LABORATORY DEPARTMENT

LABORATORY SAMPLE COLLECTION MANUAL

ACCL/MNL/005

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1. **PREAMBLE**;
   1.1. Laboratory sample collection manual acts as a guide to laboratory clients. It is aimed at providing handy information on tests performed at ACC Laboratory unit, as well as information on sample type, turnaround time, specimen handling, results access and communication.
2. **TERMS AND DEFINITIONS;**
   2.1. ACC - Aroha Cancer Centre
   2.2. QC- Quality Control
   2.3. QA- Quality Assurance
   2.4. SOP- Standard Operating Procedure
   2.5. TAT-Turnaround Time
   2.6. FBC- Full Blood Count
   2.7. WBC- White Blood Count
   2.8. HB –Haemoglobin
   2.9. LFT's - Liver Function Tests
   2.10. RFT's – Renal Function Tests
   2.11. U/E/C - Urea, Electrolyte and Creatinine
   2.12. IQC – Internal Quality Control
   2.13. STAT-Short Turnaround Time
   2.14. DoB- Date of Birth
   2.15. FNA- fine needle aspiration
   2.16. ZN- Ziehl–Neelsen staining
3. **INTRODUCTION**;
   3.1. The laboratory is a department of Aroha Cancer Centre Limited (ACC). ACC is a private company established through the Companies Act, 2015. The ACC laboratory derives its authority to operate under the same establishment being a laboratory that supports ACC.
   3.2. The Aroha Cancer Centre Laboratory specimen collection manual has been prepared for the purpose of providing both general and specific information with a variety of laboratory procedures, reports, specimen identification and submission of specimens, the handling of emergency requests and technical coverage of the laboratory.
   3.3. Proper collection and submission of specimen is fundamental and vital to having accurate laboratory results. Specimen collection is a critical initial step in laboratory diagnosis. Meaningful laboratory results require careful attention to the specimen source, the method of collection, and the timing, storage, transport and handling of the collected specimens. In addition, a completed request form with relevant history, if appropriate is essential for optimal and efficient laboratory workup of the collected specimen.
   3.4. This manual on specimen collection is designed as a guide for clinicians, phlebotomists, nurses and other allied health professionals in charge of ordering, selecting and collecting specimens from patients.
   3.5. The laboratory division has several sections that work together to provide the best in investigative medicine. These include;

3.5.1. Clinical biochemistry
3.5.2. Hematology
3.5.3. Histopathology and cytology
3.5.4. Blood transfusion
3.5.5. Digital pathology

3.6. Please note that all laboratory investigation not indicated in this manual shall still be collected and referred to our sub contracted laboratory herewith indicated as referral laboratory.

4. **Scope**;

4.1. This manual applies to all sample collection points from where samples are forwarded to Aroha Cancer Centre Laboratory for referral and testing.

4.2. This manual is a controlled document and is reviewed after every 2 years or whenever there are major operational changes, which will be communicated. Therefore, all users are requested to check with Aroha Cancer Centre Laboratory for the latest copy of the Sample Collection Manual.

5. **Quality Policy Statement;**

5.1. The management of ACC laboratory is committed to providing high quality, timely, cost effective and environmentally friendly diagnosis and monitoring services, through use of procedures that are fit for purpose, continuous staff training on professional values and ethics and commitment to compliance with ISO 15189 requirements with principle aim to consistently meet the expectations of customers.

6. Quality Assurance (QA);

6.1. High quality sample collection is a crucial element in the process of patient diagnosis, treatment and management of patient. QA will be monitored regularly but not limited to the areas listed below;

6.1.1. Equipment and supply inspection.
6.1.2. Procedure review.
6.1.3. Patient preparation.
6.1.4. Specimen handling.
6.1.5. Specimen quality.
6.1.6. Monitoring storage areas for both Laboratory Consumables and Reagents.
6.1.7. Adhering to IQC
6.1.8. Participation in EQA scheme \Proficiency Testing
6.1.9. Staff training and competency assessment

7. **Location of the laboratory**;

