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Welcome to the CBACS Laboratory Handbook.

1. INTRODUCTION

This manual is designed to give an overall view of the services available at the Center for Biomedical Analytical and Consultancy Services (CBACS) as well as to give a detailed information on sample collection, handling, and testing. This is all geared towards ensuring that all samples are managed properly and that persons collecting samples have the needed information to provide an acceptable sample at the CBACS laboratory for processing.

2. SCOPE

This manual applies to all persons using CBACS for its services. The manual shall be reviewed from time to time and, it is a controlled document for CBACS and therefore, all users are requested to check with the center for the latest copy.

3. ABOUT US

Health care is a significant part of any country´s economy, with accessibility to quality healthcare being fundamental to economic growth. Provision of healthcare services, and safeguarding the well-being of the population is recognized in the sustainable development goals (SDGs) as crucial in ensuring the continued development of a country.

There are many challenges facing the The Gambian healthcare sector that include but are not limited to: (i) lack of the necessary legislation or proper enforcement mechanisms to protect the population from certain health hazards, (ii) limited resources to setup fully equipped infrastructure with regular provision of supplies, reagents, and test kits for better health outcomes and, (iii) shortage of skilled personnel to carry out quality technical work. All these deficiencies lead to a lack of proper internationally acceptable quality control standards and mechanisms in the country's healthcare infrastructure, which has serious negative consequences for the population.

In The Gambia currently, there are very few laboratories where reliable laboratory diagnostic tests could be carried out. Conversation with many senior clinicians in the Healthcare sector (both public and private), revealed that they generally have serious concerns about the reliability of laboratory test results they receive and, on which they rely to diagnose and prescribe drug treatments for their patients. Doctors are guided by laboratory test results to make proper clinical diagnosis and prescribe the right pharmaceutical drugs to help their patients have a better outcome and recover from their disease condition. Without accurate laboratory test results and reliable clinical diagnosis, doctors will be severely handicapped in their work and will most probably resort to guessing the disease type and stage of their patients. That is indeed a very unsatisfactory situation for any population to be in.

Diagnostic imaging forms a key component in modern health care, playing a vital role in the diagnosis and prognostication of disease as well as in monitoring response to treatment. The

condition of radiological diagnostic capability in the country is probably even worse. There are apparently only a few functional Computed Axial Tomography (CAT/CT) scans for a population of over two million. The demand for this service is in such short supply that patients travel to neighboring Senegal to seek diagnosis and treatment. This is completely unacceptable for it to continue, given the pain, suffering and financial costs Gambian patients incur on such trips.

The problems outlined above concerning The Gambian Healthcare Sector are very serious and require immediate attention to drastically reduce or even eliminate their negative impacts on society and the economy at large. It is precisely because of these reasons that CBACS came into being. We have entered the diagnostic scene, joining those already in it, to assure the population of the delivery of quality laboratory service for improved health outcomes.

CBACS is committed to providing a service of the highest quality and is aware of and takes into consideration the needs and requirements of its users.

Laboratory work is carried out on up-to-date equipment which meet all applicable requirements of a quality management system. All procedures for equipment and/or analyser platforms used, and performance characteristics of tests undertaken, are documented on Standard Operating Procedures (SOPs) to ensure standardization.

CBACS started operations on 1st September 2022, initially offering laboratory diagnostic and screening services in biochemistry and haematology. We have since added other biomedical sciences disciplines, such as microbiology and immunology and, have plans to be providing imaging services.

4. POSTAL ADDRESS

Manjai/Kotu Road (Close to the SPEED Petrol Station)
Kanifing Municipal Council,
The Gambia, West Africa.

5. CONTACT DETAILS

Tel: (+220) 9594728; (+220) 7167556; (+220) 3022661; (+220) 6330261

Email: info@CBACS.gm; Website: www.CBACS.gm

6. CBACS Opening Hours

Monday to Thursday 8.00am to 5.00pm

Friday 8.00am to 1.00pm

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CBACS Quality Policy

The Center for Biomedical Analytical and Consultancy Services is committed to providing an analytical, interpretative, and advisory service of the highest quality and shall be aware and take into consideration the needs and requirements of its users.

In order to ensure that the needs and requirements of users are met, CBACS will:

- ✓ provide a diagnostic service, initially, in the following disciplines: Haematology, Blood Bank, Clinical Biochemistry, with the scope to expand
- ✓ operate a quality management system
- ✓ set quality objectives and plans to implement this quality policy
- ✓ ensure that all personnel are familiar with this quality policy to ensure user satisfaction
- ✓ ensure that personnel are familiar with the contents of the quality manual and all procedures relevant to their work
- ✓ commit to the health, safety, and welfare of all its staff. Visitors to the center will be treated with respect and due consideration will be given to their safety while on site
- ✓ uphold professional values and be committed to good professional practice and conduct

CBACS is committed to:

- ✓ the proper procurement and maintenance of such equipment and other resources as are needed for the provision of its services
- ✓ the collection, and handling of all specimens in such a way as to ensure the correct performance of laboratory examinations
- ✓ the use of examination procedures that will ensure that the quality of all tests performed meet user requirements i.e. are fit for intended use
- ✓ reporting results of examinations in ways which are timely, confidential, accurate and clinically useful
- ✓ evaluation of all processes within CBACS to ensure continued quality improvement through internal audit, external quality assurance and assessment of user satisfaction

