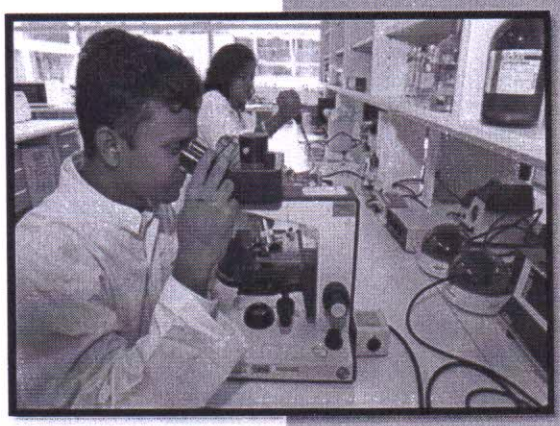
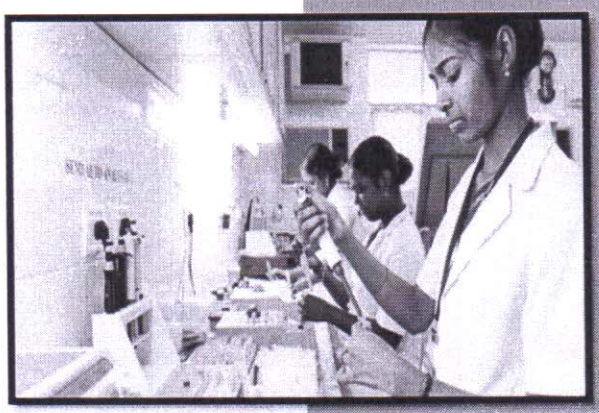
Standard Operating Procedures for Public Health Facilities- Uttar Pradesh

Laboratory Department





Quality Assurance Division
SPMU, NHM, Uttar Pradesh

Laboratory Services

1. Purpose:

To provide all kind of available diagnostic services to patients.

2. Scope:

It covers all patient care areas of hospital.

3. Responsibility:

The Pathologist / Lab technician / Treating physician are responsible for prescribing, diagnosis and further treatment based on reports.

4. Procedures:

Sl. No.	Activity	Responsibility	Reference Document / Record
4.1	**Laboratory services: SAMPLE COLLECTION AND RECEIPT**		
A.	**Out Patient Services:** The Physician prescribes the various investigations on the Investigation request slip. The Lab technician (LT) receives the requisition forms and verifies the particulars. The LT then enters the request received in the Lab. Collection Register and allots a Lab / Hospital registration number. The Lab technician collects the sample after verifying the identity of the patient, puts a label and transports it to testing area of the lab. Patients are intimated about the time for collection of report. The Lab technician segregates the specimens according to various testing areas and starts testing the samples. The Lab Technician records the details of the samples received in the respective registers. **In patient services** The lab technician / nurse collects the samples of the patients admitted in the ward and sends it to the lab with request form and the patient details are labelled on the sample test tube / container. The lab technician records all the details of the samples received in the respective registers	Lab technician	Lab investigation requisition form Lab register Haematology register, Biochemistry register, Special test register

Sl. No.	Activity	Responsibility	Reference Document / Record
	Procedure for labelling and identification of samples: Samples are identified by the Name, ID number, Age, Sex and Ward. The wards are provided with empty containers and samples are collected by the nursing staffs, who write the ID number, patient's name, age, location and investigations to be performed. The OPD samples are collected by the technicians in the sample collection room. Patient sample taken as per laboratory protocols already known. Patient informed as to the time the reports can be collected. All samples are labeled immediately, including patient name and ID no., sample type and then kept in respective laboratory repository (trays). The samples for tests outsourced to other laboratories are sent in the original vials depending on the stability of the analyte to be determined and the specimen is maintained at appropriate temperature till received by the referral laboratory.		
	Procedure for handling and transportation of primary samples with specification about time frame, temperature and carrier: All samples are labeled with the patient's name, sample identification number, sample type and patient type i.e. OP or IP, in case IP the specific ward from where the patient's sample has been collected is also indicated in the label. Sample without label is returned to the specific area from where it has been collected. Glass tubes / Vacutainers are used for transfer of samples from the specific point of collection to the main laboratory area, in closed container and transport the samples as per the test requirement within half an hour as from collection point to the testing lab. Staff responsible for handling of patient samples puts on	Lab Technician	

<table>
<tr><th>Sl. No.</th><th>Activity</th><th>Responsibility</th><th>Reference Document / Record</th></tr>
<tr><td></td><td>gloves when handling samples.</td><td></td><td></td></tr>
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Procedure on acceptance and rejection of primary samples:
The purpose is to define the conditions under which the specimens are rejected before the investigation starts and repeat sample is asked for to save precious time and cost.