7.1. Physical address:

7.1.1. Aroha Cancer Centre Laboratory is located in Meru Makutano along Meru Nanyuki highway opposite Afya millers.

7.2. Postal address: P.O. Box 414, 60200 MERU.
7.3. Nearest Town: MAKUTANO MERU.
7.4. Hospital email: info@aroha.health
7.5. Laboratory email: lab@aroha.health
7.6. Telephone: **+254799-528-973.**

8. **Laboratory Operating Hours;**
   8.1. A full laboratory service is available from each laboratory section between 8.00 am and 6.00pm weekdays and 8.30am to 3.00pm on Saturdays but each individual laboratory may have extended core services times e.g., if contracts require, a 24-hour service or weekend service, it can be put in place accordingly.
   8.2. Daily cut-off is times when the Laboratory has less personnel's e.g. during lunch hour and during field activities/ programmes.
   8.3. Requesting laboratory tests (certain) and panels are unique to each section; if you encounter problems with ordering please contact the laboratory on Tel: +**254799-528-973**. Hand filled lab request slips are accepted from clinicians, but request form MUST be legible and duly completed (*see section 9*)
9. **Laboratory Requests**;
   a) All specimens must be accompanied by a completed requisition or electronic order. The following information shall be included in the request forms:
      a. Name of the patient/study participant or initials or unique identifier matching what is labeled on the specimen/sample.
      b. The gender and age (in months or years) or DoB of the patient/study participant
      c. Patient number
      d. Tentative diagnosis or description of clinical investigation
      e. Complete and specific description of specimen/sample source and type
      f. The test(s) to be performed
      g. The date of specimen/sample collection
      h. The time of specimen/sample collection, and
      i. Name, signature and contact information (e.g., telephone number and address) of requesting clinician, responsible for using the test results.
      j. Any additional information relevant and necessary for a specific test.
   b) **Note:**
      a. Any request without complete information will be rejected in accordance with sample management (ACCL/SP/010) and criteria for sample rejection (ACCL/SP/011)
      b. Add on tests: Tests added will be performed but then the clinician will be requested to send another requisition form for results to be reported.
      c. Urgent test requests will be given priority and the clinician will be notified immediately after processing and after verification of the results. Clinician shall be required to indicate 'urgent/STAT' on the request form.
      d. Telephone requests in an emergency are permitted but an appropriately completed request form must follow as soon as possible.
10. **Clinical History**;

    It is important that clinical history of the patient is provided with each request form as it helps laboratory staff to validate the results before release. Test results which are not in cohesion with the provided clinical history are not released until all possible sources of error are eliminated. This helps to avoid releasing results which do not have any clinical value hence cannot help in patient management.

11. Verbal Requests;

In the event that the clinician requesting investigations has already sent the request form and sample/s to the laboratory and then decides to add another test/s, the laboratory allows that to be done. The procedure is as follows:

a) The clinician calls the laboratory staff requesting more tests to be done on the already submitted sample;
b) The laboratory staff receiving the call verifies that indeed the sample was received, the volume is enough to do the additional tests and that the integrity of the sample is still suitable for the tests;
c) The laboratory staff confirms to the requesting clinician that the additional tests will be done. If any of the above (b) conditions are not met, then another sample should be collected;
d) The laboratory staff informs the requesting clinician to fill-in another request form for the additional tests; in the meantime, the sample will be processed to ensure the results are not delayed;
e) Results of the additional tests will only be released upon receiving the request form.

12. SAMPLE ACCEPTANCE AND REJECTION CRITERIA

If the laboratory request form is not complete or if the specimen is not with the request form, the laboratory administrative assistant or the assigned laboratory personnel will mark the form to indicate the missing information and or specimen. Then inform the QA Officer or the lab staff at the bench of the non-conformance. As an alternative the person requesting may be contacted by telephone to inform them.

For histology samples there is no sample rejection but rather the samples are treated as problematic samples as based on details contained on sample rejection and acceptance procedure (Refer to ACCL-SP-011)

Once the form is completed and the corresponding sample/s also labeled correctly, they will be accepted in the laboratory.