Signed on behalf of CBACS

Dr. Bakary J. Sonko

Director Date……..…

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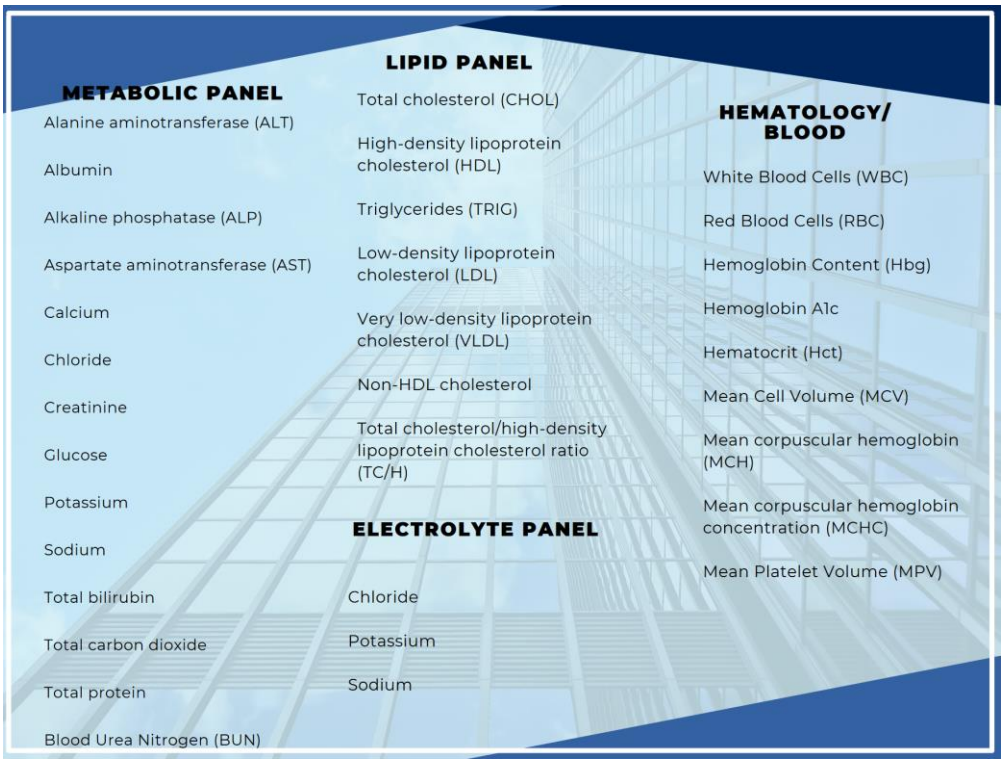
Picture 1.0: CBACS Brochure:



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7. DUTIES AND RESPONSIBILITIES

Each individual person is responsible for complying with the standards set out in this document if they collect, handle and/or transport pathology specimens. They need to be aware of their personal responsibilities in preventing the spread of infection.

CBACS will make every effort to ensure requests are processed in a safe and timely manner, but it is essential that request forms and samples are labelled appropriately and legibly in compliance with this policy.

7.1 Secretary/Patient reception

- ***Organizing the sample collection***

Collecting samples is done in the order in which the patients arrive, as defined by the Secretary, without favoritism or distinction, **except for medical emergencies, the elderly, pregnant women and people with disabilities**.

DEFINITIONS

Emergency: Requires immediate care.

Elderly Person: Any person over 60 is considered elderly.

Disabled person: Any person with a motor deficit is considered disable (in a wheelchair/crutches).

Currently not all possible analyses are done at CBACS (c.f. Laboratory Tests Conducted at CBACS, see page 19). If the analysis requested are performed at CBACS, proceed as follows:

- ✓ Communicate the price of the analyses requested to the patient/escort. If the price is accepted, it should be paid in full before starting to collect any sample.
- ✓ Do the bill for the analyses.
- ✓ Collect the payment.
- ✓ Generate a receipt.
- ✓ Forward the analyses request sheet together with the receipt to the Phlebotomist for sample collection.

7.2 Phlebotomist/Sample collection

- ✓ Receive and welcome the patient, reassure, and make him/her comfortable.
- ✓ Complete the laboratory request form with the details of the patient and the request.
- ✓ Explain to the patient the type of sample(s) to be collected.

- ✓ Collect sample(s),and ask patient to wait in the reception area for the results (communicate results turnaround time to the patient/escort).

- ***It is the responsibility of the Laboratory Manager to ensure that –***

- ✓ Staff in their area of responsibility are aware of the content of this policy.

- ***It is the requestor's responsibility to ensure that –***

- ✓ All requestor and patient details on the request form are correct, clearly legible.

- ✓ The investigations required are clearly identified with relevant supporting information, where necessary.

- ***The person responsible for taking the specimen(s) MUST ensure that -***

- ✓ All the necessary information is present on the request form. The Phlebotomist should NOT proceed with the specimen collection procedure if this is not the case.

- ✓ Containers are legibly labelled with the correct details of the patient. That the specimen details match those on the form.

- ✓ Containers are securely packaged so that they do not leak and, for samples collected outside of CBACS, that they are unlikely to be broken on the way to the laboratory.

8. SAMPLE COLLECTION AND MANAGEMENT

Phlebotomy has the capability to accommodate patients with a waiting/reception area. There is a separate phlebotomy room which provides privacy for blood sample collection. There is a toilet facility within the building.

The Center can process samples either collected by the Phlebotomist or received from referral institutions, according to the analysis available. Correct sample identification and handling is a mark of good laboratory practice. Samples that cannot be properly identified because they fail to meet the criteria laid out in this Handbook are a risk to the patient. Irrespective of the origin of the sample, there are strict requirements in both the sample quality and the accompanying information that must be adhered to for the sample to be accepted for processing.

The following are the sources of samples for analysis at CBACS:

8.1 Patient's personal request without a prescription

The Laboratory Manager meets the patient to discuss his/her needs. Once it is certain that CBACS can offer its services (laboratory investigations) to the patient, the patient is informed of the laboratory tests relevant to his/her condition and referred to the Secretary for billing.

8.2 Medical prescription/request from a pharmacy/hospital/clinic

The Secretary will receive the patient with the prescription/request and provide billing information. She may consult the Laboratory Manager for clarification on the request, if necessary.

8.3 Request from another laboratory

Treat as above and proceed below.

