# 28. Laboratory Collection manual

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**ANNUAL REVIEW:**

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**SUPERSEDES: Procedure titled** _____

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**Principal:**

This policy present step by step of sample processing from collection until reporting

The samples will be collected by the local Phlebotomist from different locations, and this will be clearly identify in clinisys as well as the request form receive and the laboratory reports issued.

Chemistry Samples will be centrifuged at 3000 relative centrifugal force (RCF) within 60 minutes from collection, Urine will be collected with sterile provided cups and all the samples will be kept refrigerated to be delivered Via FedEx, UPS, the shipment code will be shared MMCCLs to trace the shipment which will be delivered to MMCCLs next morning.

**GENERAL GUIDELINES:**

Guidelines for Test Request

**A: Test request through cliniSys**

- Only physicians are entitled to order tests for laboratory analysis.
- Specimens without an online or/and paper printed request form shall not be analyzed
- Test requisition data elements are entered accurately into the laboratory information or record system, it should include:

-Adequate patient identification information (name, registration number, location, medical record Number.

-Patient sex /-Patient date of birth or age.

-Name and address (if different than the receiving laboratory) of physician or legally authorized person ordering the test

-Tests requested -Last menstrual period (for gynecologic specimens)

-Time and date of specimen collection when appropriate

-Source of specimen, when appropriate -Specimens requiring special procedure shall only be collected by a qualified staff.

- Specimens shall be sent to the laboratory for analysis as soon as possible in transport boxes with proper temperature control.
- All specimens shall have at least two identifiers.

- Specimens without or legible patient details, name, Medical Record Number shall be rejected

- Specimens shall be analyzed as per physician request and shall be traceable in the laboratory through all stages of analysis.

- Specimens shall be retained in the laboratory as per section retention policy and disposed of as biological waste.

**If a new test needs to be added to a previous test request (ADD-ON)**

The physician should first call the lab to check if adequate and stable sample is available for additional testing. On receiving confirmation of sample adequacy and stability for additional tests, the physician should then add the test under another new order and inform the section, provide the needed information including patient name, MRN, ordering staff and test details.

**B. Test request during CliniSys Downtime (Downtime procedure)**

The physician should manually fill the Clinical Laboratory request including:

- Clinic details
- Specimen type: Blood, Urine, stool …
- STAT, routine; Fasting.
- Date & time of collection.
- Patient details: MRN #, Name, Gender, Date of birth or Age, clinic, Physician name.
- Tests requested (tick the required tests and/or clearly write any other test(s) not indicated on the form)
- Requesting physician signature.
- The clinic name and telephone extension must be written clearly and correctly on the request form.
- Date and time of sample collection must also be added to the form.
- The sample container must be tightly closed, and the request form must not be contaminated by blood, urine etc.
- Contaminated form is a health hazard and needs special handling by laboratory staff
- The form and sample must be submitted together in a Biohazard bag in separate pocket.
- Stapling must not be used under any circumstances (use of sharps).

**C: Test request for send out:**

1. The request form should be filled legibly with all patient demographics, tests requested and signed by the requesting doctor (clinic)
2. The specimen must be labeled correctly with patient name, MRN, age, gender, specimen type, collection date and time,
3. The specimen must be properly packed to avoid breakage/leakage and transported at the correct temperature (ambient, ice packs etc.)

4. The specimen(s) and request received by the laboratory specimen reception staff will be checked to confirm if test requesting, specimen labeling, and transportation criteria are met or not.
5. The sample will be sent to the laboratory contracted reference laboratory.

**Guidelines for Specimen Collection:**

Color codes of blood collection tubes preservative and volume, please see the template, print, and display.