The samples which are received in testing laboratory are verified for Demographic details of testing patients, diagnosis of patients, lab test request form, quantity of sample, quality of sample, appropriate container, required temperature and mode of temperature are. If the aforesaid requirements are met the samples are accepted.
Otherwise the samples will be rejected requested for a new sample.

<table>
<tr><th>S. N.</th><th>Rejection Criteria</th></tr>
<tr><td>1</td><td>Unlabelled specimen</td></tr>
<tr><td>2</td><td>Specimen with illegible label</td></tr>
<tr><td>3</td><td>Mislabelled specimen</td></tr>
<tr><td>4</td><td>Insufficient quantity of specimen</td></tr>
<tr><td>5</td><td>Wrong container type</td></tr>
<tr><td>6</td><td>Mismatch between Patient's name listed on specimen and test requisition</td></tr>
<tr><td>7</td><td>The time lapsed between the sample collection to processing is more than the permitted time limit under the actual storage condition of the specimen.</td></tr>
<tr><td>S. N.</td><td>Specimen</td><td>Rejection Criteria</td></tr>
</table>
</td><td>Lab Technician</td><td></td></tr>
</table>

Sl. No.	Activity			Responsibility	Reference Document / Record
	8	Improperly or incompletely labelled specimen	If the primary sample is irreplaceable or critical, the sample is initially processed but the report is not released until the requesting physician or person responsible for primary sample collection takes responsibility for identifying and accepting the sample or for providing proper information.		
	9	Blood collected in plain vials for biochemistry tests on serum	Samples with turbidity indicating poor preservation, Haemolysed samples, blood which does not clot. Sample collected in EDTA, citrate or glucose vial,		
	10	Plasma for glucose	Blood collected in vial other than fluoride		
	11	Citrated blood collected for coagulation tests	Blood showing haemolysis or clot formation, blood showing increase or decrease in volume of more than 20%		

Sl. No.	Activity	Responsibility	Reference Document / Record
	12 | EDTA Blood | Blood showing haemolysis or clot formation, blood showing increase or decrease in volume of more than 20%		
	Procedure for processing of primary sample: Samples are processed as per guidelines in 'Laboratory operations manual' present for laboratory. Staff wears gloves and laboratory coats (aprons) at all times when handling and processing patient specimen, decontaminating instruments and cleaning. **Urine** – freshly voided specimen is preferred, When there is delay in testing / transporting, the sample is refrigerated to prevent bacterial contamination. To use uristix / multistix strips for samples. Any abnormality detected is to be confirmed by conventional methods i.e. – a. Proteins- heat acid test etc. For 24hrs urinary proteins special instructions are to be given to the patients on the method of collection. A container is given to the patient with required instructions. Urine is collected in any other container, other than that given by the lab. **Stool** - fresh specimen is preferable Routine analysis includes physical, chemical and microscopic examination i.e. colour, consistency, blood or mucous if present, pH, occult blood and microscopic examination for ova and cysts. In specific cases microscopic examination for ova and cysts is to be done by concentration techniques. **Semen analysis** Following instructions are given to patients for semen collection:-	Laboratory Technician	

Sl. No.	Activity	Responsibility	Reference Document / Record
	3 day period of abstinence is recommended • To receive the sample as per instructions given in point one • To do the physical examination for colour, pH, liquefaction time, viscosity, volume, sperm count for motility and morphology • To estimate fructose in case of infertility **Body fluids** - pleural, peritoneal, pericardial, cerebrospinal fluid. These are collected by consultant / medical officer on duty in PLAIN as well as EDTA TUBES, under strict aseptic precautions and sent to the lab immediately.		
	Repeat test: On request if treating doctor feel that the lab report is not correlating with the clinical diagnosis/ testing technician feels that the report may be analytical failure, the requested lab test is tested from the given sample. If HIV or other infectious diseases the positive samples are repeated based on the NACO guidelines.		
	Reporting of critical results: **Critical test result** 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. • When a critical result is identified, the Laboratory Technologist contacts the ordering physician or their assistant within 15 minutes of test readiness via a phone / intercom • For the patient who is no longer in the hospital or clinic, the Laboratory Technologist contacts the ordering physician or their assistant immediately after identification of critical result. • If the ordering physician or their assistant is not reached within 15 minutes of test readiness, the		

