Introduction- A Doctor's Guide to CML Testing

- Chromosome Analysis
- Molecular Genetics

C. DNA Paternity Testing**.....**

- Full Trio
- Motherless Testing
- Prenatal Testing
- Grand Parentage Testing
- Sibling Testing
- First Cousin Testing
- Aunt/Uncle Testing
- Deceased Sample

Immune Disorders .....

- Gastric Parietal Cell Antibodies
- Intrinsic Factor Blocking Antibodies
- HLA B27 Antigen
- Insulin Antibodies
- JO –1 Antibodies
- RNP Antibodies
- SM Antibodies
- Sjögren's Antibodies
- Thyroglobulin Antibodies

Infectious Diseases .....

A. Chlamydia Trachomatis **.....**

- Antigen Identification Test / Spot Test
- Nucleic Acid Amplification Test

B. Helicobacter Pylori **.....**

- Antibody Detection
- Antigen Detection

C. Human Papilloma Virus, DNA**.....**

D. Hepatitis C Virus (HCV)**.....**

- HCV, Antibody, EIA
- HCV, Antibody, RIBA
- HCV, Genotyping
- HCV, RNA, Qualitative
- HCV, RNA, Quantitative

Thrombophilia Testing.....

A. Hereditary Thrombophilia**.....**

- Activated Protein C Resistance
- Antithrombin III Antigen and Activity
- D- Dimer
- Factor V Leiden

- Homocysteine
- Protein C - Antigen and Activity
- Protein S - Antigen and Activity

B. Acquired Thrombophilia .....

- Cardiolipin Antibodies
- Lupus Anticoagulant

Toxicology .....

- Amphetamine
- Cannabis
- Cocaine
- Heroine
- Lead, Blood
- Nicotine
- Mercury, Blood
- Mercury, Urine

Tumor Markers .....

- CA 125
- CA 15-3
- CA 19-9
- CA 27-29
- CA 72-4
- CEA
- Alpha Fetoprotein
- Neuron Specific Enolase

Tests Requiring Special Collection/ Handing .....

Samples Requiring Special Collection/ Handing .....

General Information .....

- Overseas Tests .....
- Cross Matching of Blood & Blood Products .....
- Malaria Testing .....
- Pap Smears .....
- Semen Analysis .....

Appendix .....

Introduction - A Doctor's Guide to CML Testing

Central Medical Laboratories Ltd (CML) is pleased to announce that we have added three new Collection Centres to our existing 20 locations. These collection centres were strategically placed to serve you our doctors and patients better. The new locations are as follows:-

- Shop # 37, Winchester Business Centre, 15 Hope Road, Kingston 10
- Alma Jones Medical Centre, 109 Hagley Park Road, Kingston 11
- Liguanea, 129 Old Hope Road, Kingston 6

Our guiding principle at CML is Quality through Excellence and, Excellence through Quality.

We have a comprehensive Quality Assurance Programme in place utilizing the best commercially prepared Quality Control materials, and through our participation in external quality assurance programmes we ensure constant monitoring of our testing processes.

We regularly upgrade our laboratory equipment to incorporate new test methods as they become available and invite you to suggest new tests or procedures that will assist you in your diagnostic process.

At CML we also provide a reference service for tests not available locally through our affiliations with some of the most reputable overseas laboratories.

Our state-of-the-art Laboratory Information System (LIS) facilitates the generation of unique patient identification numbers, performance of audit trails for each patient, fast and accurate data-entry, improved turn-around-time for results and the ability to fax results directly to our doctors.

MOTTO

"The Complete Laboratory Service"

VISION STATEMENT

To be the leader in quality diagnostic services, through highly qualified staff, state-of-the art equipment, efficient information systems and excellent customer service relationships.

OBJECTIVE

- To observe the highest international standard of medical laboratory testing, by keeping up-to-date with technological innovations.
- To maintain the integrity of our highly professional staff.
- To be good corporate citizens.
- To offer excellent customer service backed by technical competence and technology.
- To continue building and growing through teamwork.
- To provide "Quality through Excellence" and "Excellence through Quality"

SERVICES AND POLICIES

A. RESULTS

Our turn-around-time for routine tests is within a 24-hour period. Cultures and other special tests analyses can take up to 3 days. All results that are needed promptly will be given priority over routine requests.

We are proud to have a Laboratory Information System (LIS), which captures patient data with a unique patient ID. This patient ID assists us to track the patient's results and monitor trends in their condition.

Our Medical Records department dispatches results twice daily using six in-house couriers for the corporate area.

Most of our reference ranges are age and gender specific.

It is important to keep us updated with your contact information (Fax number, Cellular number, and Pager service) to ensure prompt delivery of patient results.

B. QUALITY ASSURANCE

We participate in recognized External Quality Assurance Programmes with reputable overseas companies to ensure accuracy and reliability. Quality Control materials are analyzed daily and results are carefully reviewed before test results are reported.

C. REPEAT DETERMINATION

Whenever a test result appears inconsistent with the clinical evaluation of the patient, we will gladly repeat the test at no additional charge.

It is important that you call **immediately** upon receipt of the report for a repeat determination as we normally hold specimens for a limited time only.

D. COURIER SERVICE

We provide a daily pick-up and delivery service (Kingston Metropolitan area only) and will be happy to arrange a daily schedule so that specimens taken in the office can reach to us promptly. Please contact our Medical Records Department to make these arrangements.

