1.0 POLICY

Laboratory provides comprehensive services in the areas of- Clinical pathology, Haematology, Microbiology, Serology, and Biochemistry which are required by the scope of clinical services of the hospital.

Laboratory possesses the staff that are suitably qualified and trained to carry out laboratory tests.

The organization employs well qualified personnel for performing the respective work ensuring the best laboratory service, quality and accuracy

Sample is collected, identified, handled, transported, processed and disposed in a proper channel.

The test results for the laboratory test performed in the hospital's laboratory are available to the patient / relatives / ward in-charge in the defined time frame.

Laboratory tests not available in the Hospital and as required for the clinical management of patient are outsourced to the centre with which our hospital has a MOU. This laboratory is selected on the basis of desired level of quality of service, which has been checked and approved by the hospital management.

2.0 PURPOSE

- To provide laboratory services to the patient.
- To adhere with the quality of diagnostic techniques
- To avoid any mistake in managing the department and getting expected result on time.
- To channelize the system
- To avoid any confusion in collection, identification, handling, transportation, processing and disposal of specimen.
- To avoid barrier in controlling infection
- To provide the report to the patient on time
- To minimize any reporting error
- To avoid any confusion in reporting area for getting the report by the patient and relatives
- To smoothen the function of the department
- To provide a protocol for notification of critical patient test results
- To make available related facility for the patient

3.0 Definition:

Normal: A test result that is within the normal variation and does not require follow-up.

Critical: A test results beyond the normal variation with a high probability of a significant increase in morbidity and/or mortality in the foreseeable future and requires rapid communication of results for determination of intervention.

4.0 ABBREVIATIONS:

MoU: Memorandum of Understanding

NABH: National Accreditation Board for Hospital and Healthcare providers

NABL: National Accreditation Board for Laboratory

5.0 SCOPE

Laboratory Services are in commensurate to the services provided by the organization. This policy also applies to all sections of the laboratory ensuring that the competent& adequate human resources are available to perform the work in the best possible way.

Each department is responsible for ongoing assessments and to identify and implement a process, as needed, for the reporting of critical values.

6.0 RESPONSIBILITY Laboratory Department, Administration Department

7.0 DISTRIBUTION

Registration clerk, Laboratory Department, Administration Department, in patient department, BMW Department

8.0 PROCESS DETAIL:

<u>8.1 Scope of Laboratory Services:</u>

Following laboratory tests are provided in house by laboratory department

- **Haematology**
- **Pathology**
- **Serology**
- **Biochemistry**
- **Blood Bank (Blood donation, VBD camps, Blood grouping, cross matching, ELISA for HIV, HBsag, HCV, MP(manual) & VDRL(rapid)**

SPECIALTY	**RELATED ADDITIONAL SERVICES**
Haematology	1. Haemoglobin estimation 2. Total Leucocyte count 3. Differential Leucocyte count 4. Absolute Eosinophil count 5. Haemogram 6. E.S.R. 7. Bleeding time 8. Clotting time 9. Peripheral Blood Smear 10. Malaria/Filaria Parasite 11. Platelet count 12. Packed Cell volume / Hemogram 13. Blood grouping 14. Rh typing 15. Rapid test for HIV & VDRL
Pathology	• Stool tests (For Ova, cyst) • Urine and semen analysis. • Routine blood counts • Peripheral smear examination

Serology	• Pregnancy test (Urine gravindex) • WIDAL test • Dengue • Chikengunia • RA factor test • CRP • HBSAg • HCV
Biochemistry	• Blood Sugar • Glucose Tolerance Test • Glycosylated HbAIc • Blood urea, Serum cholesterol • Serum bilirubin • Liver function tests • Kidney function tests • Lipid Profile • Serum uric acid • T3, T4 & TSH
Microbiology	• Water Bacteriology Exam. • Urine Culture

All tests performed in the laboratory are described in the laboratory test minimal list.

8.4 Sample Collection.

Sample collection is carried out from 8 am to 11 am daily (summers) & 9:00 am to 12:00 pm daily(winters) and for the Emergency and IPD it is carried out on 24 hours basis. Sample collection facilities are provided in patient care areas like IPD and within the Laboratory itself.