Criteria for specimen rejection include:

a) The laboratory request form not completed correctly or fully.
b) Specimens not accompanied with any request.
c) The specimen is collected in a wrong container.
d) Specimen lacking proper identification or not labeled
e) Specimen labeled with information that does not match that on the request form.
f) Specimen containers that are broken, leaking or have evidence of contamination of outer surfaces or the request form.
g) Delay in delivery of samples to the laboratory which might invalidate test results.
h) Inadequate specimen volume collected.

13. Labeling of Specimens

The health provider submitting the specimen is responsible for the correct labeling and completion of request form for the specimen.

(General requirement)**;** The specimen/sample must be properly labeled and include:

- **a.** Patient Name/Initials matching the test requisition
- **b.** Patient number
- **c.** Patient Age
- **d.** Date and time of specimen collection

13.1. Note: All slides prepared directly from specimens must be labeled individually with the patient/study participant name/initials, a 2nd identifier (i.e., patient number, age, date and time of specimen collection etc.) and the specimen source.

13.2. Any additional information relevant and necessary for a specific test.

14. PREPARATION OF THE PATIENT

i. Explain the blood drawing procedure to the client and reassure him/her.

ii. Seat the patient in a comfortable chair with the extremity from which blood will be drawn supported on a study table or other support. The preferred sites for phlebotomy are the medium ante-cubital and basilic veins of the upper extremity. Veins on the dorsum on the hand and other forearm veins are possible alternative sites. A tourniquet may be used to transiently distend veins prior to blood drawing. Do not leave the tourniquet on the arm for longer than necessary 1 minute) as this s uncomfortable to the client and may alter the results of certain laboratory tests such as serum potassium measurement and some enzyme measurement. (For biochemistry tests)

iii. For pap smears and FNAC collection (patient preparation) refer to specific SOPs ACCL/SOP/CYT/003 for FNAC and ACCL/SOP/CYT/008 for pap smears

15. SPECIMEN COLLECTION

15.1. Arrange the following supplies on the table next to the drawing table.

15.1.1. Safety needle
15.1.2. Tubes
15.1.3. Tourniquet
15.1.4. Gloves
15.1.5. Alcohol swab
15.1.6. Dry swab.
15.1.7. Pap smears kits
15.1.8. Slides
15.1.9. Pencil
15.1.10. 95% methanol
15.1.11. Sample transportation tray

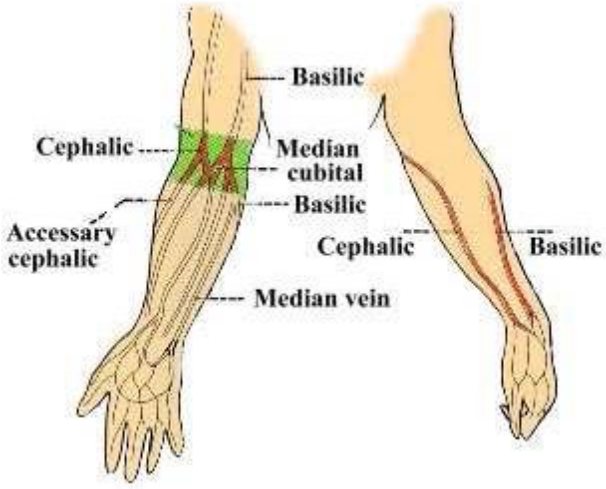
N/B - A sharps container should always be within reach

15.2. Confirm the name indicated on the request form by having the patient say their name. Be sure to verify the identity of the client and clinics number/lab number before labeling tubes

15.3. Ensure to collect the required amount of blood as indicated on the Vacutainer tube

15.1.Procedure for Vein Selection:

a) The median cubital and cephalic veins of the arm are used most frequently. See diagram below:



b) Palpate and trace the path of veins with the index finger. Arteries pulsate, are most elastic, and have a thick wall. Thrombosed veins lack resilience, feel cord like, and roll easily.