E. STATS

STAT testing is available for some laboratory procedures. Please tick box provided on the request form.

STAT reports will be telephoned or faxed to you as soon as the analysis is completed: Written confirmation of the test result will be delivered by courier on the following working day.

There is a Per Test **STAT FEE** – Please see schedule.

F. HOUSE CALLS and OFFICE CALLS

House calls and office calls can be readily arranged by phoning our offices, and a trained phlebotomist will be provided. Please contact our headquarters for instructions, and to schedule the appointment.

It is usually best to make these arrangements the day before service is required.
Where the service is required on a Saturday additional notice will be necessary.

A FEE IS CHARGED FOR THIS SERVICE.

G. EMERGENCY SERVICE

The laboratory offers a 24-hr EMERGENCY SERVICE in the Corporate area only for hospitalized or critically ill persons.

This service is activated after our offices close. **Calls for Reports cannot be handled by the Emergency Medical Technologist.**

After closing time the Medical Technologist is available on a call out basis via **835-8400**.
There is a Fee for this service.

H. CHARGE/BILLING SERVICE

Prior arrangements must be made by a physician or company, in writing to the Financial Controller to activate a chare/billing service. One (1) month's notice is required for processing and approval.

Verbal requests for credit will **not** be accepted. No junior member of staff is authorized to extend credit.

Fees for patients may be billed to the doctor/company only where this is clearly indicated on the request forms and **prior** arrangements made. These charges will be billed weekly and payment of all invoices is due upon receipt of said invoice.

I. HEALTH INSURANCE

We accept all the major health insurance cards – Blue Cross, EBA, etc.

Most insurance companies have restrictions on the provision of service to their clients.

1. They restrict payment for tests such as:
    - Infertility checks
    - Pregnancy tests
    - Pap Smear (1 per year)
    - Hormone Assays
    - Any test related to Pregnancy (sugars, urinalysis, etc.) for persons on an individual plan, etc.

Health insurance cards have to be taken on individual merit.

2. Some businesses have different types of coverage and will therefore have varied benefits for the different categories of employees.

Based on any of these above-mentioned factors the patient may be charged for the tests and in turn will have to claim from their insurance company. A detailed receipt will be provided.

Receipts will not be given where insurance cards only are used.

THE LAB WILL ONLY ACCEPT THE ORIGINAL AND VALID MEMBERSHIP CARD BEARING THE PATIENT'S NAME

J. OVERSEAS REFERRALS

CML works closely with accredited laboratories overseas to expand our test menu in order to provide our clients with a comprehensive service.

Due to low volume request and the need for certain specialized equipment, some tests are referred. Referral services to some United States laboratories such as **Quest Diagnostics**, **Specialty Laboratories**, **GeneCure Laboratories** (formerly Cytogenetics Laboratory) and **LabCorp** are offered.

Special arrangements can be made for the handling of these specimens by contacting the Laboratory at 754-6199 to 6202 or 960-4391-2.

Specimens are sent off in most instances by the following day of receipt by courier and most reports are received within 7 days by FAX (followed by the original report in the mail).

THERE IS A SUPPLEMENTAL CHARGE FOR THE SERVICE – MADE UP OF OVERSEAS CHARGES IN US$ AND LOCAL HANDLING CHARGES.

K. LOCAL REFERRALS

CML works with other labs and medical professionals in Jamaica to provide processing of certain specimens e.g. HISTOLOGY, CROSS MATCH, PAP SMEARS, etc.

THESE SERVICES ARE USUALLY VERY EXPENSIVE AND THEREFORE COLLECTION OF CHARGES UP FRONT MAY BE REQUIRED.

THE CHARGES FOR THESE SERVICES ARE NOT SUBJECT TO DISCOUNTS OR PROFESSIONAL COURTESIES.

L. PROFESSIONAL COURTESY

Professional courtesy is extended to physicians and their immediate family (spouse and children only) in regard to tests and services done in our laboratory.

There will be a charge for tests which have to be referred (Cross Match, Histology, etc. – unless prior arrangements have been made) and for some special in house tests which are particularly expensive.

M. BLOOD BANK – CROSS MATCHING

Requests for blood for transfusion are handled by the Blood Bank. The Bank suffers from a chronic shortage of available blood and it is therefore important that all requests represent only what is necessary.

If the blood supplied is not transfused it is important that it be released back to the Blood Bank by the physician within a couple days.

The charge for cross matching is not for the unit of blood (blood product) itself , but for the processing and preparation of the supply – and therefore will be incurred in any of the following circumstances: -

a) Cross-Matching but no available supply at the time transfusion is required;

b) Blood delivered but not transfused.

PROFESSIONAL COURTESY DOES NOT APPLY TO THIS SERVICE.

N. SPECIAL PROJECTS AND MEDICALS

CML offers services for special medical investigations and company medicals. Discounts are offered based on volume. Please contact the Business Development Manager to make arrangements for scheduling of specimen collection and processing.

SPECIMEN COLLECTION AND PREPARATION

To ensure accurate results it is important that these instructions below are strictly followed. Laboratory results are as dependent on the integrity of the specimen, as they are upon the actual testing procedure. Where the lab provides the collection supplies, there is an additional charge to the patient or client. (See Service Fees)

LABELLING

This must be accurate. Each Specimen should be labeled in waterproof ink.

