Never wash mercury contaminated items in a washing machine – it will pollute the water system.

STEPS TO BE TAKEN ON EXPOSURE TO MERCURY:

Get medical aid immediately.

Eyes : Do not rub eyes. Extensive irrigation with water.

Skin : Flush skin with plenty of water. Remove contaminated clothes and shoes.

Ingestion : Drink 2-4 cups of milk, do not vomit. Wash mouth with water.

Inhalation : Move to fresh air. Give oxygen if necessary.

Antidote: d-Penicillamine.

17. EMPLOYEE HEALTH POLICY

Deenanath Mangeshkar Hospital is committed to the health and welfare of all ITS employees. The health care needs of employees are closely monitored through staff clinic conducted by Casualty Medical Officer (CMO). Though all employees are not involved in direct patient care and thereby not exposed to the potential risk of infectious diseases it is advisable that all employees are aware of prophylaxis and safe work practices.

- Administration advices all staff members to undergo periodic screening on a voluntary basis, and is encouraged to get themselves immunized against Hepatitis B. Anti HBs antibody titers of all employees are done and recorded.
- Practice of Standard Precautions is mandatory and is constantly monitored by the immediate Superiors. Gross and habitual violations are brought to the notice of the quality manager.
- Employee education training programs or lectures are conducted at periodic intervals whenever any new employees are recruited.
- Hospital infection control committee holds meetings approximately once every two months or whenever an issue arises.
- Hospital has needle stick injury protocol. In the event of a needle stick / sharp injury during the conduct of work in the hospital premises, a report is documented. PPE, if required is given free to the health care personnel.
- Confidentiality is maintained if an employee is detected to be HIV positive and counseling is done by Infectious Diseases consultants.
- The Staff Physician monitors the treatment of all employees suffering from infectious diseases and refers patients for appropriate treatments to infectious diseases consultants.
- Investigations to rule our HIV / HBsAg are included in the Pre-employment check up.

18. VENTILATION

TYPES OF VENTILATION SYSTEMS

There are **2 types** of ventilation systems:

1. **HVAC** (heating, ventilation, air conditioning) systems are designed primarily for temperature, humidity and air quality movement.

2. **Local ventilation systems** are designed to remove contaminants generated by work procedures or equipment from the workplace. Examples are biological safety cabinets, chemical fume hoods and vent.

Biological Safety Cabinets

- Class I - a primary barrier which offers protection to laboratory personnel and to the environment
- Class II - a primary barrier which offers protection to laboratory personnel and to the environment and also provides product protection from external contamination of the material
- Class III - a gas-tight (glove box) which provides the highest attainable level of protection to personnel and the environment. Require special design and construction.
- Do not operate centrifuges in a biological safety cabinet since the motor may produce strong air currents and turbulence which may disrupt the laminar air flow
- Must be inspected and certified once a year (cabinets are inspected as per hospital contract)

Chemical Fume Hoods

Lab air flows are balanced at time of fume hood installation to achieve designed fume hood face velocities and uniformity of airflow patterns

- Factors affecting fume hood performance e.g., open doors or windows nearby, room air currents, movement near fume hood face openings
- Fume hood should be inspected and certified annually
- Routine maintenance is required on exhaust fans

Vents

- Vent at the exterior of the bench connected to an exhaust duct
- For maximum benefit, place work as close to the vent as possible, e.g., urinalysis bench

19. HOUSEKEEPING

- Mopping of the floor is done with 0.1 % sodium hypochlorite twice a day, once in the morning and then in the afternoon.
- Cleaning of the work benches is done with 0.1% sodium hypochlorite at the beginning of the day.
- Changing of hypochlorite solution at the work stations is done at the beginning of the day or whenever necessary.
- All equipments are cleaned at the beginning and at the end of the day by wiping with a soft cloth.
- Plastic bags are placed in the color coded wastebaskets for collecting biomedical and non-biomedical waste and are emptied at the end of the day or whenever necessary (Refer for details to procedure for waste disposal).
- Personal belongings are not kept in the laboratory work area. Lockers have been provided for the same.
- Eatables are not allowed inside the lab area.
- Samples spills are exposed to 1% sodium hypochlorite solution with a minimum of contact period of 30 minutes and cleaning is done.(For details refer to spillage handling pg.34 of safety manual)

Workplace Health and Safety Inspection Procedures

FREQUENCY OF INSPECTIONS

Monthly

REGULAR SAFETY AUDITS REQUIRED IN THE LABORATORY

As part of the inspection process, the officer checks that the audits listed below are carried out with the frequency indicated and are documented.

The officer records observations on an inspection audit form, as per the checklist enclosed.

Documents hazards on this form as they are identified.

Immediate Hazards:

These are hazards that could cause injury or illness unless they are corrected right away. The Manager / Supervisor is responsible for ensuring that the following are checked with the frequency indicated.

LABORATORY INSPECTION CHECKLIST

The following guide has been developed to assist the lab in safety surveillance of laboratories and departments in full, partial or non-compliance. The laboratory inspection form is as follows. Each print is commented as fully complaint, partially complaint or non complaint.