Due consideration is given for space, seating, ventilation and privacy. Adequate toilet facilities are made available close to the sample collection area.

Sample Identification

Test requisition form (TRF) contains sufficient information to identify the patient, doctor requesting the test and pertinent clinical details. These are filled by doctor and stamped. The TRF is in the paper form and contains the following:

1. Hospital number which is the registration number in the OPD slip of the patient.

2. Name of the ordering physician

3. Type of primary sample (s) and anatomic site of origin where appropriate.

4. Examinations requested

5. Clinical information relevant to the patient including age, gender etc.

6. Date and time of sample collection

7. Date and time of receipt in the laboratory.

8. Whether the test is Urgent or Routine

Acceptance of sample in the laboratory and allotment of laboratory serial number in the respective sections. The serial number is written using permanent marker on sample container and the accompanying TRF.

The lab reception receiving the samples will enter the details in lab register.

The primary sample can be traceable through the lab serial numberand date to the TRF and finally to the patient. If for any reason the primary sample lacks proper identification or the accompanying TRF does not have the information needed to register the sample, the sample shall not be accepted or processed.

When the primary sample is critical or irreplaceable and the identification is uncertain the lab may choose to process the specimen but withhold the result until the requesting physician or

person responsible for collecting the sample takes responsibility for the identification of the sample, accepting the sample or providing proper information. The signature of the person taking the responsibility shall be affixed on the TRF and on the report as the person who identified the sample.

Sample Handling

- All samples are handled as per the infection control guidelines
- Universal precautions are to be observed while handling samples

Safe Transportation of Samples

- The laboratory monitors the transportation of samples from the point of collection to the Lab ensuring the time frame within which the sample has to be processed, and care to be taken to prevent spillage or contamination of the environment or people handling the specimens.
- The staff nurse on duty to ensure safe transportation of the sample from the ward to the lab for the IPD patient's samples.
- All samples requiring transportation are transported in test tubes and further in a well-sealed primary container.
- All measures are taken so that samples doesn't deteriorated
- Necessary precautions are to be taken depending on prevailing environmental factors

Processing of Samples

- Criteria for rejection of a sample are laid down as follows :
    - Samples with incomplete forms or illegible writing are summarily rejected.
    - Any leaking containers or inappropriate samples to the requested investigations are rejected.
    - Un-labelled specimens are rejected; however in case of body fluids the concerned nurse or the clinician is requested to come to the laboratory, identify and label the specimen
    - Haemolysed specimens are rejected or clotted blood in case of hematology tests are rejected
    - Samples with insufficient quantity of specimens are rejected.

- Samples grossly soiled with body fluids are rejected.

- If for any reason a less optimal sample is to be processed the reason for this and caution in interpretation of the test result are indicated in the report.
- The examination process shall be accurate and reliable.
- Test procedures are selected based on standard methods that have been published in text books or journals and have been accepted in international/national/ regional guidelines. The details are given in the list of tests.
- The procedures are validated for use by running of controls and calibrators. All these records are maintained in calibration file. The procedures for selection of methods are reviewed once a year and the modifications/changes, if any, are recorded.
- All procedures to perform the tests are documented and are available at the place of work for ready reference.
- Processing of samples is to be carried out as per the requirements of individual tests
- Procedure for testing is to be standardized and necessary instructions issued to all concerned personnel
- Whenever a new kit from a different manufacturer is used, it is evaluated against the kit in use and compatibility with old kit, range, linearity, etc. established. The new kit is introduced only after it meets these criteria. In case any changes are to be made then the corresponding information is modified accordingly
- Samples are processed without delay, and on priority for emergency cases.
- All results are authorized by senior technical staff in the respective sections and are reviewed by doctor if required. The results are checked, evaluated and verified.