1. Ask the patient to repeat their name.
2. Check this against the request form.
3. Write the
    (a) Patient's full name
    (b) Test/s
    (c) Lab #
4. Attach the label to the container.

BLOOD COLLECTION

Blood collection tubes (vacutainers) are designed to be filled via their internal vacuum to a predetermined volume which is optimue for the amount of additive in the tube.
DO NOT remove the stopper to fill, as this may result in an unequal ratio of specimen anticoagulant, leading to clotting or excessive specimen dilution.

Vacutainer Tube Guide -

STOPPER COLOUR	ADDITIVE	No. of Inversions at Blood Collection	LABORATORY USE
RED 	**None**	**None**	For Serum determination in Chemistry, Immunology, Haematology, Endocrinology
LIGHT BLUE 	**Sodium Citrate**	**4**	For coagulation determinations of plasma specimens e.g. (PT, PTT, Fibrinogen, Lupus Anticoagulant)
GREEN 	**Sodium Heparin/ Lithium Heparin**	**8**	For Blood Chromosome Analysis
GREY 	**Sodium Fluoride**	**8**	For Glucose determination. Antiglycolytic additives stabilize glucose values for up to 24 hours at room temperature.
PURPLE 	**Liquid EDTA or Freeze dried EDTA**	**8**	For whole blood Haematology determination.
YELLOW 	**Acid Citrate Dextrose (ACD)**	**8**	For whole blood in special tests e.g. Lymphocyte surface markers
ROYAL BLUE 	**-Sodium Heparin** **-Sodium EDTA** **-None (Serum)**	**8** **8** **None**	For Trace elements, toxicology and nutritional chemistry determinations. Special stopper formulation provides low levels of trace elements.

TUBE INVERSION PREVENTS CLOTTING.

SERUM SEPARATOR TUBES (SST) with barrier gel.
SST should not be used to obtain specimens for Therapeutic Drug Monitoring, Toxicology analyses or Immuno-haematology testing - UTILIZE RED TOP TUBES FOR THESE SAMPLES.

Instructions for use of SST:

1. Draw 5 ml of whole blood for every 2 ml of serum required.
2. Fill the tube by vacuum – DO NOT REMOVE THE RUBBER STOPPER
3. Invert the tube gently 4-5 times.
4. Allow the blood to clot for 25-30 minutes.
5. Centrifuge the tube at 2200-2500 RPM for 15-20 minutes.
6. Do not remove the serum from the tube.
7. Send the SST tube to the laboratory.

SERUM: (Red stopper – no preservative)

1. Using a vacutainer tube or syringe and needle to collect specimen.
2. Draw sufficient blood to yield the necessary serum volume.
3. Allow blood to clot at room temperature in the tube (not in the syringe).
   Separate serum by centrifugation within one hour after collection – THIS IS ABSOLUTELY NECESSARY TO PRESERVE CHEMISTRY VALUES. AVOID HAEMOLYSIS.

PLASMA: Specimens requiring plasma for analysis should be handled in the following manner:

1. Fill the appropriate tube (lavender/purple top, green top, etc.) by vacuum. Draw 5 ml. of blood for every 2 ml of plasma required.
2. Gently invert the tube 8 times to allow mixing of the sample with the anticoagulant.
3. Immediately centrifuge the sample.
4. Remove the supernatant plasma and transfer to a plastic tube.

FROZEN SPECIMEN: Specimens for certain assays must be kept frozen because the constituent to be assayed is not stable at higher temperatures.

1. **SERUM OR PLASMA**
   The specimen (serum/plasma) must be frozen immediately after separation.
   Never freeze samples in a glass tube. Following centrifugation and separation from the cells, transfer the serum or plasma to a tightly stoppered, properly labeled plastic tube and freeze.
2. **WHOLE BLOOD**
   Whole blood should not be frozen due to the haemolytic effect of thawing red blood cells.
3. **URINE**
   When indicated, freeze in a tightly sealed, screw-top, water-tight plastic container which has been properly labeled.
4. **CEREBROSPINAL FLUID (CSF)**
   When freezing CSF, the specimen should be placed in a properly labeled, tightly stoppered plastic tube.

TRACE METALS
Opaque 3000 ml brown glass/plastic bottles are required for metal analyses in urine.
Blood for trace metals must be drawn into special tubes. **Contact the Lab for supplies**.

BLOOD – ALCOHOL
The blood collection site MUST be free from alcohol i.e. Alcohol swab should not be used at the point of venipuncture.

CORTISOL
If AM and PM samples are requested, the PM sample must be collected at least 7 hours AFTER the AM sample.

BLOOD – GLUCOSE
RANDOM specimens – The time of the patient's last meal is not relevant.

FASTING specimens – The time of the patient's last meal is **very** important. (Minimum of 3 hours fast/ maximum of 10 hours fast). If patients is fasting for less than 10 hours this should be noted on the request form.

BLOOD GLUCOSE – O'Sullivan
Patient is given 50gm. of glucose solution and samples of blood and urine collected one hour after. Patient does not need to be fasting.

GLUCOSE TOLERANCE (GTT)
Patient for a GTT should have completed a 10 hour FAST. No food or drink to be taken before the test is started. Patients MUST remain in the Laboratory throughout the procedure, and timed collections taken as prescribed. *The GTT test may last from 2 to 6 hours.*

The patient must be carefully monitored for signs of distress:-

- -Sweating
- -Faintness
- Nausea
- Lethargy
- Dizziness

When any sign of distress is observed, terminate the test, and contact the requesting physician for instructions.