Sl. No.	Activity	Responsibility	Reference Document / Record
	Laboratory Technologist follows the order of notification. Order of Notification: • Ordering / Treating Physician / Staff nurse on duty / Casualty Medical Officer Whenever in-patient reports are communicated to the staff nurse the **'read back'** method is followed. The individual, accepting the critical test result, records and then reads back the critical test result, in its entirety, to the reporter at the time the result is given. In the case of an outpatient, the result is intimated to the patient directly through available telephone or mobile number. With any applicable communication system failure a hard copy of the critical result is delivered to the ordering physician or their assistant. The Laboratory Technologist documents the name and credentials of the person receiving the report with the time of delivery.		
C.	**Reporting** • Test results are corroborated • Reports are typed • Reports are checked and signed • Results are entered in lab register The Lab Technician records the reports and gets it approved by the Lab. Incharge / Pathologist and issues the reports to patient / treating physician. **Reports distribution and collection** • Reports segregated as per OPD, IPD and Outside samples • IPD reports dispatched to wards • Entry is made in 'Report received' register in ward and report results are entered against patient's name in Ward patient's investigations register.	Lab technician	
	Validation of reagents: All the stains, Reagents, media, Kits etc which are used for		

Sl. No.	Activity	Responsibility	Reference Document / Record
	testing the samples are validated on known valued samples or calibrators or Know controls before using on real samples and the reports of validated reagents are documented and filed. If any deviation from the original results is found corrective and preventive actions are taken.		
	Validation of examination procedure: Validation of the examination procedure technically and clinically is done by qualified, well trained pathologist. • Control material similar to patients sample matrix is used for examination of specimens • Quality Control (QC) are used to detect systematic and random errors. Each batch of patients sample is analyzed for various parameters with 2 levels of QC material daily. QC values are documented daily; control charts are maintained daily to check the stability of analytical measuring systems • Alternate methods are also used to verify accuracy of results of tests for which controls and calibration material not available. • Results generated at the laboratory are validated by the laboratory personnel		
	Procedure for validation of test results Validation is done based on following: a. On opening any new kit validation of test is done by internal quality control or those provided in the kit. b. Daily internal QC. c. Participation in external quality control programme. d. All procedures and processes of laboratory are approved and monitored by pathologists / microbiologist. Inputs on clinical utility of the test results are obtained from consultants and analyzed.		
	Procedure for internal quality control system to verify the quality of results: Internal quality control • An adequate test menu to meet the requirement of patients is prepared for conducting the quality measurement. • Appropriate instructions and training is given to the		Internal quality co register

Sl. No.	Activity	Responsibility	Reference Document / Record
	technical staff for patient's specimen collection and for assay system. • Phlebotomy is performed efficiently without discomfort to patient. • Analytical procedures are adopted with appropriate analytical performance. • All biochemical tests are conducted in strict accordance with standard protocols. • The lab In-charge assesses the tests result quarterly. • A designated person of laboratory is responsible for overall quality control tests. He / She will carry out quality control test himself or herself and should have sufficient authority to take necessary measures to correct any fault discovered during control testing. • Putting up control with every test sample is a part of daily procedure e.g. while doing grouping and Rh, reagent control tests are to be put up in each plate. • Sterility of blood or its component is also a part of the quality assurance. A practical approach to the problem dictates that the center using equipment, plastic bags, anti coagulants and bleeding sets and needles relies on their sterility from quality control measures instituted by manufacturers. In the laboratory strict aseptic precautions are taken while bleeding donors, and cleaning the pheblotomy area. While components are to be prepared in a strictly closed system. **Internal Quality Control by Replicate Tests on "CONTROL for cell counters** <u>To check precision on coagulation analysers</u> The purpose, responsibility, procedure, principle, method and action to be taken of the internal quality control by replicate tests on "controls" are essentially same as for automated cell counters. The minor differences in the procedure are mentioned below: 1.The controls for coagulation analysers are stable and the same lot is available for almost a year. Therefore the target value is determined on the analyses of the control run for the first 20 days.		

