AROHA
CANCER CENTRE

LABORATORY DEPARTMENT

Clinician Handbook

ACCL/MNL/002

Aroha Cancer Center
Laboratory Department
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Clinician Handbook		Doc No: ACCL/MNL/002 Version: 1.0 Supersedes: None Effective Date: 20-11-23	
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PREAMBLE;

Clinician Handbook acts as a guide to laboratory clients. It is aimed at providing handy information about the following at ACC Laboratory unit,

a) the location of the laboratory;

b) types of clinical services offered by the ACC laboratory including examinations referred to other laboratories;

c) opening hours of the ACC laboratory;

d) the examinations offered by the ACC laboratory;

e) instructions for completion of the request form;

f) instruction for preparation of the patient;

g) instructions for patient-collected samples;

h) instructions for transportation of samples, including any special handling needs;

j) the ACC laboratory's criteria for accepting and rejecting samples;

k) a list of factors known to significantly affect the performance of the examination or the interpretation of the results

l) availability of clinical advice on ordering of examinations and on interpretation of examination results;

m) the ACC laboratory's policy on protection of personal information;

n) the ACC laboratory's complaint procedure.

TERMS AND DEFINITIONS

ACC - Aroha Cancer Centre

TAT-Turnaround Time

HB –Haemoglobin

LFT's - Liver Function Tests

RFT's – Renal Function Tests

U/E/C - Urea, Electrolyte and Creatinine

STAT-Short Turnaround Time

ISO-International Organization for Standardization

1. Introduction

1.1 The Laboratory Department:

1.1.1 The laboratory is a department of Aroha Cancer Centre (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.

1.1.2 The laboratory department offers a broad range of quality testing that provides clinical diagnostic services for referrals and walk-in patients, in compliance with relevant local regulations and internationally accepted standards.

1.1.3 The laboratory division has several sections that work together to provide the best in investigative medicine. These include;

1.1.3.1 Clinical biochemistry

1.1.3.2 Hematology

1.1.3.3 Histopathology and cytology

1.2 **Laboratory physical location:**

1.2.1 ACC Laboratory is located within ACC which is located in Meru, Gitoro, along the Meru - Nyanyuki Road, P.O. Box 414, 60200 Meru. Tel: +254-799-528973. lab@aroha.health

2. Scope:

The purpose of this handbook is to provide ACC Laboratories clients with information on services offered, QA, TAT for all test analysis, sample collection, sample transportation results handling and other information relevant to laboratory operations.

In order to obtain the best possible laboratory services, it is essential to ensure that the specimens are collected properly, and that both the specimen and requisition form are labeled with the appropriate information. The requisition and patient's record must provide sufficient information to demonstrate the medical necessity for the laboratory order.

The handbook covers brief description of laboratory location for specimen delivery, hours of operation, instructions concerning specimen delivery result callback policy. Specific criteria for specimens' rejection and any other special instructions are included.

It's our sincere hope that the book will be of use to all departments which are involved in the patient management and care, thus contributing to quality health care provided to all our clients.

3. Quality Policy Statement;

Aroha Cancer Centre Laboratory provides accurate, timely, reliable, cost effective and environmentally friendly diagnostic services in histopathology, cytopathology, hematology and chemistry to all its clients. Management of Aroha Cancer Centre laboratory and staff are committed to the implementation and maintenance of the quality management system that meets the requirements of ISO 15189 standard and that of national regulations on good laboratory practice and good professional practice. Aroha Cancer Centre Laboratory sets and continuously monitors and reviews for continued suitability quality objectives that are focused on meeting the needs and requirements of our valued users. The established quality management system is communicated and understood by all staff to ensure effective implementation and sustainability. The management also commits to health, safety and welfare of all staff, patients and visitors to the laboratory by putting in measures to minimize risks of infection and injury The quality policy and quality objectives are reviewed during Management Review meetings for continuing suitability.

4. Quality Assurance (QA);

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;

4.1 Equipment and supply inspection.
4.2 Procedure review.
4.3 Patient preparation.
4.4 Specimen handling.
4.5 Specimen quality.
4.6 Monitoring storage areas for both Laboratory Consumables and Reagents.
4.7 Adhering to IQC
4.8 Participation in EQA scheme \Proficiency Testing

4.9 Staff training and competency assessment

5. Laboratory Operating Hours;

5.1 A full laboratory service is available from each laboratory section between 8.00 am and 5.00pm on weekdays; Saturday from 8.00 a.m. to 2.00 p.m. and Public Holidays 8.00 a.m. to 3.00 p.m. for outpatients and sample delivery but each individual laboratory may have extended core services times Daily cut-off is times when the Laboratory has less personnel's e.g. during lunch hour and during field activities/ programmes.

