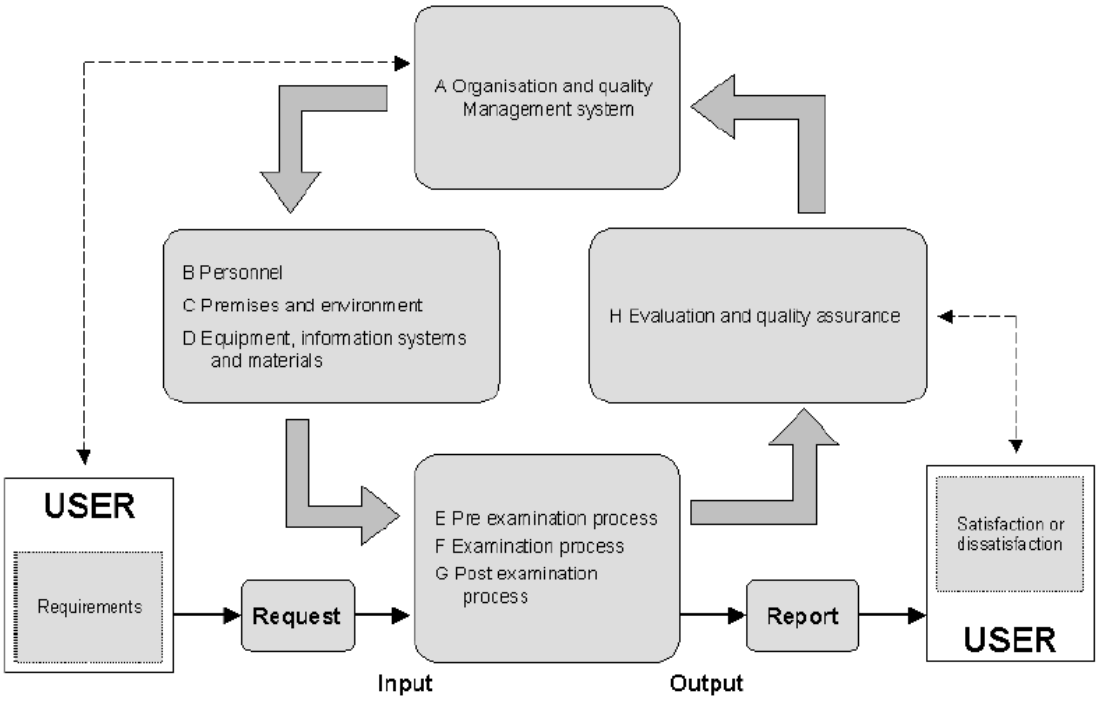
Laboratory Workflow:-

The Laboratory Testing Workflow Profile covers the workflow related to tests performed on in vitro specimens by a clinical laboratory inside a healthcare institution, for both existing and pending orders, related to identified patients and unidentified or misidentified patients. It maintains the consistency of patient and order information from registration through ordering, scheduling, pre-analytical processing, testing, technical and clinical validation, to results reporting and usage of laoratory observations and comments by the care providers.



NOTICE:-

user : person or organisation using the services of the laboratory e.g. users may include clinicians, health care bodies, health insurance companies, and pharmaceutical companies

Workflow stages

PRE EXAMINATION PROCESS

Information for users and patients

To facilitate proper use of the services, departmental policies, procedures and repertoire should be provided in a readable and manageable form. Users particularly require information about the availability of clinical advice, as well as the scope and limitations of the service.

There shall be up to date information for users. This shall be prepared in consultation with the users.

The information for users shall include:

a) contact details of key members of staff.

b) the location of the laboratory .

c) services offered by the laboratory .

d) times of opening of the laboratory.

e) details of any out of hours service or shift system.

f) instructions for completion of the request form .

g) instructions for transportation of samples, including any special handling needs.

h) availability of clinical advice and interpretation .

i) the names and addresses of laboratories to which work is routinely referred.

j) the laboratory‟s repertoire including specimens required, sample volumes, special precautions, turnaround time and reference ranges.

k) a list of those key factors which are known to affect the performance of the test or the interpretation of the results .

l) time limits for requesting additional examinations.

Notice :

There shall be up to date information for patients. This shall be prepared in consultation with patients or representative groups.

The information for patients shall include:

a) an explanation of any clinical procedure to be performed

b) instructions regarding preparation for the procedure.

Request form

Correctly designed and properly completed request forms are essential for the performance of all laboratory tests to the benefit of the patient and the satisfaction of the requesting physician.