OTHER SPECIMENS

A. CHLAMYDIA TRACHOMATIS

Contact the Lab for instructions on specimen collection.

B. CYTOLOGY

Fluids – Various body fluids are accepted for cytology (e.g. urine, sputum, aspirates, etc.). 50% alcohol should be added in equal proportions to these specimens.

Pap Smears-

1. Material collected with a spatula should be smeared horizontally on the slide in a zig-zag motion;
2. The specimen should be smeared evenly and quickly on the slide;
3. If a brush is used, rotate the brush, starting at one end of the slide, until the clear glass surface is covered. Use moderate pressure while rotating the brush;
4. It is important that Pap Smear slides be thoroughly sprayed immediately after the collection with aerosol fixative;
5. Allow the slides to dry before placing them in the slide holder;
6. Slides must be clearly labeled with the patient's name. Use slides with a frosted (opaque) end and a soft lead pencil;
7. Complete the Cytology request form;

C. FAECES/STOOL SAMPLES

FAECES/ STOOL CULTURE

Tests may be done on specimen collected in any of the following ways:

1. Collect freshly passed stool in a dry sterile container;
2. A rectal swab; or
3. Stool in glycerol saline.

FAECES FOR OVA & PARASITES

A stool specimen in 10% formalin is required.

FAECES FOR OCCULT BLOOD

A stool specimen in a clean dry container is required.

FAECES FOR AMOEBA

Fresh, warm stool without preservative is needed.
Specimen should be transported in warm water or kept close to the body for warmth.

SPECIMENS FOR CULTURE

BLOOD FOR CULTURE

The specimen must be collected in a prepackaged BLOOD CULTURE BOTTLE using aseptic technique.

1. Clean the rubber bung at the top of the BLOOD CULTURE BOTTLE with an alcohol swab,
2. Prepare the venipuncture site (using iodine followed by alcohol swab);
3. Draw the blood with a syringe. (2ml. blood to a 20ml. blood culture bottle/ 5ml. blood to the 50ml. blood culture bottle);
4. Change the needle on the syringe before specimen is vented into the blood culture bottle.

Specimen should NEVER be refrigerated. Place in an incubator 35-37°C or store at room temperature.

BODY FLUIDS FOR CULTURE

e.g. Cerebrospinal Fluid (C.S.F),
Pleural
Joint Fluids

Collect aseptically and submit in sterile container.

SPUTUM

The specimen must be collected after the patient awakens in the morning and after he/she has brushed their teeth and rinsed their mouth with water.

1. Raise sputum from deeper air passages by coughing and expectorating into a sterile wide mouth bottle – obtained from the Lab.
2. Specimen should be taken to the Lab as soon as possible. Specimen may be refrigerated until it can be brought to the Laboratory.

Sputum for CULTURE and ACID FAST BACILLI (AFB/TB) should be collected in two separate sterile containers.

SWABS - (EYES, EARS, THROAT, WOUND, H.V.S., ETC)

For best results a swab and a smear on a clear slide are desirable**.**

1. Remove swab from sterile tube;
2. Roll swab, over affected area coating all cotton surfaces;
3. Return swab to sterile tube;
4. Squeeze tip of tube to release transport medium. Invert the tube so that the medium will saturate the swab.

Record on the Swab:

1. Patient's name and ID number;
2. Date and time of collection;
3. Nature and source of the specimen.

Dispatch promptly to the Lab.
Specimen should be kept cool during transportation, and may be refrigerated for no more than 24 hours before being processed by the Lab.

SMEAR

This should NOT be made with the swab which is to be used for Culture & Sensitivity.

URINE COLLECTIONS

URINE Container Labeling:
WHERE MORE THAN ONE URINE TEST IS REQUIRED SEPARATE SPECIMENS SHOULD BE COLLECTED IF POSSIBLE.

IF NOT – 1 SPECIMEN- MUST BE RECORDED ON THE LABEL AND REQUEST FORM ALONG WITH THE NAME OF THE TEST/S TO BE DONE.

M.S.U./URINALYSIS
M.S.U represents mid-stream urine collection and is usually for culture & sensitivity. (See Urine Culture & Sensitivity for instructions on the collection of mid-stream urine).

All Insurance medicals require that the urinalysis are performed on a mid-stream specimen and will therefore so indicate. BE CAREFUL to do the procedure requested.

URINE FOR CULTURE & SENSITIVITY
A mid-stream specimen is recommended.

1. Wash hands;
2. Use antiseptic towelette (if available) to clean genital area;
3. Urinate a little bit in the toilet and stop;
4. Void (urinate) the middle portion of the urine stream directly into a wide mouthed sterile container. Keep container away from genitals.
5. Stop flow, pull container away, and finish voiding into toilet;
6. Screw cover on to container immediately. (Ensure cover is secure);
7. Write the patient's full name, collection date and time on the container label.
8. Place container in a plastic bag.

Urines should be dispatched to the lab immediately after voiding. If this is not possible the specimen may be kept refrigerated for not more than 24 hours. DO NOT FREEZE.

URINE FOR GLUCOSE
A urine specimen should be collected each time a blood specimen is collected for glucose (sugar) testing.