9. PATHOLOGY SPECIMENS

9.1 Introduction

All pathology specimens must be obtained and transported/handled with care, as accidents could result in the transmission of infection to clinical, laboratory and ancillary staff.

9.2 Purpose

The purpose of this policy is to establish the correct procedures for the collection, handling and transport of laboratory samples.

9.3 Standard Precautions

- ***Standard precautions apply to the handling of all specimens.***

✓ Always wash hands before and after obtaining and handling specimens

✓ Cover cuts and lesions with a waterproof dressing

✓ For your own protection, disposable (non-latex) gloves **MUST** be worn if there is any likelihood of contact with blood or body fluids.

✓ Only use the correct specified container for the specimen / test required. Take care not to contaminate the outside of the container with blood or other material. Tighten tops to prevent leakage

✓ Discard needles, vacutainer holders and syringes safely into sharps boxes as per CBACS Waste Policy

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9.4 Obtaining Specimens

Always ensure that the container and request form are labelled with the patient's name, age, CBACS number, date of sample collection, and that adequate clinical information is provided on the form (if referred by a clinician). Specimens will only be analysed if they fulfil the specimen acceptance criteria, as provided in this handbook.

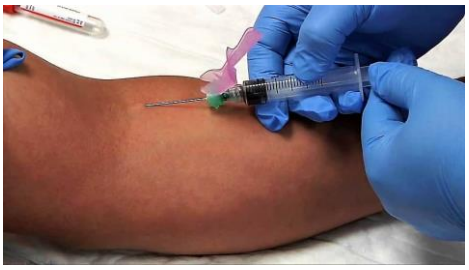
9.4.1 Taking Blood Specimens

- ***Phlebotomy***

Phlebotomy is considered a surgical procedure which involves extracting blood from the patient via venipuncture/finger/heel prick using an appropriate device. The blood extracted can later be used for performing several checks regarding the health of a patient for various laboratory tests. Phlebotomy includes performing venipuncture or a finger/heel prick for the collection of minute quantities of blood.

- ***Venipuncture***

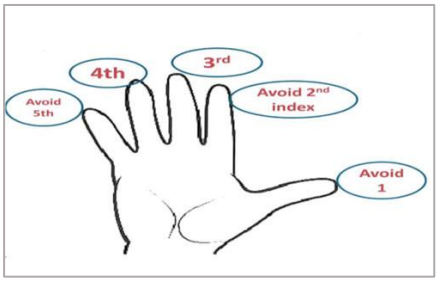
Venipuncture is blood collection from the veins of the patients. It refers to using a needle to pierce the skin and to access a vein so that a small amount of blood can be removed for various studies.

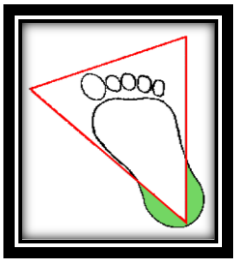


Picture 2.0: Venipuncture technique

- ***Finger/Heel Prick***

Finger/heel prick is sometimes done when only a much smaller amount of blood (a drop) is needed for a test. This sample is mostly collected from the 3rd or 4th finger or from the heel of infants (green shaded area only.





Picture 3.0: Finger/Heel Prick sites

9.4.2 Other Samples

- ***Urines***
  Mid-stream urine: - this is the most frequently collected. The patient passes the first and last part of the stream into a toilet, urine bottle or bedpan, and the middle 10-20ml into a sterile universal container.

- ***Swab***
  The cotton ended tip of the swab is rubbed within the affected area to collect sample material.

10. SPECIMEN TRANSPORT AND STORAGE

It is most appropriate if samples can be processed as soon as possible after collection. This is especially applicable to samples collected within CBACS. If samples must be collected elsewhere and transported to CBACS for processing, then it is essential to safely package these samples with a cool pack. This is particularly relevant with blood samples collected for haematology, biochemistry, serology, coagulation and immunology investigations. Every effort must be made for these samples to reach CBACS as soon as possible after collection.

Referring the patient to come to CBACS for sample collection is the preferred option.

11. CBACS TEST MENU

The laboratory performs many tests which are grouped into sets that are performed together. Examples include the Full Blood Count (FBC) or a Comprehensive Metabolic Panel (CMP). This is the usual method for requesting these tests. Within this section all tests are referred to via their common requesting set name, and within each set description, the individual test components are detailed – these are the elements of the requesting set that are reported.

There are other grouped tests whose complete elements composition within the profile are not performed in CBACS, but a selected few are available. For example, in a Hormone Profile, five individual hormone tests (TSH, FSH, Progesterone, Prolactin and Testosterone) are available.

Certain tests are also requested individually. Examples include Haemoglobin A1c (HbA1c) or Pregnancy test/Human chorionic gonadotropin (hCG) test.

The full test menu can be found in Table 5.0 in this Handbook.

12. REQUEST FORM INFORMATION

Request forms are designed to provide all relevant information required to provide a safe meaningful report and satisfying internal audit requirements.

CBACS has designed a laboratory request form that has the same layout for each department apart from the results section on a full A4 sheet (see Appendix AP001)

Full completion of request forms is encouraged through guidelines already provided in this Handbook. When request form information is unclear, the laboratories cooperate with service users to clarify information and avoid wherever possible the need for requests to be rejected.

13. REFERENCE INTERVALS

Reference intervals for any test are specific to that test and laboratory methodology. Some are also often age and sex specific. Reference intervals are contained on the laboratory request form, where relevant, taking these factors into account.

14. LABORATORY RESULTS

Laboratory results are released in one of two ways: For patients who have walked into CBACS for testing, results are directly returned to them. But if a clinician from another facility has sent in a request, through the patient, the result is enclosed in a sealed envelope and given to the patient who will return it to the requesting clinician.