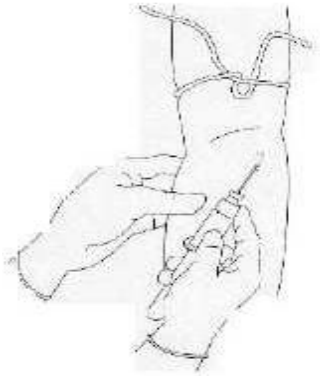
c) If superficial veins are not readily apparent, you can force blood into the vein by massaging the arm from wrist to elbow, tap the site with the index and second finger, apply warm, damp washcloths to the site for 5 minutes, or lower the extremity to allow the veins to fill.

15.2.Procedure for collecting the blood

a) Position the patient so he or she is comfortable and safe in case the patient becomes faint and falls.
b) Recommended needle size: 21G, 23G or 25G for children.
c) Closed vacutainer system is recommended.
d) Select tube or tubes appropriate for type of samples desired.
e) Select site for venepuncture.
f) Put on gloves.
g) Prepare venepuncture site with alcohol prep. Cleanse in a circular fashion, beginning at the site and working outward. See diagram on next page.

h) DO NOT PALPATE VENIPUNCTURE AREA AFTER CLEANSING. Allow site to dry.
i) Apply the tourniquet 3-4 inches above the selected puncture site. Do not place too tightly or leave on more than 2 minutes.
j) Remove needle shield. Perform venepuncture WITH PATIENT'S ARM IN A DOWNWARD POSITION AND TUBE STOPPER UPPERMOST.

This reduces the risk of backflow of any anticoagulant into the patient's circulation.



k) Push the tube onto the needle, puncturing the stopper.
l) Remove tourniquet as soon as blood appears in tube, within 2 minutes of venepuncture. Do not allow contents of tube to contact the stopper during the procedure.
m) When first tube has filled to its stated volume, remove it from the holder.
n) Place succeeding tube in holder puncturing stopper to initiate flow.
o) While each successive tube is filling invert previous tube GENTLY 5 times. DO NOT SHAKE. Vigorous mixing can cause haemolysis.
p) When all tubes of blood have been collected, remove the last tube from the vacutainer holder, place a cotton ball or gauze over the site and withdraw the needle in a smooth and cautious manner so as not to bruise the vein.
q) After withdrawing the needle fully, apply pressure to the cotton ball over the puncture site and hold pressure. If patient is able ask them to apply pressure for 3 to 5 minutes until the bleeding stops.
r) Discard the needle of the vacutainer into the biohazard container WITHOUT RECAPPING the needle.
s) Immediately invert the last tube GENTLY 5 times.

N/B: For pap smears and fine needle aspirates collection procedures refer to specific SOPs for detailed information.

16. Transportation of samples from the collection sites outside the laboratory

16.1. Sample trays and shipment containers have been provided at all collection sites within the ACC while for referral Laboratory will adhere to sample shipment guideline for biological material sample packaging and transportation manual ACCl/MNL/002

16.2. All samples are transported to the Laboratory using designated containers while adhering to safety guidelines as per Laboratory Safety Manual ACCL/MNL/005

16.3. All types of samples are accompanied by dully filled request forms, must be delivered to the Laboratory within 1 hour of collection

17. CONFIDENTIALITY OF PATIENT INFORMATION

All ACC Laboratory staff have signed confidentiality form ACCL/FRM/001 undertaking barring them from using patient information for purposes other than that of patient care. Therefore, any staff member who is reported to have divulged or used patient information other than that of patient care shall be liable to disciplinary action.

18. PROCEDURE FOR RESOLUTION OF COMPLAINTS

18.1. Complaints can be received in various ways which includes; telephone calls, verbal, e-mail, through staff suggestion box or customer satisfaction surveys.

18.2. All complaints are directed to the laboratory director who then forwards the complaints to the relevant personnel for investigations.

18.3. The suggestion box is opened weekly by the laboratory director. Complaints are identified and investigated.

18.4. Customer satisfaction surveys are conducted at least annually. The laboratory manager/Quality Officer analyses the feedback and identifies complaints.

18.5. All users of the laboratory are encouraged to raise their complaints through the Laboratory director.

18.6. After receiving the complaints, they are recorded on the Complaints Form (ACCL/FRM/044) and the original copy of complaints is attached if applicable.

18.7. The Laboratory director submits the completed form to the relevant personnel within 24 hours of receipt of the complaint(s).