Sl. No.	Activity	Responsibility	Reference Document / Record
	2.The target value for the next lot is determined 20 days before the current batch is likely to get exhausted. 3. The assigned value is provided by the manufacturer. The experience has shown that the differences between the value assigned by the manufacturer and the actual target value for prothrombin time (PT) and activated partial thromboplastin time (APTT) do not differ from each other by more than 5 %. It is therefore, decided that if for any lot the differences between the manufacturer assigned value and the actual target value determined by the laboratory differ more than 5 % recalibration of the instrument will be done. **Replicate Testing on Patients' Samples on Haematology Counters:** A random sample is taken each day in the morning shift and another one in evening shift and is run on each of the analyzers. The values and differences in the replicate values of TLC, Hb, HCT, MCV and platelets are recorded as shown in the table. If the difference between the replicates is more than ± 2 SD, it suggests one of the values is out of control. Repeat the test on another sample. If the difference is corrected, i.e. it falls between 2 SD, no further action is required. If the difference is more than 2SD, it is discussed with the pathologist. Each day the results are signed by the technician in-charge. If an error persists, it is brought to the notice of the Pathologist.		
	Procedure for External Quality Assurance Programme: External Quality Control: means a system where by laboratory produces a set of reagents and techniques, the results of which are to be compared with those produced by an approved reference laboratory. Both internal quality control and external quality control exercise a reasonably good control over the function of routine laboratory equipments, techniques reagents and staff. The Lab has a MOU with RML Mehrotra Lab, Lucknow for EQAS of Haematology and Bio-chemistry tests if available. The Lab sends the report of control tests and the z score is received and analyzed for corrective and preventive action.	Pathologist / Lab Technician	

Sl. No.	Activity	Responsibility	Reference Document / Record
	System for Storage of examined samples: The purpose is to establish and maintain a procedure for preserving the specimens after the investigation is completed to cater for repeat test, if requested by the patient / attendant. The procedure applies to all samples that are received in the laboratory. A. **Storage period of specimens to be examined** The specimens can be kept at room temperature if the examination is done within 2 hours. If the expected time of testing is beyond this then it is preserved at 2-80C and comply with the requirement of specific tests as applicable. B. **Storage period of examined specimen** The examined specimens to be stored for re-examination and/or additional tests for a minimum period as specified bellow: Clinical Biochemistry: Min. one day at 2-8 degC Haematology: Complete Blood Counts: "Min one day at 2-8 deg C" Clinical Pathology: "Till results are validated" C. Retained sample test for the stored specimen The repeat test on the stored specimens is performed to verify the storage conditions, numbering system and deterioration of the specimen during storage. **The frequency for the repeat test** is as follows: Biochemistry: Samples for five analytes once in a month Haematology: The repeat test is done monthly for the stored sample Acceptability Criteria: The percentage difference between the two results is within 15 %.		
D.	**Procedure for examination by referral laboratories:** During receipt of samples, those to be outsourced are segregated and sent to a common collection area and entered into Referral Lab. register. Samples segregated based on the investigations. The samples for tests outsourced to other laboratories are sent in the original vials depending on the stability of the analyte to be determined and the specimen is maintained at appropriate temperature till received by the referral laboratory. If the samples are sent outside, lab	Lab technician	

Sl. No.	Activity	Responsibility	Reference Document / Record
	technician records the reports when available. All communications to the referral laboratories pertaining to patient details are done by Pathologist or Lab. technician		
E.	**Stock Maintaining & Monitoring:** A stock register shall be maintained for the items and wherever required re-order shall be maintained in the stock register itself. List of the items required shall be well informed to the administrative department through indent.		
	Procedure for Preventive and Breakdown maintenance: As per Policy for Equipment Maintenance. **Preventive maintenance** schedules are prepared based on manufacturers' recommendations / review of History Card maintained. Preventive maintenance is carried out as per Maintenance Schedule and Records. The concerned engineer checks the maintenance activities regularly. After completion of maintenance (whether preventive or breakdown) the OK report is taken from the user department. All preventive maintenance jobs done are recorded in History Card maintained for each equipment / device. **Breakdown Maintenance** Breakdown of an equipment or device is reported is informed to Lab. HOD/ In-charge. Requirement of maintenance / repair is logged into Maintenance Complaint Register. After completion of maintenance (whether preventive or breakdown) the OK report is taken from the user department. All preventive maintenance jobs done are recorded in History Card maintained for each equipment / device. Instruments / devices which are given in AMC (Annual Maintenance Contract) are given to AMC Company for maintenance. A report of failure / break down is taken from company for monitoring purposes.		Preventive maintenance Schedule / record Breakdown register/ Maintenance Complaint register
	Procedure for Calibration of Equipments: A list of all Medical Electronics instrument /equipment/ devices requiring calibration is prepared and maintained using format.		Breakdown Slip/ Register History Card List of