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## BD Vacutainer®
BD Life Sciences - Preanalytical Systems

| Cap Colour | Cat. No. | Tube Type | Determinations | Special Instructions |
|---|---|---|---|---|
| | | Blood Cultures | Aerobic followed by anaerobic- if insufficient blood for both culture bottles use aerobic bottle only | Optimal volumes: Adult: 8 - 10ml Paediatric: 1 - 3ml |
| | Cat. No. 363095 / KFK119 Draw Volume 2.7ml | Sodium Citrate | D-Dimer, APTT, INR, coagulation studies | Fill to frosted minimum fill line Paediatric: KFK117 1.8ml Mix 3-4 Times |
| | Cat. No. 367837 / KFK168 Draw Volume 6ml | Serum | As requested by laboratories, cold agglutinins, Donath- Landsteiner | For cold agglutinins, Donath-Landsteiner sample must be transported at 37°C. Contact blood transfusion 20339 in advance Mix 5-6 Times |
| | Cat. No. 367954 / KFK114 Draw Volume 5ml | SST™ II *Advance* | Biochemistry/Haematology: Troponin, FSH, LH, Testosterone, Oestradiol, Progesterone, Prolactin, Cortisol, Growth Hormone, IGF1, Tumour Markers, Iron Studies, Ferritin, B12, Folate, EPO, Haptoglobin, Glandular Fever, Lithium Immunology: immunoglobulins, protein electrophoresis, autoantibodies, complement, allergy, cryoglabulins, serum free light chains, functional complement (CH50, AP50 and C1 esterase inhibitor) Microbiology: bacterial serology, viral serology, Helicobacter pylori | Cryoglobulin samples must be transported at 37°C. Contact Immunology on 25995 for advice. Functional complement samples must arrive in the Immunology lab with 4h. Mix 6 Times |
| | Cat. No. 365055 Draw Volume 3ml | Barricor™ | Biochemistry: Sodium, Potassium, Urea, Creatinine, Chloride, Bicarbonate, CRP, Bilirubin, ALT, ALP, GGT, Total Protein, Albumin, Calcium, Phosphate, Magnesium, LDH, CK, Urate, Amylase, Cholesterol, Triglyceride, Paracetamol, Salicylate, Anticonvulsants, Digoxin, Ethanol, TSH, fT4, fT3 | Mix 8-10 Times |
| | Cat. No. 367373 / KFK130 Draw Volume 3ml | PST™ II | Biochemistry: Sodium, Potassium, Urea, Creatinine, Chloride, Bicarbonate, CRP, Bilirubin, ALT, ALP, GGT, Total Protein, Albumin, Calcium, Phosphate, Magnesium, LDH, CK, Urate, Amylase, Cholesterol, Triglyceride, Paracetamol, Salicylate, Anticonvulsants, Digoxin, Ethanol, TSH, fT4, fT3, Immunology: TB Quantiferon, TB ELISpot, Lymphocyte proliferation | Lymphocyte proliferation must first be discussed with Immunology on 25995 Mix 8-10 Times Mix 8-10 Times |
| | Cat. No. 367839 / KFK171 Draw Volume 4ml | EDTA | Biochemistry / Haematology: Full Blood Count, ESR, RBC Folate, HbA1c, Sickle Cell (Hb Electrophoresis), Cyclosporin, Tacrolimus, PTH Transfusion: Group and Save, Crossmatch Immunology: Lymphocyte Markers, CD4 Microbiology: Viral & Bacterial PCR viral load | Paediatric: KFK276 2ml Mix 8-10 Times |
| | Cat. No. 368920 / KFK250 Draw Volume 2ml | Fluoride Oxalate | Glucose, Lactate | Paediatric: KFK250 2ml |

Determinations and Special Instructions contained within this guide have been provided by the named institute and are not BD recommendations or instructions for the BD products described. Please consult your organisation's guidelines or contact BD should you have any questions.

*Clinical and Laboratory Standards Institute (CLSI) Guidelines GP41-Ed7 (formerly H3-A6, 6th Edition)

0118 921 6000

### IMPORTANT MIXING GUIDELINES

All BD Vacutainer® tubes require immediate mixing following collection. Insufficient mixing can result in inaccurate test results and the need to re-draw. Correct mixing technique is to gently invert (180° and back) each tube the recommended number of times shown on the right hand side of the table.