5.2 Requesting laboratory tests (certain) and panels are unique to each section; if you encounter problems with ordering please contact the laboratory on Tel: +254 799 528 973 . Hand filled lab request slips are accepted from clinicians, but request form MUST be legible and duly completed (*see section 8*)

6. Responsibility/ Advisory Services;

6.1 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.

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

6.3 The laboratory management and staff to review and update this policy

7. Laboratory Services & Turn Around Time (TAT);

7.1 TAT refers to the time the patient sample is received (For referral samples)/collected in the laboratory (for walk-in) until the time the analysis is completed and the results are release online /dispatched to the clinician or either directly to the patient or to the ward pigeon on the department.

7.2 Different samples have different TATs. Refer to the table on clause 16.

8. Laboratory Requests;

8.1 All specimens must be accompanied by a completed requisition. The following information shall be included in the request forms:

8.1.1 Name of the patient or initials or unique identifier matching what is labeled on the specimen/sample.

8.1.2 The gender and age (in months or years) or DoB of the patient

8.1.3 Patient number

8.1.4 Putative diagnosis or description of clinical investigation

8.1.5 Complete and specific description of specimen/sample source and type

8.1.6 The test(s) to be performed

8.1.7 The date of specimen/sample collection

8.1.8 The time of specimen/sample collection (where applicable), and

8.1.9 Name, signature and contact information (e.g., telephone number and address) of requesting clinician, responsible for using the test results.

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

8.2 **Note:**

8.2.1 Any request without complete information will be rejected in accordance with sample management and criteria for sample rejection ACCL/SP/011

8.2.2 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.

8.2.3 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.

8.2.4 Telephone requests in an emergency are permitted but an appropriately completed request form must follow as soon as possible.

8.2.5 Clinical research subjects will be required to sign informed consent prior to collection of specimens

9. Sample Collection;

9.1 ***Specimen/Sample Integrity (general requirement)***;

9.1.1 Verify the identity of the patient and make sure that the correct information is specified on both request form and specimen container (e.g., tube, biopsy container, pap smear kit

9.1.2 Ensure that sufficient specimen for the requested test/s is collected in appropriate container/s

9.1.3 Check specimen container/s for expiry dates where applicable.

9.1.4 Use good phlebotomy technique to avoid hemolysis or venous stasis.

9.1.5 Do not attempt to augment low specimen volumes by transferring blood from tubes containing anticoagulant/preservative into clotted blood specimens

9.1.6 All gel-containing Vacutainer tube/s (SST/yellow top) and clotted (red top) blood specimens should be collected first based on the order of draw. Thereafter, collect specimens that require an anticoagulant or preservative.

9.1.7 **Sample Collection procedures;**

9.1.7.1 Body fluids (CSF, peritoneal, pleural ascitic etc.), aspirates (splenic/bone marrow/lymph node), FNA, PAP smear and tissue biopsies specimens are collected by clinicians.

9.1.8 For clinical advice on ordering of examinations and on interpretation of examination results, the client is advised to contact the Laboratory on the contacts provided above.

9.2 ***Specimen/Sample Labeling (general requirement*)**;

9.2.1 The specimen/sample must be properly labeled and include:

9.2.2 Patient Name/Initials matching the test requisition

9.2.3 Patient number

9.2.4 Patient Age

9.2.5 Date and time of specimen collection

9.2.6 **Note:** All slides prepared directly from specimens must be labeled individually with the patient name/initials, a 2nd identifier and the specimen source.

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

9.3 ***Packaging and Transportation*;**

9.3.1 All specimens must be transported to the testing laboratory as soon as possible preferably within 1 hour after collection for blood samples, within 1 day for cytology and 3 days for biopsies.

9.3.2 All specimens from other facilities should be triple packed; that is sample in a primary leak-proof container placed in a secondary leak-proof container or specimen bag and sealed tightly prior to transport to prevent leakage and contamination.

9.3.3 Confirm that the specimens are properly labelled with the recommended identifiers and all request forms are duly filled

9.3.4 All specimens should be properly packaged and packaging must follow the International Air Traffic Association (IATA) regulation i.e. Triple packaging

Source: WHO/AFRO/CDC 2008[11]

9.3.5 All specimen should be logged in facility specimen referral logs before dispatch

9.3.6 Specimen shipment log should be duly filled and accompany the specimen to the nodal facility.

9.3.7 Staff transporting specimen should be trained in proper procedures for packaging and shipping dangerous goods

9.3.8 Specimen referral form and/or shipment manifest should be duly filled and accompany the specimen to the referral laboratory.

9.3.9 The laboratory maintains a tracking log for all referred samples

9.3.10 All rejections should be documented with reasons for rejection and action taken

9.3.11 Requisition form for the sample must be placed in the outer pocket of the biohazard specimen bag.

9.3.12 Specimen from the wards/clinic should be transported in specimen boxes/cool boxes.

9.3.13 Fluid specimens also should be transported to the laboratory immediately upon collection (preferably within 1 hour) to maintain their integrity e.g., CSF, synovial, ascitic, pleural fluid etc.