15. TURNAROUND TIMES

The laboratory continually monitors its turnaround times to ensure that it complies with its responsibilities within the patient pathway. The laboratory measures its turnaround times as the time from which the sample is booked into the laboratory record book (which is largely equivalent to the time of receipt), until the point at which the result is authorised.

The turnaround times for each test is published in this Handbook (Appendix AP002).

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16. PRIMARY SAMPLE COLLECTION AND HANDLING

16.1 General Requirements

Primary sample collection within CBACS is conducted by the phlebotomist at the sample collection site. CBACS' policy is followed to confirm patient identity and ensure consent for the collection procedure is given wherever possible.

Phlebotomy is a low-risk invasive procedure in the outpatient setting and is generally perfumed under assumed consent i.e. patient presents his/her arm and request form for the procedure. The laboratory maintains records of all samples, regardless of source, as this is included as part of the sample collection process.

To obtain a specimen that is representative of a patient's metabolic state, regulation of certain aspects of specimen collection is often necessary. These special conditions may include time, length, and method of collection and the patient's dietary and medicinal intake. It is important to instruct patients when they must follow special collection procedures.

16.2 Sample Reception

Sample reception procedures are in place to ensure accurate identification, recording of information, dealing with urgent specimens where appropriate, and ensuring the safety of personnel.

The center has introduced a generic approach to specimen rejection procedures and this is documented in this handbook (Section 16.5; page 16) . This procedure includes the need to include appropriate comments on reports when unsuitable samples are received.

16.3 Sample Quality

Only limited samples, blood urine and swab samples are collected/received for the analysis currently available at CBACS.

- ***Blood samples***

Blood samples are collected for laboratory analysis either from a venipuncture (as whole blood collected in an anticoagulant or as a clotted sample in a plain tube for collection of serum), or from a finger/heel prick (for samples collected at CBACS only).

It is important to ensure that the right anticoagulant is used for the respective analysis:

Example:

- ✓ *For Haematology FBC/immunochemistry (whole blood) – blood is collected in an EDTA (purple top vacutainer) tube.*
- ✓ *For Biochemistry analysis (whole blood) – blood is collected in a Lithium-Heparin (green top vacutainer) tube.*
- ✓ *For Biochemistry/immunochemistry analysis (serum) – blood is collected in a dry (red top vacutainer) tube, with no anticoagulant.*

- ***Urine samples***

Urinalysis (UA) is an essential procedure for patients undergoing hospital admission or physical examination. It is a useful indicator of a healthy or diseased state and has remained an integral part of the patient examination. Routine urinalysis testing describes the results of a series of screening tests capable of detecting (in a semi-quantitative manner) renal, urinary tract, metabolic and systemic diseases.

Table 1.0: Types of Urine Samples

Types of urine sample

Sample type	Sampling	Purpose
Random specimen	No specific time most common, taken anytime of day	Routine screening
Morning sample	First urine in the morning, most concentrated	Pregnancy test, microscopic test
Clean catch midstream	Discard first few ml, collect the rest	Culture
24 hours	All the urine passed during the day and night and next day 1st sample is collected.	used for quantitative and qualitative analysis of substances
Postprandial	2 hours after meal	Determine glucose in diabetic monitoring
Supra-pubic aspired	Needle aspiration	Obtaining sterile urine

The top two sample types are the most commonly received samples for the currently available analysis. Urines must be collected in sterile containers for any of the above purposes.

For complete information on samples collected outside CBACS, please refer to Appendix AP003.

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Table 2.0: Specimen Collection and Handling Instructions

Department	Analysis	Specimen	Specimen Container (anticoagulant)	Notes
BIOCHEMISTRY (Piccolo Xpress chemistry analyzer)	Chemistry panels (various)	**Whole blood**, Plasma or Serum	**Green top Vacutainer** (Lithium heparin)	• When collecting the sample in lithium heparin collection tubes, fill the tube at least halfway • Mix well by gently inverting two or three times. • To prevent haemolysis, do not refrigerate or shake whole blood. • For accurate interpretation of glucose and lipid results, the patient should fast for at least 12 hours before the sample is collected. • **Sample collection into syringe with no anticoagulants:** Draw the sample, remove the needle, remove the tube top, then immediately add the sample to lithium heparin (green top tube). Gently invert the tube two or three times to mix.
BIOCHEMISTRY (DCA Vantage system)	Haemoglobin A_{1c}	**Whole blood**	**Venous Blood: Lavender top Vacutainer** (EDTA) **Finger Prick Blood**	• Mix the sample (venipuncture) well (by inversion or use of a tube mixer) to prevent separation of red blood cells and plasma.

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	Microalbumin/Creatinine	**Urine**	**Sterile Universal**	
Department	**Analysis**	**Specimen**	**Specimen Container (anticoagulant)**	**Notes**
HAEMATOLOGY (COULTER A^{C}•T diff Analyzer)	Full Blood Count +DIFF	**Whole blood**	**Lavender top Vacutainer** (EDTA)	• A whole blood sample is analyzed **within 24 hours** of collection. • Do not refrigerate samples for Platelet and differential counts. • If you do not need Platelet or differential results, you can store whole-blood specimens drawn in a salt of EDTA at 2^{o}C to 8°C.
Department	**Analysis**	**Specimen**	**Specimen Container (anticoagulant)**	**Notes**
BIOCHEMISTRY/ HAEMATOLOGY (Clinitek Status+ analyzer)	• Urinalysis Strip Test • Cassette Test (hCG)	**Urine**	Sterile Universal	
IMMUNOCHEMISTRY (iChroma analyzer)	Various parameters (see Table 5.0; Page 20)	**Whole blood**	**Lavender top Vacutainer** (EDTA)/Finger Prick	
MICROBIOLOGY	Stool microscopy	**Stool**	Sterile wide mouth container	

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IMMUNOCHEMISTRY (RDTs)	• HBsAg • HCV • Syphilis • Gonorrhea	**Whole blood, Plasma or Serum** **Cervical/urethral material**	**Lavender top Vacutainer** (EDTA)/Finger Prick, Red top Vacutainer **Swab**	It is recommended that specimens be processed as soon as possible after collection.