**Order of draw in descending order and Significance:**

Blood must be drawn in specific order to avoid contamination of blood culture bottle and to avoid cross-contamination of additive between tubes.

It is vital that the following order steps of draw are followed for every blood draw:

- Culture bottles should be drawn first to avoid contamination from other non-sterile tubes.
- Aerobe bottle should be drawn before anaerobe bottle
- Blood coagulation tubes with tri-sodium citrate.
- Serum tube: (non-additive red top).
- Serum tube: (SST): with gel separator and/or clot activator
- Sodium heparin (dark green)
- Lithium heparin: contains lithium heparin anticoagulant (dark green stopper)
- EDTA tubes (lavender top): for CBC and cross match.
- Oxalate/fluoride (light gray top): for glucose
- ACDA or ACDB, contains acid citrate dextrose for HLA Typing
- All tubes with additives must be thoroughly mixed as per the previously attached chart.
- Erroneous test results may be obtained when the blood is not thoroughly mixed with the additive.

NB: If heparin is introduced to a coagulation tube that would give wrong results.

**GUIDELINES FOR COLLECTION OF DIFFERENT SPECIMENS**

***VACUTAINER TUBES AND BLOOD PRESERVATION*:**

- Blood samples for routine analysis are collected by venipuncture; and capillary blood (e.g. infants) are sometimes needed
- The initial, ID# of individual collecting the specimen clearly identified and traceable
- Vacutainer tubes of different types and sizes are widely used and available.
- There are different types of vacutainer tubes, see relevant test entry for required volume and type of tube.
- Please contact the MMCCLs laboratory for more information if needed.
- The vacutainer tube must be filled with free-flowing blood to the required mark/level “till blood stops coming inside the tube”.
- Overfilling or under filling will affect the blood anticoagulant ratio and under filling in red top tubes and Yellow top (SST) tubes will yield insufficient blood quantity for analysis.
- Any tube containing anticoagulant and clot activator should be mixed immediately after collection by gently inverting the Tubes.

- Interruption of blood flow during collection, usage of small caliber needles in syringes and drawing of blood from infusion tubes should be avoided as it may lead to hemolysis.
- Hemolyzed blood, blood clots in anti-coagulated samples, use of wrong tube, overfilling or under filling may render the sample unsuitable for laboratory analysis.
- Freezing of blood destroys the cellular components and therefore it is contraindicated unless specifically requested.
- Blood samples should be sent to the laboratory as soon as possible without delay.

The minimum plasma/serum/blood volume required is:

| | |
|---|---|
| A. Biochemistry, cell count and differential count | = 0.5 mL |
| B. Routine bacterial culture, mycology or virology | = 0.5 mL for each |
| C. Bacterial antigen latex panel | = 1.0 mL |
| E. PCR based tests | = 1.0 mL |
| G. Serology | = 0.5 mL |

Larger volumes may be required to allow repetition of unexpected results

## Guidelines for Urine collection

- Clean voided urine free of feces, discharges & blood contamination is required. The patient must be instructed to void directly into a dry clean disposable specimen container. Children, infants and disables should be helped to obtain a correct urine sample.
- It is extremely important to instruct patient to tightly close the lid of the specimen container to avoid leakage. Partially or completely leaking specimens are unsuitable for analysis, inconvenient and hazardous to the laboratory staff.
- The specimen container must be properly labelled at the side and **not** on the Lid. The label should include the patient's name, the patient file number, date and time of collection and state/clinic.
- If urine sample cannot be delivered to the laboratory within 1 hour, it must be refrigerated. Delay in testing causes the following detrimental changes:

- Increased: pH, nitrite, bacterial count, turbidity.

- Decreased: glucose, lactose, bilirubin, urobilinogen.

- Disintegration of RBC and Casts, changes in urine color.