1. This urine should be checked with a dipstick (Rapignost or Uristix) and the reading for glucose recorded on the request form.
2. If the patient is doing a Glucose Tolerance Test (GTT) or any other test requiring that a glucose drink be given and the urine glucose is anything other than NIL (i.e. Trace, +, ++, +++,++++) the fasting blood specimen must be analyzed BEFORE the GLUCOSE drink can be given.
3. Each urine collection must be labeled indicating the timed collection of blood (e.g. fasting, 1/2hr, 1hr, etc.) this is very important information for comparing and confirming results.

NOTE: If the Fasting Blood Glucose reading is 13.8mmol/L or greater, contact MUST IMMEDIATELY be made with the DOCTOR, SO THAT THE DOCTOR CAN DECIDE If the test should be continued.

24 HOUR URINE COLLECTION

Accurate collection is vital, it is therefore important that the patient be given clear instructions. 3 Litre Amber/brown bottles should be used for the collection process.
Contact Laboratory for supply.

THE PATIENT SHOULD BE ADVISED TO SELECT A DAY FOR COLLECTION WHEN HE/SHE WILL BE AT HOME.

1. Discard the first urine voided upon arising in the morning (DAY 1) – note the time;
2. Thereafter save ALL urine passed during the day in the 24 hour container;
3. All urine passed in the night and the first morning voiding of DAY 2 to the exact time at which he/she started the collection on the preceding day, should also be saved in the container;
4. If only a portion of the collection is being submitted to the Lab, the following must be recorded on the specimen or the request form:
    - The period of the collection must be recorded (e.g. 24 hrs. or 3 hrs.)

Fluid intake during 24 hr. period should be restricted as much as possible.

URINE:- Amylase [(1)]
Usually done on a 24 hour urine collection, but can be done on any timed collection. Minimum of 2 hours.

URINE FOR CREATININE CLEARANCE[(2)]
24 hour urine collection. A blood sample must be taken either during the collection period or at the end of the 24 hour urine collection.

URINE:- Microalbumin [(4)]
Usually done on a 24 hour urine collection, but can be done on any timed collection. Minimum of 3 hours.

For Microalbumin/Creatinine ratio first morning urine can be collected.

SPECIAL INSTRUCTIONS FOR 5 H.I.A.A. & VMA – 24 HOUR URINE

In order to obtain accurate results the patient is required to refrain from taking the following for at least 72 hours prior to the collection of the specimen:

5 H.I.A.A. (5-Hydroxyindole Acetic Acid) [(3)]
Pineapples
Bananas
Plums (Red)
Avocados
Tomatoes
Egg Plant

VMA (Vanillylmandelic Acid)[(5)]
Alcohol
Coffee
Tea
Tobacco
Bananas
Citrus Fruit
Strenuous Exercise

URINE FOR TB:
Three consecutive early morning urines. (The specimens need not be from a catheterized or mid-stream specimen).

The specimen should be collected in a large clean bottle containing a crystal of thymol to reduce the growth of contaminants.

PRESERVATIVES USED IN 24 Hour URINE COLLECTION

Amylase (1)	No Preservative	3L Plastic Bottle
Arsenic	No Preservative	3L Plastic Bottle
Calcium	10mls. Concentrated Hydrochloric Acid	3L Glass bottle
Citrate (Overseas Test)	No Preservative	3L Glass bottle
Cortisol	No Preservative	3L Glass bottle
Creatinine Clearance (2)	No Preservative	3L Plastic Bottle
Electrolytes	No Preservative	3L Plastic Bottle
5 HIAA (Serotonin) (3)	25mls. Glacial Acetic Acid	3L Glass bottle
17 KGS	10mls. Concentrated Hydrochloric Acid	3L Glass bottle
17 KS	10mls. Concentrated Hydrochloric Acid	3L Glass bottle
Microalbumin (4)	No Preservative(24hr or timed collection)	3L Plastic Bottle
Oxalate (Overseas Test)	25mls. 6N Hydrochloric Acid	3L Glass bottle
Phosphorous	10mls. Concentrated Hydrochloric Acid	3L Glass bottle
Proteins	No Preservative	3L Plastic Bottle
Uric Acid	No Preservative	3L Plastic Bottle

VMA **(5)**	10mls. Concentrated Hydrochloric Acid	3L Glass bottle

VIRAL SEROLOGY

Although it is sometimes possible to make a specific diagnosis based on a single viral serology result, two (2) samples are usually required called ACUTE and CONVALESCENT samples, taken at a an interval of 10-14 days apart.

The ACUTE sample will not be processed until the CONVALESCENT sample is received, unless otherwise indicated by the doctor. The test is a comparative one hence the need for both samples.

A single sample may be processed as a SCREEN test on those tests indicated in the Fee Schedule.

Serum should be frozen while awaiting analysis**.**

SEMEN ANALYSIS

Please instruct patients to adhere to the following (Written instructions available to be given to the patient):-

1. Abstain from sex for three (3) days;
2. Collect semen by masturbation or by interrupted sex;
3. The specimen (semen) should be passed directly into a sterile container;
4. It should be kept warm (body temperature), until it gets to the laboratory. (e.g. by keeping the specimen close to the body, in a breast pocket);
5. It should get to the laboratory as soon as possible, i.e. not later than one (1) hour after it is passed;
6. Record the time the specimen is passed on the container and the time it is received at the laboratory.
7. SPECIMEN MUST NOT BE REFRIGERATED.