18.8. If the complaint is such that it affects or has already affected patient/s results, the Quality officer is informed and this is treated as a non-conformance.

18.9. If complaint has been qualified as a non-conformance, Quality Officer registers the complaint in the Non-conformance form (ACCL/FRM/006)

18.10. The Laboratory director shall investigate/delegate a member of staff to carry out resolution of the complaint. Corrective action shall be done according to procedure for corrective action (ACCL/SP/012).

18.11. If it has been established that the complaint is incorrect or fake or too subjective, the corrective action shall not be conducted and the complaint is closed without investigation.

18.12. If the complaint is of the magnitude that it requires hospital management, the Laboratory director shall inform the administrator for appropriate action.

18.13. Whether corrective action has been taken or not, the Laboratory director shall inform the complainant within a month on the status of the complaint(s) either using e-mail, letter or by telephone. Such communication shall be documented in the communication log (ACCL/FRM/031) that is at the reception.

18.14. The Quality manager reviews completion of corrective actions for all complaints within a month of receiving them.

18.15. The Quality Officer reviews all closed and active complaints quarterly to establish any trends and to come up with preventive actions where necessary.

19. Responsibility/ Advisory Services;

19.1. It is the responsibility of all the qualified laboratory personnel to provide advice on choice of examination, use of services, repeats frequency, required type of sample and interpretation of results whenever called upon.

19.2. The laboratory staff shall maintain records of communication with laboratory users.

19.3. The laboratory management and staff to review and update this manual

20. Laboratory Services & Turn Around Time (TAT)

20.1. TAT refers to the time the patient sample is received /collected in the laboratory until the time the analysis is completed and the results are release online /dispatched to the clinician or either directly to the patient.

21. SCOPE OF SERVICE

21.1. Table below gives details of the tests offered by Aroha Cancer Centre Laboratory however, it engages referral laboratories for services not available in the laboratory or in case of system failure

No.	Test	Turn Around Time (TAT)	Specimen type	Tube/ container type	Remarks	Specimen storage requirements
	Haematology Section					
1.	Complete Blood Count (CBC)(FHG)	1 hour	2 mL EDTA blood	Purple top	Includes the following parameters: White blood cell count, red blood cell count, hemoglobin, Haematocrit, red cell indices, platelet count, neutrophils %, lymphocyte %, monocytes %, eosinophilis % and Basophil %. If any abnormal populations are identified by flow cytometry, a manual differential is automatically performed.	Do not store in freezer Stable for 24 hours refrigerated/room temperature (20-25^{0}C)
2.	Hemoglobin (HB)	1 hour	2 mL EDTA blood	Purple top	Do not store in freezer	Stable for 24 hours refrigerated/room temperature (20-25^{0}C)
4.	PBF and WBC differential count	2 hours	2 mL EDTA blood	Purple top	Do not store in freezer	Stable for 24 hours refrigerated/room temperature (20-25^{0}C)
	Clinical chemistry section					
1.	Liver Function Tests (LFT's)	2 hours	3 mL clotted blood (Serum)	Red or yellow top	Refer to individual parameters	Stable for 24 hours refrigerated/room temperature (20-25^{0}C)