Disposal of Specimens

- Disposal is to be carried out in accordance with bio-medical waste handling rules <**CHG/HIC/ Doc18>**.
- Precautions in accordance with the hospital infection control manual are to be observed

ACTIVITY and RESPONSIBILITY

Sample Collection and Identification Process:

Services	Process
Clinical pathology	Sample like stool, urine and semen are received and tested. Before testing, the labeling details are cross checked with the requisition. After performing the test, the observations are recorded.
Hematology	Sample labeling (Patient name, Registration no, ward name and room no.) are cross checked with requisition for correctness. Tests are conducted either manually or by using automated instruments available.
Biochemistry	Sample labeling (Patient name, Registration no, ward name and room no.) are cross checked with requisition. Samples are analyzed for the requisite Thyroid function tests, Abnormal values are repeated if required.
Serology	Sample labeling (Patient name, Registration no ward name and room no.) are cross checked with requisition.

Work Flow Process

S.No	Activity	Responsibility
	Out Patient Department	
1 **2**	Investigations written in doctor's prescription in patient notes	Doctor on Duty/ Consultant MOs/ Consultant Doctor

3	Investigation requisition form filled Patient takes requisition form to the cashier and makes relevant payment,if the required investigation is not free under Mukhya Mantra MuftIlazYojana. Patient is then directed to the Laboratory sample collection area.	OPD Cashier
4	Investigation requisition form and payment voucher produced at token counter in laboratory.	Lab Technician/ Registration clerk
5	Patient's form is taken and a token number is given to the patient .Patient is then requested to wait for his/her token no.	Lab Technician/ Registration clerk
6	Patient is then taken into the sample collection area as the token no displayed. Patient sample taken as per laboratory protocols already known. Patient informed as to the time the reports can be collected.	Lab Technician
7	All samples labeled (Patient name, Age/Sex, Date, Lab. No. &UHIDNo.). Immediately, sample type and then kept in respective laboratory repository (trays). Reports collected from the lab at time informed.	Lab Technician /Registration clerk
8		Lab Technician

	IN PATIENT	
1.	Investigations written up in patient case file and investigation requisition forms filled.	Consultant doctor/ Senior resident/Nurse
2.	Samples taken as per protocols by the lab technician in the ward every shift	Nurse/ward boy
3.	Samples labelled and are sent to the laboratory within 1 hour.	Nursing aid
	OPERATION THEATRE	
1.	Investigation in case of an emergency in the OT.	Consultant Surgeon or Any Consultant
2.	Laboratory consultant phoned and informed about need for urgent sampling, instructions taken, if any	Anaesthetist or Any Consultant
3.	Sample container labelled	Circulating Nurse
4.	Sample requisition form filled and labelled urgent.	Anaesthetist
5.	Sample sent to Laboratory	Nursing aid

	Receipt of sample in lab	
1.	All OPD and Outside samples collected by lab technician on arrival	Lab Technician assigned for collecting samples in laboratory.
2.	IPD samples taken by ward boy/patient attendant	Ward Boy
3.	Cross checking of patient ID, name, type of sample and test with the requisition form	Lab Technician
	Segregation of samples in lab	
1.	Samples are segregated as per test type in lab	Lab Technician
2.	Lab number given to samples and entry is made in lab register (all technician duties as are set per set lab protocols and jobs matching skill – part of lab operations manual).	Lab Technician
	Testing/Processing of Samples	
1.	Samples processed as per guidelines in instrument operations manual'.	Laboratory consultant/ Technician

8.5 Turnaround time

OPD & IPD samples received till 11.00AM (summers) & 12:00 PM (winters) ,reports are dispatched on the same day till 2.00PM (summers) and 3.00PM (winters).Results for samples collected after 12:00 hours are dispatched after 05:30 hrs on the same day.

Investigation requestsfor routine biochemistry will take approx.3 hrs.

Day is fixed for thyroid function tests (Thursday) and reports of the same are dispatched on next day

Any critical results found are informed to the respective doctors or in-charge.