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## RANDOM URINE SAMPLE COLLECTION

| Type of collection | Collection time | Specimen volume | Preservative | Test | Handling |
|---|---|---|---|---|---|
| First morning | First morning collection | 2-20 ml | No | Nitrate, protein, pregnancy test, routine screening, microscopy | Refrigerate after 1 hr of collection if not tested |
| Random (most common) | Any time | 2-20 ml | No | Chemical analysis, routine screening, microscopy | Refrigerate after 1 hr of collection if not tested |
| Mid-Stream | Any time (midstream urine) | 2-20 ml | No | Bacterial culture, Chemical screening | Refrigerate after 1 hr of collection if not tested |
| Post prandial | 2 hours after meal | 2-20 ml | No | Diabetic monitoring (at point of care) | Refrigerate after 1 hr of collection if not tested |

## TIMED OR 24 HOURS URINE COLLECTION

- The patient is requested to empty their bladder, and this specimen is discarded. The exact time is recorded and considered as the starting time of the collection.
- The time at end of 24 urine collection should be 24 hrs., or as close as possible to 24 hrs., after the first sample was collected. Both start and end time should be recorded on urine container. The last urine collection should always be added to the urine container. Use of right preservative and storage conditions and strict adherence to the above procedure is essential for correct results.
- The 24 hours urine sample should be collected into a tightly stoppered clean glass or plastic container. The container should bear the patient's name, MRN and clinic. For timed urine collection both start and end time should be recorded on urine container.

| | TIMED URINE COLLECTION | | OTHER SPECIMEN / ASPIRATE | |
|---|---|---|---|---|
| | 2 HRS | 24 HRS | CATHETER | SUPRA PUBIC |
| Collection time | 2 hrs collection | 24 hrs collection | Clamp catheter 15-30 minutes before collection | _ |
| Sample volume | All 2 hrs urine to be saved | All 24 hrs urine to be saved | Variable (2-20ml) | Variable (2-20ml) |
| Preservative | _ | May require preservative (See specific test or contact Laboratory) | _ | _ |
| Test(s) | Urobilinogen | Quantitative chemical test | Bacterial culture Foley catheter is not suitable for culture | Bacterial culture |
| Handling | Test or refrigerate keep in dark bottle | Refrigerate after 1 hr of collection if not tested | Refrigerate after 1 hr of collection if not tested | Refrigerate after 1 hr of collection if not tested |

Full lists of tests are available.

## GUIDELINES FOR TRANSPORT OF SPECIMENS

- Blood and urine specimen for biochemical, hematological, serological, genital and microbiological tests should be transported from phlebotomy collection aria to the nearest site were the sample will be centrifuge if needed and prepared for transportations
- The form and sample must be submitted together in a Biohazard bag.
- Stapling must not be used under any circumstances (use of sharps).
- Transporter company should know how to handle the specimen
- **CBC specimen should not be in direct contact with ice pack in the specimen container**
- Specimens such as serum, plasma, urines from laboratories or from clinics outside Meharry location shall be transported under controlled temperature (2-8 $^{0}$C optimum) and blood for CBC at ambient temperature or chilled (avoid placing whole blood directly on the ice packs when shipping) in bags with large label of MMCCLs address and tracking number to follow shipments should be submitted to laboratory personal to keep tracking and avoid delay of delivery
- The laboratory shall be contacted when a specimen requires special transportation.
- Blood culture specimens, swabs and gynecological should be transported at ambient temperature
- All samples collected should be transported considering that it will be delivered to MMCCLs next morning to keep sample integrity and suitability for testing.

## Guidelines for specimen reception and processing

- The sample reception and processing unit is one of the most important elements of the primary process. If this unit is not properly organized, the integrity of the complete analytical process is at risk.
- Without precisely following the correct procedures in the sample reception and processing stage, the traceability of the sample is not guaranteed, the quality of results is not assured, and the health of the patient is at risk.