The design of the request form shall allow the inclusion of the following items.

a) sufficient information to allow unequivocal identification of the patient

b) Identification and the location of the requesting individual

c) Date and time of specimen collection

d) Type of specimen and, where appropriate, anatomical site of origin

e) Investigations requested

f) Date and time of receipt of samples by the laboratory

g) Relevant clinical information

h) Identification of priority status

i) Location to which the results are to be sent

j) Laboratory accession number.

Notice

1- The laboratory shall encourage the proper completion of request forms
2- The request form may be in paper or electronic format.

Specimen collection and handling

Proper preparation of the patient, specimen collection and handling are essential for the production of valid results by a laboratory.

Laboratory management shall establish a procedure(s) for the specimen collection and handling that includes:

a) Checking the completion of the request form and confirming the identity of the patient

b) Checking that the specimen container is labelled correctly

c) Checking that the patient is appropriately prepared

d) Ensuring that the specimen is collected correctly

e) Minimizing the risk of interchange of samples and sub samples

f) Ensuring that environmental and storage conditions are fulfilled

g) Ensuring the safe disposal of all materials used in specimen collection

h) Ensuring that high risk specimens are identified and processed correctly

i) Ensuring that all spillages and breakages are dealt with correctly

j) Minimizing the risk to ensure the safety of the specimen collector, carrier, the general public and the receiving laboratory.

NOTICE:

1- These procedures shall be available to users of the service and those who are responsible for specimen collection and handling.
2- The laboratory shall periodically review its sample volume requirements for phlebotomy (and other samples such as cerebrospinal fluid) to ensure that neither insufficient nor excessive amounts of sample are collected.

Specimen transportation

Specimen transportation systems need to ensure the timely arrival of specimens at the correct destination at minimum risk to both laboratory and non-laboratory personnel.

Laboratory management shall establish a procedure(s) for the transportation of specimens, that includes :-

a) Ensuring the safety of the courier, the general public and receiving laboratory

b) Packaging, labelling and despatch .

c) Ensuring that the specimens arrive within a time frame appropriate to the nature of the requested examinations and protects the specimens from deterioration

d) Reporting incidents during transportation that may affect the quality of the specimen or the safety of personnel.

Specimen reception

For examinations to be correctly performed, specimens have to be received into the laboratory efficiently and safely.

Laboratory management shall establish a procedure(s) for specimen reception that includes:

a) Linking of the request and specimen.

b) Recording of request form and specimen information.

c) Recording the date and time of receipt of specimens.

d) Handling urgent specimens.

e) Ensuring staff safety.

There shall be a procedure(s) for specimen rejection that includes:

a) The criteria for rejection of specimens

b) The recording of rejected specimens

c) Notification of the user concerning rejected specimens.

EXAMINATION PROCESS

Selection and validation of examination procedures

The selection of examination procedures needs to be clear, appropriate and subject to regular evaluation with the users.

1- Examination procedures, including those for sampling, shall meet the needs and requirements of users and shall be validated by the manufacturer/method developer for their intended use
2- Manufacturer/method developer‟s performance claims shall be verified prior to introduction and records kept of the methods used and results obtained.
3- When examination procedures are changed so that results or their interpretation may be significantly different, the implications shall be explained to users, prior to the introduction of the change.

Examination procedures

Adherence to examination procedures is essential to ensure a quality diagnostic laboratory service.

There shall be procedures for the conduct of all examinations that include and/or refer to, as applicable, the following:-

a) Clinical relevance / purpose of examination

b) Principle of examination

c) Specimen requirements and means of identification

d) Equipment and special supplies

e) Reagents, standard or calibrants and internal control materials

f) Calibration

g) Instructions for the performance of the examination

h) Limitations of the examination, including interferences, cross reactions and reportable intervals

i) Recording and calculation of results

j) Internal quality control procedures and criteria against which examination processes (measurement and observation) are judged

k) Reporting reference limits

l) alert/critical values, where appropriate

m) Responsibilities of personnel in authorising, reporting, and monitoring reports

n) Hazards and safety precautions

o) Performance criteria.

THE POST EXAMINATION PHASE

Reporting results

The purpose of the laboratory is to produce the results of examinations in reports that are correct, timely, unambiguous and clinically useful.

The report

The main method of communicating the results of examinations to the users of the laboratory is by the production of a report.

The report shall be clear, unambiguous, and contain sufficient information to enable the user to interpret the results. The report shall be designed to comply with the needs of the users and with the requirements of the local medical records system.

The report shall allow the inclusion of the following items:

a) The laboratory name

b) The unequivocal identification of the patient

c) Requester and/or address for delivery

d) Type of specimen, date and time of collection

e) Time and date of report

f) Results, including reasons if no examination is performed.

g) Reference intervals as appropriate

h) Interpretive comments as appropriate

i) Highlighting of abnormal results and/or inclusion of critical limits

j) Status of report as appropriate, eg, copy, interim or supplementary