Results of the outsourced test are given on the next day

ACTIVITY and RESPONSIBILITY

S. No.	Pathology , Haematology& Biochemistry Tests	Turnaround Time
1.	**OPD samples** received till 11.00AM (summers) & 12:00 PM (winters) ,reports are dispatched on the same day till 2.00PM (summers) and 3.00PM (winters).	Within 24 hours
2.	**IPD Samples** *** Some samples require higher processing time hence will be informed to the patient as required.**	Within 24 hours

8.6 Critical results policy:

Communication Tools

- **Manual:** including the manual processing, hand delivery or pick up to/by the testing area, patient care area or physician / nurse / ward staff.
- **Verbal:** including verbal report in person or by telephone / intercom / mobile phone

Order of Notification:

- Ordering: Treating Physician / Casualty Medical Officer / The attending staff physician/ Staff nurse on duty.
- Each department reporting critical values must have in place a defined process which documents the reporting of pre-approved critical values.

Normal / Non Critical Test Results Reporting and Documentation

Results are reported manually. The reports are printed from auto analyzer / manually.

Critical Test Results Reporting and Documentation

1. Included in this report is the name of the notifying technologists.
2. When a critical result is identified, the Laboratory Technologist contacts the ordering physician or their assistant.
3. For the patient who is no longer in the hospital or clinic, the Laboratory Technologist contacts the ordering physician or their assistant.
4. If the ordering physician or their assistant is not reached, the Laboratory Technologist will follow the order of notification.

System Failures

With any applicable communication system failure a hard copy of the critical result will be delivered to the ordering physician or their assistant.

<u>List of Critical results/ Values</u>

CRITICAL PANIC TEST RESULTS

HAEMATOLOGY				
Analyte	**Age Range**	**Panic Values**	**Units**	**Policy**
Hb	Any age	Less than 6.0	Gm%	Immediately

WBC	Any age	Below 2000 Above 20,000	Per cumm	Immediately
Platelet Count	Any age	Less than 50,000	Per cumm	Immediately
Parasitic index	Any age	≥ 5%		Immediately
Pyrexia	Any age	{ HC+ PCV } >52%		Immediately

BIOCHEMISTRY				
Analyte	**Age Range**	**Panic Values**	**Units**	**Policy**
Glucose	Any age	<40 or >400	mg%	Immediately
Total Bilirubin	<1 day >1 day < 2days >2 days <30 days Adult	>8 >/=13 New Born > 18 >/=15 > 10	mg%	Immediately

ACTIVITY AND RESPONSIBILITY

- All laboratory tests results, which are so far from the reference range that they indicate a potentially dangerous condition requiring immediate attention, are intimated to the concerned consultant.
- In case the consultant is not reachable the result are brought into the notice of Doctor on Duty.
- The resultsare also informed to the ward nurse if the patient is admitted to hospital.
- In the case of an outpatient, the results are intimated to the patient directly through available telephone or mobile number.
- The individual accepting the critical test result must record and thenread back the critical test result, in its entirety, to the reporter at the time the result is given
- All results are reported in standardized manner. This includes name of organization, name of patient, unique identification number, and reference range of test (where applicable) and

name and signature of the person reporting the test result. In case of outsource test results the same shall be on the lab's letterhead.

8.7 Outsourcing of Lab tests:

Selecting lab for outsourcing of tests:

- The lab should be accredited by recognized body like, NABL, NABH etc.
- The lab should maintain confidentiality of patient records.
- The lab should have a low turnaround time.
- Safe and adequate transportation of sample should be assured.

ACTIVITY AND RESPONSIBILITY

Requests for tests of a specialized nature are accepted and patient are sent to the outsourced laboratories sample collection room present inside the laboratory

The outsourced laboratories should ensure that the following requirements are met:

a. All requirements including pre-examination and post-examination procedures are adequately defined, documented and understood.

b. The referral laboratory being NABL accredited are able to meet the requirements, as there are no conflicts of interest.

c. Selection of procedures is appropriate for intended use.

d. Results and interpretations reported by the referral laboratory are reported as such without any amendment.

The reports received from outsourced laboratory are given to the client in original by the outsourced lab

9.0 REFERENCES:

Policy of Scope of services **(CHG/AAC/Doc no 01)**

Admission Policy **(CHG/AAC/Doc no 02)**

Lab Quality Assurance Policy **(CHG/AAC/Doc no 07)**

10.0 RECORDS AND FORMATS : Requisition slips