10. *Referred tests / specimen*;

10.1 samples are sent to selected referral laboratories as per the SOP for selection of referral labs and list of approved referral labs (ACCL/SP/009)

11. *General criteria for specimen rejection*;

11.1 Sample without accompanying requisition form

11.2 Unlabeled / incompletely labeled/ incorrectly labeled specimens
11.3 Insufficient quantity of specimen for the test(s) requested
11.4 Inadequate volume of blood collected in an additive tube (i.e., incorrect specimen anticoagulation ration)
11.5 Blood specimens with visible hemolysis, lipemia
11.6 Anticoagulated Blood specimens with clots
11.7 Samples that do not conform to the type of sample needed for the requested test(s)
11.8 Samples in wrong container or preservative
11.9 Leaking samples
11.10 Contaminated sample/containers/requisition forms
11.11 Improper sample transportation or delayed transport time

11.12 **For compromised but irreplaceable samples**

11.12.1 Irreplaceable samples such as CSF or tissue biopsies cannot be rejected even if their integrity is compromised or their accompanying forms are not properly filled in.
11.12.2 Laboratory staff at the reception receives these samples in sample reception book and forward them to the respective sections.
11.12.3 If the sample is not accompanied by all necessary documents, the technical staff proceeds to process these samples while communicating with the requesting clinicians to provide missing information. The result of the processed sample is retained and only released when the clinical staff has taken responsibility in completing all missing information.
11.12.4For compromised samples but with accompanied documents, they are documented on the problematic sample log(ACCL/LBK/020) and a communication made to the referring facility/ user. A nonconformance form is also filled for corrective action.
11.12.5 If the vital information is not availed the sample should not be analyzed instead it is held for maximum of 10 days if the information is not availed the samples are rejected returned to referring hospital.
11.12.6 If the sample itself is compromised e.g. autolyzed biopsies/autopsies, blood stained CSF, the technical staff proceeds to analyze the sample, prioritizing the most critical tests. The final report should then have a comment stating in which way the sample was compromised and how that might have affected the results.

12. Getting back results

12.1 ***Outpatient and Inpatient results*;**
12.1.1 Inpatient results for various tests are dispatched to the requesting hospital through their respective labs and or the channel used to submit sample through Dispatch log book.
12.1.2 Outpatient results are dispatched to/or collected by owners once the results are ready.
12.2 ***Referral Sample Results*;**
12.2.1 Tests referred to referral labs, results are delivered via courier and through e-mail.
12.2.2 All patient information is maintained in a confidential manner. All staff sign confidentiality forms as required by standard.

13. Complaints;

13.1 The lab has a customer satisfaction survey procedure (ACCL/SP/16), that provides for clients to register their complaints and other forms of feedback.

13.2 Complaints/feedback forms (ACCL/FRM/044) are available at the specimen reception/phlebotomy room, as well as the in ACC treatment room. The form can also be downloaded from ACC website on the resource section.

13.3 The complaints may be channeled directly to the Laboratory director/Hospital admin/ designee through the contacts provided in the SLA

13.4 Complains can also be sent through emails info@aroha.health or lab@aroha.health

14. Communication;

Effective communication between Clinicians and Laboratory is an essential component of quality diagnostic and research services. Clinicians and Laboratory staff should show respect and und Problems will be solved through discussion and dialogue. Clinician-lab meetings will be conducted as outlined in quality improvement procedure.

14.1 Other form of communication will be through emails, memos and Official calls.

15. Critical values for tests performed;

15.1 It is the responsibility of the laboratory analyst/technologist performing tests/assays in their respective sections to inform the duty clinician on the critical values

15.2 Communication of critical values will be reported verbally or by phone to the clinician immediately the result is obtained and validated

15.3 The laboratory staff to document the verbal / telephone transmission of the critical results onto respective assay critical value reporting form. ,erstanding towards the knowledge and skills of their colleagues.

16. SCOPE OF SERVICE

16.1 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 Aroun 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)

7. References;

Reference Number	Document Title
ACCL/EXT/002	ISO 15189:2012-Medical laboratories Requirements for quality and competence

8. Supporting Documents;

Appendix No.	Title
ACCL/FRM/029	Referral Laboratory Evaluation Checklist
ACCL/FRM/030	A register of all referral laboratories
ACCL/SP/001	Document and Records control
ACCL/LBK/012	Specimen Referral Logbook

9. **Document Review and Approval**;

By Initialing and dating below I understand and approve of the changes to the attached Policy.

Document Changes		Changes Approval Name/Initials & Date		
Date	Nature of Change	Reviewer	QA/ designee	Approving Authority

10. Attestation:

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