Sl. No.	Activity	Responsibility	Reference Document / Record
	List identifies the measurement instruments by name, type, serial number, location, applicable calibration requirements, date of calibration done and calibration due date. The calibration status is updated continuously. • Calibration records are maintained in the file. • Dates of current and next calibration due are displayed on the equipment. • Tri-level Controls are checked against the calibration and if controls do not fall within the assigned value the situation is brought to the attention of the representative of the firm and consultant, haematology. The action taken is documented. • Calibration record is signed by senior technical staff and consultants. Where required the Calibration agency is provided with needed facilities and support to carry out the calibration in the hospital campus. Such instruments that are to be calibrated at an outside location are collected and sent to the identified calibration agency. Whenever the calibration is done, the following is checked up a) Physical condition of instrument /test equipment b) Calibration report verification c) Calibration certificate to be obtained from calibration agency and after verification marked as O.K./ Not O.K. Sticking of calibration sticker. History of calibration is maintained using format and calibration certificates filed. The equipment is well maintained to preserve their accuracy and fitness for use. If equipment is out of calibration or is otherwise not fit for use, it is withdrawn. Accessories associated with Test instruments are identified and calibrated along with Test Instruments. In case an instrument is found with error – the materials already checked by this instrument are quarantined. This lot is re-checked with other instruments which are in order/the same instrument after its re-calibration. Persons using instruments are trained on aspects like Do's, Don'ts, handling, storage, safety, preventive maintenance and		instrument requiring calibration Calibration Sticker Calibration Reports

Sl. No.	Activity	Responsibility	Reference Document / Record
	minor repairs as and when required. Records of training imparted are maintained. Faulty instruments are re-calibrated when received after repair.		
	Procedure for Document Control: Documents related to quality control, calibration, machine maintenance, staff training and proficiency runs are well maintained by the department and reviewed periodically by quality improvement committee. **Procedure for validation of results of reagents, stains, media and kits etc.** Quality control provides the means to ensure and to regulate the quality of procedures, reagents, instruments and products and to determine whether they come within specified limits. Reference material, consumable, reagents and analytical systems are safeguarded from adjustments or tampering that might invalidate test results		
	Procedure for resolution of complaints and other feedback received from stakeholders: The purpose is to establish and maintain a procedure for handling of patients' complaint and their feedback. The procedure applies to all complaints received in the laboratory. The patient can complain about the lab functioning either through feedback form or directly. These can be related to: • Test results • Behaviour of staff • Delay in report • Result not tallying with other lab • Clinician – results not in line with the treatment and patient's response. • Cleanliness of lab • Any other issue All complaints are taken seriously and actions taken to satisfy the customer immediately. Subsequently the actions are taken to ensure that such complaints are not repeated. Regarding result variations, the Quality Control data of the day when test was conducted is checked and verified for		

Sl. No.	Activity	Responsibility	Reference Document / Record
	correctness. If it is OK then the patient is told about the accuracy of test. However, for his / her satisfaction the test is repeated, if required. In some cases the specimen is sent for cross reference to referral lab (NABL accredited) and the result compared. In case of behavioural complaints, the problem is discussed with the concerned staff. They are trained / told to be courteous and empathetic in future. For delay - the effort is made to deliver all reports in time, however, due to reasons beyond our control the delay may occur. In such cases, if patient asks and if possible, the reports are delivered to the patient or their clinician. Thus the patient need not come again for collection of report. Patient feedback is analyzed and the point for which the rating is low, action is initiated to improve it.		
4.2	**Infection Control:** Following infection control measures shall be followed in the hospital.		
A.	**Staff health plan:** To control spread of infection from staff to patient or to protect staff from occupational hazards annual medical check-up of staff should be done and required vaccination is provided to all members.	Hospital Infection Control Committee	
B.	**Hand Hygiene:** Adequate hand washing facility should be available in all patient care areas. Elbow operated taps and washbasin and soaps are available in service provider's room & in-patient care areas. If water facility is not available alcohol rub may be provided in patient care area. Scrub area should have elbow/foot operated water taps.	On duty doctor, staff nurse and all paramedic as well as house keeping staff involved in patient care.	
C.	**Aseptic techniques:** Aseptic techniques are followed strictly.	LAB OT I/C	
D.	**Segregation of contaminated materials and instruments:** Contaminated pieces of linen, sputum cups, bedpans, instruments & biomedical waste are kept separately to avoid mixing with the clean ones.	LAB Ward I/C	
E.	**Disinfection:** Disinfection of equipment and furniture's are carried out with bleaching powder solution. At least once a day or as required.	Housekeeping staff or General duty attendant	