16.4 Managing Sample Information

It is as important in ensuring that complete and accurate information accompanies the sample as it is for the quality of the sample. Therefore, the laboratory form should be fully completed, and all relevant information is also provided with the accompanying sample for easy matching.

- ***The following information MUST be provided on the laboratory form:***
  - ✓ Patient's Full Name (Name & Surname)
  - ✓ Patient's Age & Gender
  - ✓ Type of sample
  - ✓ Examination(s)/Tests requested
  - ✓ Sample collection date
  - ✓ Name of requesting Health Officer (where applicable) and telephone number
  - ✓ Requesting Hospital/Clinic/Pharmacy (where applicable)
  - ✓ Relevant clinical information appropriate to the test(s) requested

- ***Minimum Data Set for Identification on a Written Request:***
  - ✓ Patient Surname and Forename (in full, not initials)
  - ✓ Age/Date of birth (DOB)
  - ✓ Date of sample collection
  - ✓ Examination(s)/Tests requested

- ***Minimum Data Set for Identification on sample container:***
  - ✓ Patient Surname and Forename (in full, not initials)
  - ✓ Age/Date of birth (DOB)
  - ✓ Date of sample collection

A minimum of 3 identical patient identifiers must be present on both the request form and on each individual specimen container to demonstrate that it corresponds with the associated request.

As soon as samples collected from outside CBACS are received by the Phlebotomist, they are immediately given unique identification numbers (these numbers are available with the Laboratory Manager), to ensure samples with the same name are not mixed.

- ***Additional Specific Details:-***
  - ✓ For glucose and lipids (Lipid Profile), state fasting or non-fasting.
  - ✓ Patient gender **must** be included, as some reference ranges are gender specific.

16.5 Sample Rejection Criteria

The Laboratory Manager will make every effort to ensure requests are processed in a safe and timely manner, but it is essential that request forms and samples are labelled appropriately and legibly in compliance with this policy.

If you have any doubts regarding this policy, please contact the Laboratory Manager for further information.

Specimens will not be accepted for analysis if: -

- ✓ There is no unique identification of the patient i.e. they do not meet the minimum data set for identification.
- ✓ Specimen is collected in wrong tube.
- ✓ Improper transportation conditions (for samples collected outside of CBACS).
- ✓ Sample is received in a hazardous condition e.g. leaking or sharps attached.
- ✓ Request form is incorrectly completed with less than the minimum data sets for patient identification.
- ✓ Sample is un-labelled or incorrectly labelled with less than the minimum data sets for patient identification.
- ✓ Mismatch of details between the form and sample(s).
- ✓ The information provided is illegible.
- ✓ Clots in any tube containing an anticoagulant (e.g. EDTA – pink top vacutainer)
- ✓ Inadequate volume of blood in anticoagulant tube
- ✓ Specimens in nonsterile containers
- ✓ Insufficient specimen
- ✓ Presence of hemolysis
- ✓ Lipemic sample
- ✓ Collected at wrong time

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Picture 4.0: Sample Container Labelling

Table 3.0: Sample collection: *Guide for Sample Type, Container & Volume*

DEPARTMENT	TEST	SAMPLE	CONTAINER	VOLUME
Biochemistry	Comprehensive Metabolic Panel	Blood (VB)*	Lithium Heparin (Green top) vacutainer	3ml (100µl)
	Electrolyte Panel			
	Lipid Panel			
	Urinalysis	Urine	Sterile container	15ml
	Microalbumin/Creatinine	Urine	Sterile container	5ml (40µl)
Haematology	Full Blood Count Blood Grouping	Blood (VB)	EDTA (Violet top) vacutainer	3ml
	HbA1c	Blood (FP)*	NA	(1µl)
	Malaria RDT	Blood (FP)	NA	(5µl)
	hCG	Urine	Sterile container	5ml (200µl)
Immunochemistry	iChroma Parameters	Blood (VB/FP)	EDTA (Violet top) vacutainer	3ml
Microbiology	Stool microscopy	Stool	Sterile container	1g
Immunochemistry	RDTs (HBsAg; HCV; Syphilis) Gonorrhea	Blood (VB/FP) Swab	EDTA/Plain vacutainer Swab	3ml
*	*(VB) – Venous blood; (FP) – Finger prick*			

Table 4.0: Monitoring Compliance with Procedural Document

What is being Monitored	Who will carry out the Monitoring	How often	How Reviewed/ Where Reported to
Accuracy of request form & specimen container labelling. Suitability of samples for analysis.	Phlebotomist	Every request checked.	As detailed above **(16.5)**, breaches which prevent analysis will be recorded on outgoing reports in place of the results. Clinical staff may have to re-label unrepeatable specimens before they can be analysed.

Table 5.0: Current Laboratory Tests Conducted at CBACS

LABORATORY SECTION	PANEL/SET NAME	Tests conducted
BIOCHEMISTRY	**COMPREHENSIVE METABOLIC PANEL** **(14 Parameters)**	• Sodium; Potassium • Chloride; Total CO_2 • Glucose; BUN • Aspartate aminotransferase • Alanine aminotransferase • Alkaline Phosphatase • Creatinine; Calcium • Total Protein; Albumin • Total Bilirubin
	ELECTROLYTE PANEL **(4 Parameters)**	• Sodium; Potassium • Chloride; Total CO_2
	LIPID PANEL **(10 Parameters)**	• Triglycerides; ALT; AST • Total Cholesterol; Glucose • HDL; LDL; VLDL • Non-HDL Cholesterol • TC:HDLC
	URINALYSIS **(10 Parameters)**	• Bilirubin, Blood; Glucose • Ketone; Leucocytes; Nitrite • pH; Protein; Specific Gravity • Urobilinogen
	MICROALBUMIN/CREATININE **(3 Parameters)**	• Albumin; Creatinine • Albumin/Creatinine Ratio