NOTE: A condom should not be used to collect the specimen. This contains a spermicide which will kill the sperms.

SEMEN SPECIMENS ARE ONLY ACCEPTED ON A TUESDAY AND THURSDAY BETWEEN THE HOURS OF 8:00am to 10:00am. These specimens are not accepted on a Saturday.

Please contact Lab to find out the branch at which the sample should be delivered.

INTRODUCTION

This booklet was designed to provide doctors with a quick reference guide to some of the specialized laboratory tests offered by Central Medical Laboratories Ltd., including their uses and clinical significance.

In addition we have included important aspects of specimen collection, storage and handling in order for doctors to assist us in ensuring that our laboratory results meet the highest standards of clinical care.

We hope that you find this information useful and look forward to your continued support.

PROPER IDENTIFICATION OF SPECIMENS

Specimen Labels

Each specimen submitted must have a label. The label should be clear and should include the following:

a) First and Last Name as on Requisition Form
b) Date and time of collection
c) Name of requesting Doctor

Please ensure that the label is securely attached. If the label is hand written, it is best to use a ballpoint pen as this decreases the likelihood of smudging.

Test Requisition

Specimens must be accompanied by a paper requisition. The requisition at minimum should contain the following information: -

1. Patient name
2. Patient gender
3. Patient Date of Birth
4. Address
5. Telephone Number
6. Physician name and address
7. Sample type and source
8. Diagnosis – This is critical to the internal interpretation of results.

Note:
Improperly labelled specimens will be rejected.

PACKAGING AND TRANSPORTING SPECIMENS

The following are guidelines that should be used in the packaging and transporting of specimens to the laboratory: -

1. Ensure that specimen(s) is (are) collected and transported in the appropriate container.
2. Ensure that all specimen container caps and lids are properly tightened to prevent leakage.
3. Ensure that Requisition Form is completed.
4. Needles or other sharp or breakable objects should not be included in the package.
5. Ensure prompt delivery to Laboratory while adhering to specific handling criteria for specimen preservation.
6. When not otherwise indicated, specimen(s) should be kept from extreme temperatures i.e. cold or hot, as this will affect sample quality and ultimately results.

CLINICAL GUIDE TO SELECT SPECIALIZED TESTS OFFERED BY CENTRAL MEDICAL LABORATORIES

CARDIOVASCULAR DISEASE (CVD)

A. Markers of Lipidemia (** Denotes tests referred overseas)

Test Name	Use(s)	Special Considerations
**Apolipoprotein A1	Assess CVD and diagnose dyslipidemia	➢ Reported to be better predictor that HDL cholesterol and triglycerides for Coronary Artery Disease (CAD). ➢ May be of value in identifying patients with atherosclerosis. ➢ Decreased levels associated with increased CHD risk.
** **Apolipoprotein B**	Assess CVD risk and diagnose dyslipidemia	➢ Powerful indicator of CAD. ➢ May be elevated in some patients with CAD with normal LDL Cholesterol. ➢ Increased levels associated with increased CHD risk.
LDL Cholesterol	1. Stratify risk of CAD 2. Monitor non-drug & drug therapy	The target LDL-cholesterol level varies according to the risk profile of the patient.
*Lipoprotein (a)	Assess risk of CVD	➢ Treatment of elevated Lipoprotein (a) has been Controversial.

B. Non – Lipid Markers of Cardiovascular Disease

Test Name	Use(s)	Special Considerations
**Activated Protein C Resistance	Asses risk of CVD, venous thromboembolic disease and cardiovascular disease	A positive result increases risk of CVD especially in women who smoke.
**B- Type Natriuretic Peptide (BNP)	1. Rule out congestive cardiac failure in symptomatic individuals 2. Determine prognosis in individuals with CHF or other cardiac disease 3. Maximize therapy in patients with cardiac failure	➢ In patients with normal results, heart failure is unlikely. ➢ Elevated in CHF, left ventricular hypertrophy and pulmonary hypertension. ➢ Sample must be taken in plastic red top tube, as glass tubes are unsuitable.
Cardio CRP/ High-Sensitivity C-Reactive Protein (hs-CRP)	1. Determine the relative risk of CVD 2. Asses risk of recurrent cardiovascular events in patients with CAD	➢ Should ideally be measured on two occasions, two weeks apart using the average value for risk assessment. ➢ Elevated BP, elevated BMI, cigarette smoking, low HDL, DM, metabolic syndromes and high triglycerides may increase cardio CRP levels.
**Cardiolipin Antibodies	Assess risk of CVD & thromboembolic disease	Detected in subgroup of patients with autoimmune disorders who are at risk for vascular thrombosis, thrombocytopenia, cerebral infarct and/or recurrent spontaneous abortion.
**Homocysteine (Serum and Urine)	1. Assess CVD risk 2. Diagnose and monitor treatment of homocysteinuria, folate deficiency or B12 deficiency	➢ Elevation also signifies increased risk of stroke, dementia & chronic renal disease. ➢ May be elevated in hypothyroidism, cigarette smokers and patients treated with corticosteroids and anticonvulsants.
Microalbumin (24-hour urine or spot urine)	1. Assess risk of cardiovascular events 2. Assess risk of heart failure in individuals with CVD	Exercise within 24 hours of collection, infection, CHF, fever marked hypertension, marked hyperglycemia, haematuria and pyuria may cause falsely elevated results.