Sl. No.	Activity	Responsibility	Reference Document / Record
F.	**Sterilization practices:** The efficient CSSD ensures the supply of properly sterilized articles to all users of the hospital. The unsterile items are stored separately.	Ward I/C or CSSD In-charge	
G.	**Good housekeeping:** Cleaning of OT walls, floors, tables and fixtures are organized as per a schedule programme at pre-determined intervals and use of appropriate disinfectant is strongly advocated. (*Procedure 20, Hospital housekeeping & General Upkeep Management)* Biomedical waste is collected, segregated, transported, stored and disposed off as per BMW management & handling rule, 1998. (*Procedure 24, Hospital Waste Management)*	Housekeeping staff	Housekeeping Check list Biomedical waste Management & handling rule, 2016.

The documentation and its accessibility is as follows:

S.N.	Name of the record	Form of the record	Maintaining Personnel / Controlling authority	Access mode	Who has the access
01	Patients report Records	Computerized/ Hard Copy	IT Head	Password	IT Personnel in computerized Lab
02	Procedure Manual	Hard copy and soft copy	Quality Manager and Supervisors	Free	All Technicians
03	Standard Operating procedure	Hard copy and soft copy	Quality Manager and Supervisors	Free	All Technicians
04	QC Data	Hard and Soft copy	Quality Manager and Supervisors	Restricted access	Quality Manager, Sr. Lab Technician and Pathologists

05	Quality audit report and review Reports	Hard and soft copy	Quality Manager	Restricted access	Quality Manager, Sr. Lab Technician and Pathologists
07	Histopathology and cytology reports	Hard copy/ Soft Copy	Technician	Free	All lab technologists and IT Executive who work in the lab
08	Patients test requisition	Hard copy/ Soft copy	IT Executive	Free	All Technicians and Pathologist
09	Outsourced tests' report copies	Hard copy	Technologist	Free	All Technicians and Pathologist
10	Patients tests value observation record	Hard copy/ Soft copy	All Technicians	Free	All Technicians
11	Calibration reports	Hard copy	All Technicians	Free	All Technicians
12	Instrument manuals	Hard copy	All Technicians	Free	All Technicians
13	MOUs with Labs for Out Sourcing Tests	Hard copy		Restricted	SIC/CMS

5. Records:

S.N.	Record
1	Collection Register (IP/OP)
2	Biochemistry Register
3	Haematology Register
4	Special Tests Register