## Guidelines for specimen rejection

The laboratory reserves the right to refuse improperly labeled specimens. The laboratory takes specific measures to maintain specimen integrity during the process. Following up on the receipt of an improperly identified specimen. The laboratory recognizes that, in certain cases where the specimen is **less common**, involves an **invasive procedure** or could not otherwise be easily recollected, it may be acceptable to apply an exception to specimen rejection. Exceptions are applied using strict and explicit criteria in accordance with established procedures. Generally, improperly identified specimens are not discarded until the collection site or the responsible nursing/clinic unit is notified by laboratory Processing staff. The high number of specimens received

by the laboratory makes it impossible to positively identify specimens that are not clearly labeled in accordance with specimen identification (labeling) criteria. Checking sample integrity and deciding if the sample is accepted or rejected, a log sheet is filled by accession staff:

- The information in the log sheet should include patient name, clinic, DOB, Gender, Ref Physician
- Reasons for non-acceptance of specimen in the laboratory is either due to specimen or to demographics details
- The Processing/accessioning staff will inform the physician in charge of the patient details and cause of rejection to recollect new appropriate sample

**The rejection Criteria are as follow:**

*Specimen related issues:*

- Wrong specimen:

Specimens submitted in the improper tube or container cannot be accepted. The submitting physician/clinic will be asked to recollect the specimen in the proper container.

- Inadequate specimen:

Specimen received in the laboratory is not enough or not good enough to do the tests requested by the physician, then the laboratory will call the ordering physician/clinic t to collect enough sample.

- Poor quality specimen:

If a sample is of poor quality e.g. hemolysis or clotted, the required tests will not be performed. A repeat sample will be required to complete the request.

- Aged specimen:

Specimen must be delivered to the laboratory in a timely manner. Example: All PCR samples must reach the lab within 24 hours from collection time otherwise it will affect the result.

- Missing specimen:

When the laboratory receives urine samples with blood requisition or vice versa, the Laboratory Processing staff will notify the physician or the clinic.

- Leaked specimen:

Leaking containers cannot be accepted. The submitting physician or clinic will be asked to submit a fresh specimen in the proper container, with a new request form if soiled.

To summarize:

- Wrong transportation mode: ambient, refrigerate, frozen.
- Demographic issues: no patient details

- Specimens not accompanied by a requisition cannot be accepted. A properly completed request must be submitted.
- No test name or test code
- Unlabeled specimens cannot be accepted, the submitting physician or clinic will be expected to submit a fresh properly.
- Sample mismatch: Specimens which are labelled with the wrong patient's name compared to that of the accompanying requisition or with a different patient's ID number, the same criteria as for unlabeled Specimens apply.
- No physician name or Payment not cleared.
- Soiled requisition forms are required with physician's details (Name, License number Etc.) before submitting the sample to the laboratory, financial (insurance) part must be completed by the patient or the person who is responsible.

**Specimen Labeling Criteria**

To protect patients from adverse errors made due to improperly labeled specimens, the laboratory policy demands that proper labeling criteria are always met. Every specimen brought to the laboratory must have a single label on the container in which it is held. It is not acceptable to label only the lid, transport bag, or other container used to transport the specimen. The label must contain the following legible information:

- Patient name, Patient medical record number
- Patient location, Collection date and time
- Specimen type and/or source, Test required.
- Primary specimen containers are labeled by at least 2 identifiers:
- The phlebotomist or care giver initial and ID number

**Guidelines for specimen priority of testing**

1. STAT Tests: These are test results that have an immediate impact on patient management and are limited to a specific list of tests that is governed by multidisciplinary STAT. Analysis must be done at once with immediate communication of the result by telephone / fax as soon as feasible. Usual turnaround time (TAT) is 60 minutes, but some tests may require longer time if validation is required, see lists of tests and TAT in respective section.

2. URGENT Tests: Urgent priority is used when physician cannot wait for results till the end of working day. The result will be communicated as soon as it is ready, by telephone / fax.