1. Entrances, Exits, Hallways and Stairways - All entrances, exits, hallways and stairways must be clear and unobstructed.

2. Personal Protective Equipment - Personal Protective Equipment such as goggles, masks, gloves and cover gowns must be readily available and not worn outside the immediate work areas. Lab coats and appropriate shoes shall be worn to avoid any contact with harmful materials.

3. Fire Extinguisher/Inspection and Location - All fire extinguishers must be inspected monthly. Extinguishers must be properly mounted, unobstructed and be properly labeled for the intended use.

4. Pressurized Cylinders - All cylinders must be stored in proper locations. All cylinders must be secured in an upright position and properly restrained to prevent falling. Containers must be labeled for contents and usage.

5. Room Use Identification - All access doors must be marked when rooms or areas are being used for chemical or biological purposes. All doors must remain closed and the vision panel must remain unobstructed. Unattended labs shall be locked at all times.

6. Electrical Equipment and Cords

7. Biological Safety Cabinets - Certification is required annually or any time the hood is moved or has had maintenance performed. Cabinets must not be located near high traffic areas or air supply ducts.

8. Hazardous Chemicals - All chemicals must be appropriately labeled and shall not be placed near or over floor drains. Flammable liquids must be stored in appropriate containers.

9. General Safety (Dress, Eating, Smoking, etc.) - Eating, drinking, smoking and applying cosmetics is not permitted in the lab

10. Use of Flame and Heat - No heat generating devices should be left unattended.

11. Ventilation - Laboratory doors shall be kept closed when laboratory procedures are in progress. Volatile hazardous materials shall not be used on the open bench top.

12. Housekeeping/Drains Flushed - All unnecessary material, boxes, and containers must be disposed off in the appropriate manner. All drains, including floor drains and cup sinks should be flushed with water on a weekly basis to eliminate sewer odors. Proper housekeeping must be maintained to provide adequate clearance of sprinkler systems and emergency equipment.

13. Sharps (Glass, Scalpel, Blades, Syringes, Etc.) - All sharps, needles and glass must be disposed off in an approved labeled container. Glass containers and other potentially sharp objects shall not be disposed off in common office refuse. Containers must not be overfilled and must be labeled and sealed for proper handling and disposal.

14. Emergency lighting - Where necessary, emergency lighting units shall be properly mounted and unobstructed. If emergency lighting exists, it should be checked periodically to ensure it is functional.

15. Emergency Plans/Posted Numbers - All emergency and contingency plans and evacuation routes shall be clearly posted in conspicuous places. A list of emergency numbers and contacts must be kept updated and posted along side the emergency plans.
16. Safety Manuals - Manuals must be current and readily available for all employees.

LABORATORY INSPECTION CHECKLIST

- Are general signs and information properly posted?
- Are all floors clean and dry?
- Are passageways, storerooms, work areas & aisles clear?
- Is proper illumination provided in the work area?
- Is proper clothing being worn by employees in the work area?
- Are fire safety and training for all employees documented?
- Are telephones in the work area conveniently located?
- Are first aid supplies adequate for potential hazards and are they available?
- Is Personal Protection equipment (PPE) available to the employees and is it being utilized properly?
- Are hand wash stations available and easily accessible?
- Are electrical and / or phone cords properly secured on the floor?
- Chemical stored by classification and not alphabetically?
- Are good housekeeping practices followed by employees?
- Are all materials piled, racked or stored in a safe manner?
- Are the work areas or bench tops uncluttered?
- Are fume hoods and biological safety cabinets uncluttered and accessible?
- Are waste containers properly labeled and in good condition?
- Are sharp containers available and in good condition?
- Are compressed gas cylinders properly secured and labeled?
- Are fire extinguishers mounted in accessible locations?
- Are explicit instructions posted for acid splashes and acid spills?

2. Provide NABL certificate

National Accreditation Board for Testing and Calibration Laboratories

NABL

CERTIFICATE OF ACCREDITATION

DEPARTMENT OF PATHOLOGY, DEENANATH MANGESHKAR HOSPITAL AND RESEARCH CENTER

has been assessed and accredited in accordance with the standard

ISO 15189:2012

"Medical laboratories - Requirements for quality and competence"

for its facilities at

DEENANATH MANGESHKAR HOSPITAL AND RESEARCH CENTER, ERANDAWANE, PUNE, MAHARASHTRA, INDIA

in the field of

Medical Testing

Certificate Number: MC-2177

Issue Date: 23/09/2019 **Valid Until:** 22/09/2021*

*The validity is extended for one year up to 22.09.2022

This certificate remains valid for the Scope of Accreditation as specified in the annexure subject to continued satisfactory compliance to the above standard & the relevant requirements of NABL.

(To see the scope of accreditation of this laboratory, you may also visit NABL website www.nabl-india.org)

Name of Legal Identity : DEPARTMENT OF PATHOLOGY, DEENANATH MANGESHKAR HOSPITAL AND RESEARCH CENTER

Signed for and on behalf of NABL

N. Venkateswaran
Chief Executive Officer