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LABORATORY SECTION	PANEL/SET NAME	Tests conducted
HAEMATOLOGY	**FULL BLOOD COUNT**	• Haemoglobin; WBC; RBC; PCV • MCV; MCH; MCHC; Platelets • Lymp%; Mono%; Gran%; Lymp# • Mono#; Gran#; RCDW; MPV
	Haemoglobin A1c	• Haemoglobin A1c
	Malaria RDT	• Malaria RDT
	PREGNANCY TEST	• hCG
	ABO GROUPING; RhD TYPING	• Blood Grouping

LABORATORY SECTION	PANEL/SET NAME	Tests conducted
MISCELLANEOUS	**MICROSCOPY**	• Stool ova, cysts & parasites • Urine deposit
	RDTs	• HBsAg • HCV • Syphilis • Gonorrhea

LABORATORY SECTION	PANEL/SET NAME	Tests conducted
IMMUNOCHEMISTRY	**CARDIAC MARKERS**	• Tn1; D-Dimer; Myoglobin; Cardiac Triple
	CANCER MARKERS	• PSA; AFP; ifob Neo; CEA
	HORMONE MARKERS	• FSH; Progesterone; Prolactin; Testosterone;
	INFECTION MARKERS	• CRP; Procalcitonin
	GASTRO-INTESTINAL	• ROTA
	OTHERS	• H. pylori

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17. General Safety Information

- ***Protecting Yourself from Biohazards***

By definition, a biohazardous condition is a situation involving infectious agents biological in nature, such as the hepatitis B virus, the human immunodeficiency virus, and the tuberculosis bacterium. These infectious agents may be present in human blood and blood products and in other body fluids.

This information summarizes the established guidelines for handling laboratory biohazards.

Use this summary for general information only. It is not intended to replace or supplement your institution's biohazard control procedures.

The following are the major sources of contamination when handling potentially infectious agents:

- ✓ needlesticks
- ✓ hand-to-mouth contact
- ✓ hand-to-eye contact
- ✓ direct contact with superficial cuts, open wounds, and other skin conditions that may permit absorption into subcutaneous skin layers
- ✓ splashes or aerosol contact with skin and eyes

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To prevent accidental contamination in a clinical laboratory, strictly adhere to the following procedures:

- ✓ Wear gloves while servicing parts of the system that have contact with body fluids such as serum, plasma, urine, or whole blood.
- ✓ Wash your hands before going from a contaminated area to a noncontaminated area, or when you remove or change gloves.
- ✓ Perform procedures carefully to minimize aerosol formation.
- ✓ Wear facial protection when splatter or aerosol formation are possible.
- ✓ Wear personal protective equipment such as safety glasses, gloves, lab coats or aprons when working with possible biohazard contaminants.
- ✓ Keep your hands away from your face.
- ✓ Cover all superficial cuts and wounds before starting any work.
- ✓ Dispose of contaminated materials according to the laboratory's biohazard control procedures.
- ✓ Keep your work area disinfected.
- ✓ Disinfect tools and other items that have been near any part of the system sample path or waste area with 10% v/v bleach.
- ✓ Do not eat, drink, smoke, or apply cosmetics or contact lenses while in the laboratory.
- ✓ Do not mouth pipet any liquid, including water.
- ✓ Do not place tools or any other items in your mouth.
- ✓ Do not use the biohazard sink for personal cleaning such as rinsing coffee cups or washing hands.
- ✓ Do not recap, purposely bend, cut, break, remove from disposable syringes, or otherwise manipulate needles by hand. Needlestick injuries may result.

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APPENDIX-001 Laboratory Request Form (Haematology Form)

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H A E M A T O L O G Y

Request Date:		**Type of Specimen:**	**Blood**		**Urine**		
Request(s) Full		**Blood Count**	**HbA1c**		**Blood**		**Grouping**
Malaria RDT		**hCG**					
Requesting Hospital/Clinic/Pharmacy							
Requesting Health Officer; Name:					**Tel.:**		
Patient's Name:				**Age:**	**Sex:**	**M/F**	

L A B O R A T O R Y R E S U L T S

BLOOD ASSAY	RESULT	REF RANGE	BLOOD ASSAY	RESULT	REF RANGE
Haemoglobin	g/dl	Children at birth..13.5 - 19.5g/dl Children 2 - 5y..11.0 - 14.0g/dl Children 6 - 12y..11.5-15.5g/dl Adult men……13.0 - 18.0g/dl Adult women..12.0 - 15.0g/dl (Pregnant women) 11.0 - 13.8g/dl	Lymphocytes %		20 – 40%
			Monocytes %		2 – 8%
			Granulocytes %		55 – 70%
			Lymphocytes #		1000 - 4000/mm^3
White Blood Cells	$x10^9/L$	Children at 1 y..6.0 - 18.0 $x10^9/L$ Children 4 - 7y..5.0 - 15.0 $x10^9/L$ Adults……4.0 - 10.0 $x10^9/L$ Adults of African origin …… 2.6 - 8.3 $x10^9/L$ Pregnant women…… Up to 15 $x10^9/L$	Monocytes #		100 - 700/mm^3
			Granulocytes #		2500 - 8000/mm^3
			Red Cell Dist. Width		11.5 - 14.5%
Red Blood Cells	$x10^{12}/L$	4 - 6.5 $x10^{12}/L$	Mean Platelet Volume		7.5 - 11.5fl
PCV	%	Children at birth…..44 - 54% Children 2 - 5y…..34 - 40% Children 6 - 12y…..35 - 45% Adult men……40 - 54% Adult women……36 - 46%			
MCV	fl	76 - 97fl	Haemoglobin A_{1c}	%	Normal 4% - 5.6% Prediabetic: 5.7% - 6.4% Diabetic ≥ 6.5%
MCH	pg	27 - 31 picograms			
MCHC	g/dl	31.8 - 36 g/dl	Blood Group		
Platelets	$x10^9/L$	142 - 424 $x10^9/L$			
			URINE ASSAY	RESULT	
			hCG		
Malaria RDT					
Date Reported:			Laboratory Manager's Signature:		