3. ROUTINE TESTS: Routine Laboratory reports will only be released after verification, validation and approval by technologist/Supervisor/Lab director. The Turn Around Time (TAT) for completing the analysis is according to the type of test, load of work, nature of specimens, availability of reagents and scheduling / batching etc. The laboratory tries to release results of un-batched tests on the same working day or within 24 hours. This is not applicable to weekends or public holidays.
4. Send out tests

## Guidelines for reporting results

All results are reported electronically in cliniSys except during downtime when hard copy results are reported via secure HIPPA compliance fax number or encrypted email.

The report includes the following elements.

**1**. Name and address of testing laboratory
2. Patient name and identification number, or unique patient identifier
3. Name of physician of record, or legally authorized person ordering test, as appropriate as well as location
4. Date and time of specimen collection, when appropriate
5. Date of release of report
6. Time of release of report,
7. Specimen source, when applicable
8. Test result(s) and units of measurement
9. Reference intervals, as applicable
10. Conditions of specimen that may limit adequacy of testing

## GUIDELINES FOR INQUIRY ABOUT LABORATORY RESULTS

Laboratory results are confidential and should only be conveyed by secure means (CliniSys, phone, fax or by hand) to the physician in charge of the patient or his delegates.

**INQUIRY PROCEDURE**:

- Inquiry of a STAT or routine result by contacting the laboratory is permitted only if the delay experienced is more than the laboratory specified TAT for that test. Please provide full details of the submitted samples.
- Only qualified clinic/ (Dr Delegate) should contact the laboratory sections for reports of STAT tests.
- If delay in result transmission is expected for reason(s) out of laboratory control (equipment out of order, lack of reagents etc.) the concerned section in the laboratory will contact the relevant Physician/clinic and inform them of the expected delays.
- To make an inquiry, the ward/clinic should call the laboratory at office at extension (615)-3276013 between 8:00 am – 17:00 Monday to Friday.
- The lab is closed During Weekends, public holidays
- The inquiring Clinic/Physician should give his/her name, ID # the location, patient name and MRN number, when the sample(s) was submitted, if it was STAT or routine and most importantly to specify the test or group of tests he/she is looking for.

- The laboratory staff will check and will report back as soon as possible. If the result is still pending or awaiting verification, the laboratory staff will advise when it is expected to be released.

**Guidelines for critical results reporting**

The laboratory identifies critical results to be reported as being life threatening in consultation with publish data and other reputable laboratories:

Table of Critical as per MMCCCL:

| Test Name | ≤ | ≥ |
|---|---|---|
| Calcium (mg/dL) | 6 | 13 |
| T CO2 (mmol/L) | 10 | 40 |
| Bilirubin, Total (mg/dL) | | 15 |
| Glucose (mg/dL) | 55 | 450 |
| Iron (µg/dL) | | 500 |
| Potassium (mmol/L) | 3.1 | 6.1 |
| Sodium (mmol/L) | 120 | 160 |
| Magnesium (mg/dL) | 1.0 | 9.0 |
| Phosphorous (mg/dL) | 1.0 | 9.0 |
| Hematocrit (%) | 21 | 65 |
| Hemoglobin (g/dL) | 7.0 | 21 |
| Leukocytes (x $10^3$/ µL) | 2.0 | 40 |
| Absolute Neutrophil Count (x $10^3$/ µL) | 0.5 | |
| Platelets (x $10^3$/ µL) | 20.0 | 1000 |

A brief description is outlined below:

The laboratory staff shall access the name of the Ordering Physician/clinic for all patients. When critical result identified it must be reported **within one hour of test results availability and ready for verification**. If the staffs are unable on making successful contact, in this case, this should be oscillated to the laboratory director to make sure the results will be delivered.