(** Denotes tests referred overseas)

CHRONIC RENAL DISEASE

Test Name	Use(s)	Special Considerations
Glomerular Filtration Rate, Estimated (eGFR)	1. Used in adults for early detection of renal disease 2. Monitor therapy of chronic renal disease and/ or disease progression	Calculated using serum creatinine (red top tube); a simpler test than the 24 hr creatinine clearance, as 24 hr urine collection not needed.
Microalbumin (24-hour urine or spot urine microalbumin: creatinine ratio)	1. To detect and monitor early renal disease in DM 2. To detect and monitor microalbuminuria in patients with CVD 3. To detect kidney damage in individuals at risk for renal disease	➢ Ideally, 2 of 3 specimens collected within a 3 to 6 month period should be abnormal before considering a patient to have microalbuminuria. ➢ First voided urine sample for the day recommended for testing.

(** Denotes tests referred overseas)

ENDOCRINE DISORDERS

Test Name	Use(s)	Special Considerations
Adrenocorticotropic Hormone (ACTH)	1. Diagnose disorders of hypothalamic-pituitary- adrenal system 2. Differentiate Cushing's syndrome from normal when ACTH levels are low	➢ Increased in ACTH secreting tumor, Pituitary Cushing disease, Addison's disease, stress. ➢ Decreased in adrenal adenoma, adrenal carcinoma, and secondary adrenal insufficiency.
**Aldosterone, 24-hour Urine	1. Assess adrenal aldosterone production 2. Diagnose primary hyperaldosteronism due to adrenal adenomas or bilateral adrenal hyperplasia	➢ Increased in primary and secondary hyperaldosteronism, very low sodium diet & pregnancy. ➢ Decreased in congenital adrenal hyperplasia, aldosterone synthetase deficiency, Addision's disease and very high sodium diet.
**Aldosterone, Serum	1. As in 24hr urine aldosterone 2. Differential diagnosis of fluid and electrolyte disorders	➢ Same as for 24-hour urine aldosterone.
Dehydroepiandrosterone Sulfate (DHEAS)	1. Marker for adrenal cortical function and disease 2. Differential diagnosis of a virilized patient	➢ Increased in Congenital adrenal hyperplasia, adrenal carcinoma, virilizing tumors of the adrenals & Cushing's disease (pituitary dependent). ➢ Decreased in Addison's disease and adrenal hypoplasia.
Growth Hormone	Assess pituitary growth hormone disorders	➢ Increased in gigantism, acromegaly, selected pituitary tumors, pregnancy and Laron dwarfism. ➢ Decreased in pituitary GH deficiency, hypopituitarism (congenital or acquired) and GH secretory dysfunction. ➢ Random GH results not reliable for diagnosis because of diurnal variability.
5- Hydroxyindoleacetic Acid (5-HIAA)	Diagnose carcinoid tumors	➢ Drugs to avoid prior to testing include phenothiazines, glyceryl guaiacolate, reserpine, MAO inhibitors, and imipramine. ➢ Foods to avoid 3-4 days prior to testing include tobacco, tea, coffee, avocado, banana, tomato, plum, walnut, pineapple and eggplant.
Vanillylmandelic Acid (VMA), Urine	Diagnose catecholamine – producing tumors	➢ Increased in pheochromocytoma, neuroblastoma, ganglioblastoma and stress. ➢ Patients should ideally be off medications for three days prior to the test. ➢ Patients should avoid foods containing vanilla extracts, banana, alcohol, coffee, tea, tobacco and strenuous exercise 3-4 days prior to collection.

(** Denotes tests referred overseas)

GENETIC TESTING

A. Maternal Serum Screen

Test Name	Use(s)	Special Considerations
** Maternal Serum Screen – 3 / Maternal Triple Test	Prenatal (second trimester) risk assessment for neural tube defects, Down syndrome and Trisomy 18	➢ Includes AFP, unconjugated estriol and hCG. ➢ Performed between 14 and 22.9 weeks (optimal period 15-16 weeks). ➢ Patient data must include collection date, maternal birth date, estimated date of delivery, patient's weight, patient's race, patient's diabetic status, number of pregnancies and whether sample is a repeat. ➢ Preferred specimen 3 ml serum (red top tube).
** Maternal Serum Screen – 5 / Maternal Quadruple Test	As in Maternal Serum Screen 3	➢ Includes AFP, unconjugated estriol, hCG, Dimeric inhibin A, invasive trophoblast antigen. ➢ Preferred specimen – 4 ml serum.

(** Denotes tests referred overseas)

B. Cytogenetics

Test Name	Use(s)	Special Considerations
** Biochemical Genetics	Assays used to screen for various conditions including inborn errors of metabolism, aminoacid- opatahies and prenatal screening (AFP in amniotic fluid)	Sample type- contact CML for special instructions.
** Chromosome Analysis	To determining genetic causes for mental retardation, congenital anomalies, infertility, miscarriage, stillbirth, ambiguous genitalia, to confirm or exclude known chromosomal syndrome, to diagnose neoplastic conditions	Sample type – peripheral blood or solid tissue.
** Molecular Genetics	Used to screen for carrier status or assess risk of a child having a particular genetic disorder e.g. Fanconi's Anemia	Testing for oncology related genetics also possible.