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APPENDIX-002 Laboratory Request Form (Biochemistry Form)

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B I O C H E M I S T R Y

Request Date:	**Type of Specimen: Blood**		**Urine**		
Request(s)		**Comprehensive Metabolic Panel Electrolyte**		**Panel Lipid Panel**	
Urinalysis		**Microalbumin/Creatinine**			
Requesting Hospital/Clinic/Pharmacy					
Requesting Health Officer; Name:			**Tel.:**		
Patient's Name:			**Age:**	**Sex:**	**M/F**

L A B O R A T O R Y R E S U L T S

BLOOD ASSAY	RESULT	REF RANGE	URINE ASSAY	RESULT	REF RANGE
Sodium		128 - 145 mmol/L	Bilirubin		0.1 – 1.2mg/dl (1.71-20.5µmol/l)
Potassium		3.6 - 5.1 mmol/L	Blood		<3RBC's/HPF
Chloride		98 - 108 mmol/L	Glucose		0 – 0.8mmol/l
Total CO_2		18 - 33 mmol/L	Ketone		<0.6
Glucose		73 - 118 mg/dL	Leucocytes		0 – 5 WBC/HPF
Blood Urea Nitrogen		7 - 22 mg/dL	Nitrite		1.003 – 1.030
Aspartate aminotransferase		11 - 38 U/L	pH		4.6 – 8.0
Alanine Aminotransferase		10 - 47 U/L	Protein		150mg/24hr
Alkaline Phosphatase		53 - 128 U/L	Specific Gravity		1.005 – 1.030
Creatinine		0.6 - 1.2 mg/dL	Urobilinogen		0.1-1.8mg/dl (1.7-30µmol/l
Calcium		8.0 - 10.3 mg/dL			
Total Protein		6.4 - 8.1 g/dL	Albumin		<30mg/g
Albumin		3.3 - 5.5 g/dL	Creatinine		955-2936mg (M); 601-1689mg (F)/24hr
Total Bilirubin		0.2 - 1.6 mg/dL	Albumin/creatinine ratio		≤17mg/g (M); ~25mg/g (F)
eGFR		≥ 60 ml/min			
Triglycerides		< 150mg/dl			
Total Cholesterol		≤ 200mg/dl			
HDL		≥ 40mg/dl			
LDL		≤ 100mg/dl			
VLDL		2 - 30mg/dl			
Non-HDL Cholesterol		< 130mg/dL			
TC:HDLC		≤ 6			

Date Reported:	**Laboratory Manager's Signature:**

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APPENDIX-003 Laboratory Request Form (Immunochemistry Form)

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IMMUNOCHEMISTRY

Request Date: | **Type of Specimen:** ☐ **Blood**

Request(s) ☐ CARDIAC MARKERS ☐ HORMONES ☐ CANCER MARKERS ☐ AUTOIMMUNE ☐ INFECTION MARKERS

Requesting Hospital/Clinic/Pharmacy

Requesting Health Officer; Name: | **Tel.:**

Patient's Name: | **Age:** | **Sex:** M/F

LABORATORY RESULTS

BLOOD ASSAY	RESULT	REF RANGE	BLOOD ASSAY	RESULT	REF RANGE
CARDIAC MARKERS					
Troponin-1 (Tn-1)		0.10 – 50ng/mL	Cardiac Triple: Tn-1		0.01-15ng/ml
D-Dimer		50-10,000ng/mL	CK-MB		3-100ng/ml
Myoglobin		5-500ng/mL	Myoglobin		5-500ng/ml
HORMONES					
Thyroid Stimulating Hormone (TSH)		0.34-5.6µIU/mL (Adult)	Progesterone		MALE (Mean): 0.84ng/mL FEMALES mid-follicular phase (0.69) mid-luteal phas 11.42 post-menopaus 0.25 PREGNANCY first trimester 22.17 second 29.73
Follicle-stimulating Hormone (FSH)		FEMALES: Follicular Phase (3-11mIU/mL) Mid-Cycle 6-21 Luteal Phase 1-9 Postmenopausal 22-153 MALES: 1-11mIU/mL			
Prolactin (PRL)		WOMEN Menstrual cycle 5-35ng/mL Menopausal phase 5-35ng/mL MEN 3-25ng/mL	Testosterone		2-8ng/mL
AUTOIMMUNE					
Rheumatoid arthritis IgM (RF IgM)		15IU/mL	Anti-Cyclic Citrullinated Protein (Anti-CCP)		5.0U/mL
CANCER MARKERS			**INFECTION**		
Prostate Specific Antigen (PSA)		4.00ng/mL	C-Reactive Protein (CRP)		10mg/L
Alpha-fetoprotein (AFP)		≤10.9ng/mL	Procalcitonin (PCT)		0.5ng/mL
Carcinoembryonic antigen (CEA)		Non-Smoker 4ng/mL Smoker 5ng/mL			

Date Reported: | **Laboratory Manager's Signature:**

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APPENDIX-004 Laboratory Request Form (Miscellaneous Form)