Procedure on calling critical results, the staff shall:
1. identify herself/himself and establish the reason for the call
2. ask that the result be written down
3. share the name and MRN of the patient
4. call out the result along with units
5. request the recipient to ***'Read Back'*** the result communicated
6. confirm that the result has been ***'Read Back'*** accurately, and

On completing the above, the staff shall record details of the identity of the recipient in cliniSys or manual logs. If the recipient refuses to accept the results or read back the same, this shall be documented in the Critical Result Call Template/logs, as also communicated to the laboratory Director, Laboratory Manager for extra steps to be taken.

**Laboratory Quality**

The Laboratory director will make sure the laboratory is following state rules and regulations in terms Quality and Safety.
This lab will be assessed by Tennessee department of health within the first 3 months of Testing, is applying for accreditation by COLA and later stage will apply for CAP accreditation.
The laboratory continuously improves the effectiveness of its Quality Management System and its processes by monitoring the Quality Indicators on a monthly basis.
The following KPIs are monitored and reviewed by Laboratory director:

- STAT turnaround time for Hemoglobin
- STAT turnaround time for potassium
- Percentage of corrected laboratory reports
- Proficiency Testing: Percentage of achieved 80% acceptable performances for CAP PT

## Specific Specimen Retention

Proficiency test/material: until final participant result received as per CAP Requirements, however it can be kept frozen at -80C for possible future use to troubleshoot quality controls or part of possible method validation.

| Source of Specimens | Storage Durations | Storage Temperature |
|---|---|---|
| Whole Blood | 48 hours | 2 – 8 °C |
| Coagulation Plasma | 72 hours | 2 – 8 °C |

| | | |
|---|---|---|
| Peripheral Blood/Body fluid smear | 7 days (CAP) | Room temperature |
| Storage of material following analysis of nucleic acids | 1 month | at – 80 °C |
| Aliquots of send out tests | Until final report | at – 80 °C |
| All serum/plasma specimens for serology/Chemistry | 2 weeks-1 moth | at – 20 °C |
| Urine | 48 hours | at 2– 80 °C |
| | | |

## **General Laboratory** Record Retention

| **Record** | **Record Retention** | **Comments** |
|---|---|---|
| **Equipment and instrument:** monthly performance testing, function checks, major repairs, parts replacements and annual maintenance | Life of equipment | CAP Requirements |
| Analyzer correlation results | 2 years | CAP Requirements |
| Software application validation record | Life of instrument | |
| Method/process validation records | Life of instrument +2years | CAP Requirements |
| Instrument printouts | 2 years | CAP Requirements |
| Accession records | 2 years | CAP Requirements |
| Proficiency testing records | 2 years | CAP Requirements |
| Quality control records | 2 years | CAP Requirements |
| Register of referral Specimens | 3 months | |
| Referral lab arrangements and contract | Duration of contract | |
| Specimen rejection log | 3 months | |

| | | |
|---|---|---|
| Incident reports (customer complaints) | 2 years | |
| Management review records | 2 years | |
| Annual review of policies, processes & procedures | 2 Years | CAP Requirements |
| Records of external inspection, self & peer assessment | 2 years | CAP Requirements |
| Accreditation, certification documents, records of inspections | 10 Years | |
| Staff Records Training, qualification, competency | 3 Years past last day of employment | |
| Signature/ID traceability | 2 Years | CAP Requirements |
| Discontinued procedures and method manuals | 2 years | CAP Requirements |
| Records of Method performance specification | retained while method in use, if discontinue 2 Years | CAP Requirements |
| Records containing personal health inform. | 2 years | CAP Requirements |
| Records of changes to software, test library and major functions in program | 2 Years beyond the service life of the system | CAP Requirements |
| Work sheets, printouts used for manual computer entry of patient result data | 2 years | CAP Requirements |
| Data directly transmitted from instrument to lab computer via interface. | on-line system computer retains the data for 2 Years. | CAP Requirements |
| Instrument calibration records (Thermometers, balance, pipettes | 2 Years | |
| Patient Test Records | Indefinitely through LIMS | |
| | | |
| | | |