2.	Alanine Aminotransferase (ALT)	2 hours	3 mL clotted blood (Serum)	Red or yellow top	The test is primarily used to diagnose liver disease and to monitor the course of treatment for hepatitis, active post necrotic cirrhosis and the effects of later drug therapy. ALT also differentiates between hemolytic jaundice and jaundice caused by liver disease.	Stable for 24 hours refrigerated/room temperature (20-25^{0}C)
3.	Aspartate Aminotransferase (AST)	2 hours	3 mL clotted blood (Serum)	Red or yellow top	The test is used in the evaluation of liver and heart diseases.	Stable for 72 hours refrigerated/room temperature (20-25^{0}C)
4.	Alkaline Phosphatase (ALP)	2 hours	3 mL clotted blood (Serum)	Red or yellow top	ALP is used as a tumor marker and an index of liver and bone disease, when correlated with other clinical findings. In bone disease it rises to new bone cell production resulting from osteoblastic activity while in liver disease it rises when its excretion is impaired as a result of obstruction in the biliary duct.	Stable for 24 hours refrigerated/room temperature (20-25^{0}C)
5.	Total protein (TP)	2 hours	3 mL clotted blood (Serum)	Red or yellow top	see applicable SOP	A
6.	Albumin (ALB)	2 hours	3 mL clotted blood (Serum)	Red or yellow top	Excessive intravenous fluids will decrease albumin levels and thus decrease calcium	Stable for 72 hours refrigerated/room temperature (20-25^{0}C)
7.	Bilirubin (total)	2 hours	3 mL clotted blood (Serum)	Red or yellow top	A normal level of total bilirubin rules out any significant impairment of the excretory function of the liver or excessive hemolysis of red cells. Only when the levels are elevated, a differentiation of the bilirubin according to the conjugated and unconjugated becomes necessary.	If protected from light, specimen is stable for 24 hours refrigerated.

8.	**Gamma Glutamyl Transferase**	2 hours	3 mL clotted blood (Serum)	Red or yellow top	The test is useful to determine liver cell dysfunction and to detect alcohol induced liver disease.	Stable for 24 hours refrigerated/room temperature (20-25^{0}C)
9.	Bilirubin (direct)	2 hours	3 mL clotted blood (Serum)	Red or yellow top	Measurement of bilirubin evaluates liver function, hemolytic anemia and hyperbilirubinemia (in newborns). Elevated bilirubin levels occur in; Cancer of the head of the pancreas Choledocholithiasis (presence of at least one gallstone in the common bile duct). Dubin – Johnson syndrome - Is an autosomal recessive disorder that causes an increase of conjugated bilirubin in the serum without elevation of liver enzymes (ALT, AST).	If protected from light, specimen is stable for 72 hours refrigerated.
10.	Renal Function Tests (RFT's)	2 hours	3 mL clotted blood (Serum)	Red or yellow top	see applicable SOP	Stable for 5 days refrigerated/room temperature (20-25^{0}C)
11.	Creatinine (eGFR)	2 hours	3 mL clotted blood (Serum)	Red or yellow top	estimated glomerular filtration rate calculation (eGFR) can be reported once requested for each result. **eGFR Reference range**: >60 ml/min/1.73m2	Stable for 5 days refrigerated
12.	Potassium (K^+)	2 hours	3 mL clotted blood (Serum)	Red or yellow top	Avoid hemolysis and delay in transit time	Stable for 5 days refrigerated
13.	Sodium (Na^+)	2 hours	3 mL clotted blood (Serum)	Red or yellow top	see applicable SOP	Stable for 5 days refrigerated
14.	Chloride (Cl^-)	2 hours	3 mL clotted blood (Serum)	Red or yellow top	Measurement of Chloride is usually done for inferential value and is helpful in diagnosing disorders of acid base and water balance in the body.	Stable for 5 days refrigerated

15.	Blood Urea Nitrogen (BUN)	2 hours	3 mL clotted blood (Serum)	Red or yellow top	**:** The test is used as a gross index of glomerular function and the production and excretion of urea.	Stable for 72 hours refrigerated
16.	Lipid Profile	2 hours	3 mL clotted blood (Serum)	Red or yellow top	see applicable SOP	Stable for 72 hours refrigerated
17.	Cholesterol	2 hours	3 mL clotted blood (Serum)	Red or yellow top	**:** Fasting specimen is preferred	Stable for 5 days refrigerated
18.	Triglycerides	2 hours	3 mL clotted blood (Serum)	Red or yellow top	see applicable SOP	Stable for 72 hours refrigerated
19.	High-density lipoprotein cholesterol (HDL-C)	2 hours	3 mL clotted blood (Serum)	Red or yellow top	Fasting specimen preferred	Stable for 72 hours refrigerated
20.	Low- density lipoprotein cholesterol (LDL-C)	2 hours	3 mL clotted blood (Serum)	Red or yellow top	LDL is a calculated result based on the Cholesterol, HDL, and Triglyceride results. This test is specifically done to determine coronary heart disease (CHD) risk. LDLs are closely associated with increased incidence of atherosclerosis and CHD.	Stable for 5 days refrigerated
21.	Random Blood Sugar (RBS)	2 hours	4 mL EDTA blood(plasma)	Purple top	see applicable SOP	specimen stable for 1. hour.
22.	Fasting Blood Sugar (FBS)	2 hours	4 mL EDTA blood (plasma)	Purple top	Patient should be fasting	specimen stable for 1. Hour
23.	Calcium (Ca)	2 hours	3 mL clotted blood (Serum)	Red or yellow top	Tourniquet application should be as brief as possible when drawing ionized calcium to prevent venous stasis. The test measures the concentration of total and ionized calcium in the blood to reflect	Stable for 72 hours refrigerated