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Request Date:		**Type of Specimen:**	☐	**Blood**	☐	**Urine**	☐	**Stool**	
Request(s)	☐	**Urine Microscopy**	☐	**Stool Microscopy**	**HBsAg**	☐	**HCV**	☐	**Gonorrhea**
Syphilis	☐		☐						
Requesting Hospital/Clinic/Pharmacy									
Requesting Health Officer; Name:							**Tel.:**		
Patient's Name:						**Age:**	**Sex:**	**M/F**	
L A B O R A T O R Y R E S U L T S									
					Rapid Diagnostic Tests				
Urine microscopy					**HBsAg**				
					HCV				
Stool Microscopy					**Gonorrhea**				
					Syphilis				
Date Reported:				**Laboratory Manager's Signature:**					

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APPENDIX-005 Laboratory Investigations Instructions (Sample collection/Turn Around Times)

TESTS	SPECIMEN TYPE	SPECIAL INSTRUCTIONS	TURN AROUND TIME	COMMENTS
CBC (Complete Blood Count)	3 ml EDTA whole blood (PURPLE Top tube)	Specimen cannot be clotted.	1 hour	Includes RBC, WBC, Hgb, Hct, Indices, Platelet Count, RDW, MPV, Differential and Morphology
Complete Metabolic Profile (CMP)	3ml Li. Hep./1 ml Serum/ Plasma (GREEN or RED Top tube)	Discs can be used directly from the refrigerator (stored at 2–8 °C) without warming.	1 hour	Usually a fasting specimen. Profile includes: Glucose, BUN, Creatinine, Bun/Creatinine ratio, Sodium, Potassium, Chloride, Calcium, Alkaline Phosphatase, AST/SGOT, ALT/SGPT, Bilirubin Total, Total protein (serum), Albumin, Globulin, A/G Ratio, Total CO_2.
Electrolyte Panel	3ml Li. Hep./1 ml Serum/ Plasma (GREEN or RED Top tube)		1 hour	Panel includes: Sodium, Potassium, Chloride, Total CO_2
Lipid Panel	3ml Li. Hep./1 ml Serum/ Plasma (GREEN or RED Top tube)		1 hour	Usually a fasting specimen. Profile includes: Triglycerides, HDL, LDL, Total Cholesterol, VLDL, nHDLc, TC:HDLC, Glucose, ALT, AST
ABO Group and Rh type Blood typing ABO & Rh	3 ml EDTA whole blood(PURPLE Top tube)		1 hour	

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Urinalysis	15ml Urine		30 mins	Profile includes: Glucose, Bilirubin, Ketone, Specific gravity, Blood, pH, Protein, Urobilinogen, Nitrite and Leucocytes
Microalbumin/Creatinine	15ml Urine		30 mins	Albumin and Creatinine
Haemoglobin A1c	Whole blood (Finger prick)		30 mins	
Malaria RDT	Whole blood (Finger prick)		30 mins	
Blood Grouping	Whole blood (Finger prick)		30 mins	
Pregnancy Test	5ml Urine	First morning urine is the best sample	30 mins	
Stool microscopy	1g stool		30 mins	
<u>RDTs:</u> • **HBsAg** • **HCV** • **Syphilis** • **Gonorrhea**	3 ml EDTA whole blood(PURPLE Top tube)/Serum/Plasma • Swab		1 hour for each test	

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i-CHROMA TESTS: (Cardiac) • **Tn1** • **D-Dimer** • **Myoglobin** • **Cardiac Triple**	• S*/P* • Whole Blood/P Whole Blood/P/S		1 hour for each test	**Anticoagulant of choice:** Sodium Heparin/Lithium Heparin/ Sodium Citrate Sodium Citrate EDTA/Heparin/Sodium citrate Heparin/Sodium citrate
i-CHROMA TESTS: (Infection) • **CRP** • **PCT**	Whole Blood/P/S		1 hour for each test	**Anticoagulant of choice:** K_2EDTA/K_3EDTA/ Sodium Heparin K_2EDTA/Sodium Heparin/Sodium citrate
i-CHROMA TESTS: (Cancer) • **PSA** • **AFP** • **CEA**	S/P		1 hour for each test	**Anticoagulant of choice:** EDTA only K_2EDTA/K_3EDTA/Sodium Heparin K_2EDTA/K_3EDTA/Sodium Heparin

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i-CHROMA TESTS: (Hormones) • **TSH** • **FSH** • **Progesterone** • **Prolactin** • **Testosterone**	S/P		1 hour for each test	**Anticoagulant of choice:** Sodium Heparin K_2EDTA/K_3EDTA/Sodium Heparin K_2EDTA/K_3EDTA/Sodium Heparin K_2EDTA K_2EDTA
i-CHROMA TESTS: (Autoimmune) • **RF IgM** • **Anti-CCP Plus**	Whole Blood/P/S		1 hour for each test	**Anticoagulant of choice:** EDTA/Lithium Heparin/Sodium citrate K_2EDTA/K_3EDTA/Sodium citrate
*S**	*Serum*			
*P**	*Plasma*			

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APPENDIX-006 Information on Samples Collected Outside CBACS

CBACS would prefer, as much as possible, to conduct its laboratory analysis from samples collected on site, within its laboratory complex. However, this may not always be possible and therefore the following instruction is provided to guide the collection, preservation and transport of samples collected outside CBACS in order to ensure sample integrity and the quality of results.

Specimens will not be accepted for analysis if: -

- ✓ Specimen is collected in wrong tube ***(Refer to: APPENDIX-005 Laboratory Investigations Instructions (Sample collection/Turn Around Times)***.
- ✓ Improper transportation conditions.
- ✓ Sample is received in a hazardous condition e.g. leaking or sharps attached.
- ✓ Sample is not labelled or incorrectly labelled with less than the minimum data sets for patient identification.
- ✓ Mismatch of details between the form and sample(s).
- ✓ The information provided is illegible.
- ✓ Clots in any tube containing an anticoagulant (e.g. EDTA – pink top vacutainer)
- ✓ Inadequate volume of blood in anticoagulant tube
- ✓ Specimens in nonsterile containers
- ✓ Presence of hemolysis
- ✓ Lipemic samples