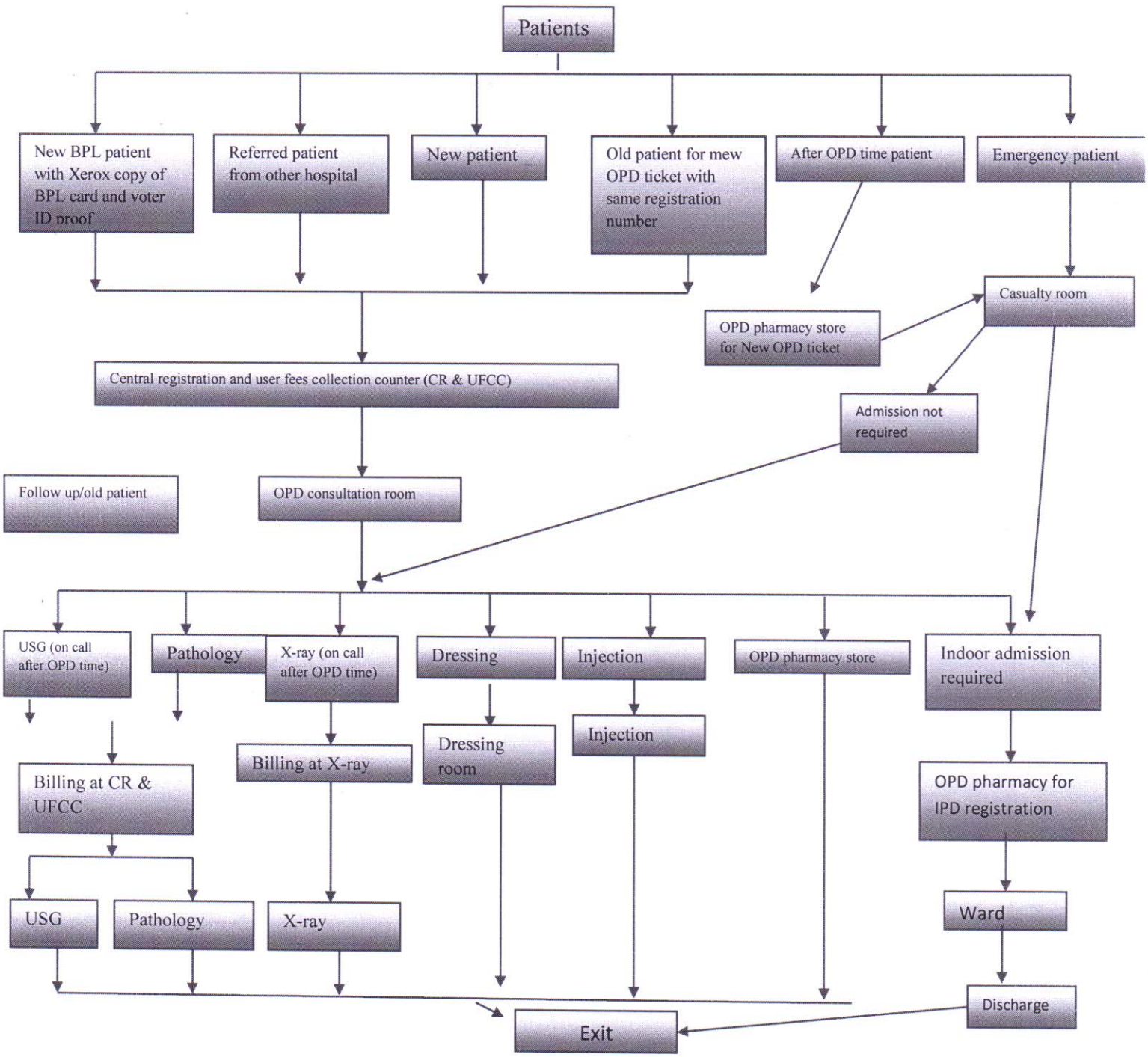
6. Process Efficiency Criteria

Sl. No.	Activity	Process Efficiency Criteria	Benchmark/Standard/Target
1	Routine Testing	Turn Around Time	
2	Utilization	Lab test done per indoor patient	
3	Emergency Testing	Turn Around Time	
4	Proficiency	Z score in external validation	

7. Reference Documents

The Bio-Medical Waste (Management and Handling) Rules, 1998
ISO 15189: 2007 - Medical Laboratories Particular Requirements for Quality & Competence
Guidelines for Good Clinical Laboratory Practice –ICMR
Manual on Quality Assurance for Laboratory Diagnosis of Malaria – NVBDCP
Guidelines for Standard Operating Procedures for Haematology – WHO

Process of Laboratory Services



Turn Around Time

Parameter	Expected TAT(in hrs./days)	
	Routine	Critical
Lipid Profile (Mini Lipid)		
Cholestrol	8	
HBL	8	
LDL	8	
VLD	8	
Triglyride	8	
KFT		
Bun	8	30Min
Creatinine	8	30Min
Sodium	8	20 Min
Potassium	8	20 Min
Uric Acid	8	
Urine Routine	8	
Serum Urea	8	30 Min
Thyroid		
T3	8	
T4	8	
TSH	8	
Hormone		
CRP	4	
Procalcotine	4	
Fluid	4	
BHCG	4	
CLINICAL PATHOLOGY		
Routine Examination	6	
Sugar	6	
HAEMATOLOGY		
CBC	6	15 Min
PTPC	4	
Blood Group	4	15 Min
MPV	6	