					parathyroid, calcium metabolism, and malignant activity. Note, Excessive intravenous fluids will decrease albumin levels and thus decrease calcium. The serum protein and albumin should be measured at the same time as calcium for proper interpretation of calcium levels.	
	Histopathology/Cytology section					
1.	PAP Smear	3 days	Smear slide	PAP smear kit	see applicable SOP	
2.	FNA	3 days	Aspirate/ smear slide	smear slide	Must always be in 95% ethanol	Room temperature (20-25^{0}C)
3.	Tissue biopsies	7 days	Tissue	Screw capped container	Must always be immersed in 10% formalin	Room temperature (20-25^{0}C)
4.	Bone tissue	10 days	Bone tissue	Screw capped container	Must always be immersed in 10% formalin	Room temperature (20-25^{0}C)
5.	Immunohisto-chemistry	7 days	Tissue block	Tissue cassette	see applicable SOP	Room temperature (20-25^{0}C)
6.	Special staining (ZN, Giemsa, Gram, PAS)	2 days	Tissue block	see applicable SOP	see applicable SOP	Room temperature (20-25^{0}C)
7.	Cytology body fluids (CSF, peritoneal, pleural etc.)	3 days	Fluid; $\geq$ 1mL	clean Screw capped container	-Do not use tubes with preservatives -Specimen volume should be $\geq$ 1mL	specimen stable for 5 days refrigerated
8.	Trephine biopsy	7 days	trephine	Clean screw capped container	Must always be preserved in 10 % formalin	Room temperature (20-25^{0}C
9.	Bone marrow aspirate	3 days	Aspirate on slides, Aspirate in EDTA tube	EDTA tubes, smear fixed in absolute alcohol	Aspirate the particles on slides and prepare squashed smears. Store remaining aspirate in EDTA Tube.	Room temperature(20-25^{0}C)

22. CRITICAL RESULTS REPORTING

It is a policy of ACC laboratory to communicate critical results expeditiously through the phone. In this case, the laboratory staff request to talk to a doctor or nurse who understand the criticality of the results. The nurse or doctor is asked to repeat the name of the patient, age and the critical result. This communication is recorded in communication log. (ACCL/FRM/031)

23. Table Critical Results

Adult and Pediatrics limits of laboratory results which, after confirmation through repeat measurement in the same sample need urgent notification of the Clinician/Doctor

Parameter	Value	Note
Aminotransferases	>1000 U/L	Requires further investigations of organ specific tests e.g. liver tests etc.
Anion gap	>20mmol/l	Indicative of ketoacidosis or lactic acidosis, uremia, alcohol consumption, salicylate intoxication, poisoning from methanol or ethylene glycol
Bilirubin	>15mg/dl (257µmol/l)	Hepatobiliary disease caused mainly by hepatotropic viruses and thus of infectious origin with risk of contagion
Chloride	<75mmol/l	Indicative of considerable metabolic alkalosis
	>125mmol/l	Indicative of massive primary metabolic acidosis or pseudohyperchloraemia in the case of bromide intoxication
Potassium	<2.6mmol/l	Occurrence of neuromuscular symptoms with hyporeflexia and paralysis of the respiratory muscles.
	>6.5mmol/l	Clinical consequences are heart-rhythm disturbances, weakness of skeletal muscles, respiratory paralysis
Sodium	<20mmol/l	Mild symptoms include a decreased ability to think, headaches, nausea, and poor balance. Severe symptoms include confusion, seizures, and coma.
	>160mmol/l	Early symptoms may include a strong feeling of thirst, weakness, nausea, and loss of appetite. Severe symptoms include confusion, muscle twitching, and bleeding in or around the brain.
Creatinine	>7.4mg/dl(654µmol/l)	Acute renal failure, e.g. in multiple organ failure or sepsis

Glucose	<45mg/dl (2.5mmol//)	Neuroglycopenic symptoms, which can range from impairement of cognitive functions to loss of consciousness
	>500mg/dl(27.8mmol/l)	Diabetic coma due to insulin deficiency. Development of osmotic diuresis with severe exsiccosis and diabetic ketoacidosis (b-hydroxybutyrate >5mmol/l, standard bicarbonate <10mmol/l)
Haemoglobin	<6.6g/dl	Supply of oxygen to the myocardium inadequate
	>19.9g/dl	Corresponds to haemtocrit of 61% and leads to hyperviscosity syndrome
Leucocyte Count	$<2\times10^{9/l}$	High risk of infection if the granulocyte count is <500/ml
	$>50\times10^{9}$/l	Indicative of leukemoid reaction, e.g in sepsis or of leukemia
Platelet	$<20\times10^{9}$/l	Risk of haemorrhage. Exclude EDTA induced thromocyopenia
	$>1000\times10^{9}$/l	Risk of thrombosis
Urea BUN	>214mg/dl(35.6mmol/l)	Indicative of acute renal failure, unlike pre-renal and post renal kidney failure, no disproportionate increase in urea compared to creatinine in serum

23.1.Neonatal Quantitative Limits of laboratory results which, after confirmation through repeat measurement in the same sample, need urgent notification

Parameter	Value	Note
Bilirubin	>14mg/dl(239µmol/l)	O the first day of life, e.g in hemolytic disease of the newborn, risk of kernicterus
Glucose	<30mg/dl(1.7mmol/l)	Hypoglycemia, caused, for example, by a congenital metabolic disorder or hyperinsulinism to maternal diabetes mellitus. Glucose concenttarions <25mg/dl (1.3mmol/l) shoul be treated by parenteral administration of glucose
	>325mg/gl(18mmol/l)	Urgent clarification of pathogenicity required

Hematocrit	<33%(L/L)	Indicative of marked anemia with an inadequalte supply of oxygento tissue
	>70 %(L/L)	Hyperviscosity of the blood with increased circulatory resistsnce
Hemoglobin	<8.5g/dl	Risk of multiorgan failure, especially if the patient has a combiantion of ischemia and hypoxia.
	>23g/dl	Abnormal flow kinetics (Hyper viscosity) with increased circulatory resistance and an increasd load on the heart.
Potassium	<2.6mmol/l	Occurrence of neuromuscular symptoms with hyporeflexia and paralysis of the respiratory muscles.
	>6.5mmol/l	Clinical consequences are heart-rhythm disturbances, weakness of skeletal muscles, respiratory paralysis
Leukocyte count	<5000/ml >25,000/ml	Values below and above these limits can be indicative of neonatal sepsis

24. Limitations of test procedures

These include but not limited to:

a) Inappropriate sample
b) Hemolyzed sample
c) Lipemic sample
d) Old sample
e) Degradation of reagent
f) Technical/ procedural error
g) Very high temperatures
h) Other limitations as per reagent inserts

25. REFERENCE

A Manual of Laboratory and Diagnostic tests, Fifth edition By Frances Fischbach.

Chemical Pathology Lecture Notes, 2011. University of Cape Town.

Critical Limits of Laboratory Results for urgent Clinician Notification, eJIFCC vol14 no 1: http://www.ifcc.org/ejifcc/vol14ni1/140103200303n.htm

26. DOCUMENT CHANGE HISTORY:

Amendment sheet:

Review/Revision log		
Date of review	**Summary of Changes**	**Initials of reviewer**

27. ATTESTATION

I have read, understood and agree to follow the procedure as documented:			
No	**Name**	**Signature**	**Date**
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