(** Denotes tests referred overseas)

C. DNA Paternity Testing

Principle of Test

DNA is isolated from each sample (buccal swab, blood, amniotic fluid, hair etc.) and a genetic profile of each individual is constructed using 16 different DNA markers. These markers are compared against each other and a statistical analysis is performed to calculate the probability of paternity.

Test Name	Use(s)	Special Considerations
Full Trio (mother, alleged father, and child)	To determine paternity status	➢ Enable most accurate determination of probable paternity (up to 99.999%). ➢ Turn around time 2-5 working days.
Motherless Testing (alleged father, and child)	To determine paternity status	➢ Turn around time 2-5 working days.
Prenatal Testing	To determine paternity status prior to birth of child	➢ Sample from baby obtained by chorionic villous sampling or amniocentesis by Obstetrician. ➢ Turn around time 7-10 working days.
Grand Parentage Testing	To establish a biological relationship between a child and his/her grandparents; usually required in absence of an alleged parent	➢ This test assumes the grandparents are the true biologic parents of the alleged parents in question. ➢ Turn around time ~ 5 working days.
Sibling Testing	To determine if two or more alleged siblings share the same father, with a different mother (half siblingship test) To determine if two or more alleged siblings share the same parents (full siblingship test)	➢ The probability of obtaining more conclusive results is increased when both biological parents participate in the test. ➢ Turn around time ~ 5 working days.
First Cousin Testing	To determine the probability that two individuals are cousins	➢ Results vary between 1% to 99% accuracy with a probability > 80% considered as strong proof of relatedness and a probability < 20 % considered as strong proof of non-relatedness. ➢ Turn around time ~ 5 working days.
Aunt/Uncle Testing	To determine the probability that two individuals are related to each other as aunt/uncle and niece/nephew	➢ Results vary between 1% to 99% accuracy with a probability > 80% considered as strong proof of relatedness and a probability < 20 % considered as strong non-relatedness. ➢ Turn around time ~ 5 working days.
Deceased Sample	To determine paternity status using tissue/cells taken from deceased participants	➢ Sample integrity (attracts separate sample verification fee) must first be performed to determine presence or absence of suitably preserved DNA to enable processing. ➢ For Legal Paternity test the doctor collecting the sample must provide appropriate documentation enabling a chain of custody.

IMMUNE DISORDERS

Test Name	Use(s)	Special Considerations
** **Gastric Parietal Cell Antibodies**	Diagnosis of pernicious anaemia	➢ Parietal cell antibodies seen in small percentage normal adult population and in 80 % patients with pernicious anaemia. ➢ Rarely present in patients with gastric ulcer or gastric cancer. ➢ A negative test does not exclude a diagnosis of pernicious anaemia.
** **Intrinsic Factor Blocking Antibodies**	Diagnosis of pernicious anaemia	Blocking antibodies interfere with the action of intrinsic factor as seen in ~ 50% of patients with pernicious anaemia.
** **HLA B27 Antigen**	Assess risk & assist diagnosis of ankylosing spondylitis	Occurs commonly in patients with Reiter's disease.
** **Insulin Antibodies**	1. To assess autoantibody titres in diabetic patients on chronic insulin injection 2. To detect insulin autoantibodies in pre-diabetics and other patients with autommune disorders	Sample should be sent promptly to lab for separation of serum from the cells.
** **JO –1 Antibodies**	Diagnosis of connective tissue diseases	JO – 1 antibodies occur in patients with polymyositis, dermatomyositis and polymyositis/ scleroderma syndrome.
** RNP Antibodies	Diagnosis of SLE	➢ Occurs in ~ 45% patients with SLE. ➢ Elevated levels seen in patients with Sjögrens Syndrome, Scleroderma and mixed connective tissue disease. ➢ In SLE, RNP associated with relatively benign disease course.
** SM Antibodies	Diagnosis of SLE	Highly specific for SLE however seen in ~ 20% of patients.
**Sjögren's Antibodies (SSA, SSB)	Diagnosis of Sjögren's Syndrome	May be detected in cases of congenital heart block, neonatal lupus and in ~ 30% of SLE patients.
** Thyroglobulin Antibodies	Diagnosis and management of a variety of thyroid disorders including Hashimoto's thyroiditis, Grave's disease and certain types of goiter	Hyperlipemic samples will be rejected.

(** Denotes tests referred overseas)

INFECTIOUS DISEASES

A. Chlamydia Trachomatis

Test Name	Use(s)	Special Consideration
Antigen Identification Test (Spot Test);	Screening test for detection of C. trachomatis	➢ Test is performed from an endocervical swab in women and an urethrogenital swab in men. Swabs should be placed into dry tube after collection (see ***Appendix 1***, page 35). ➢ Positive test results are considered presumptive evidence of infection, and should be interpreted within the clinical context or confirmation testing should be considered.
** Nucleic Acid Amplification Test	1. Directly detects the presence of C. trachomatis DNA or ribosomal RNA 2. Preferred method for Chlamydia screening in women 3. Standard for diagnosis as highly sensitive	➢ False positive results may occur if sample taken too soon after treatment cessation (i.e. < 3 weeks post- therapy). ➢ Negative results are highly specific for absence of C. trachomatis infection. ➢ Test is best performed from an endocervical swab.

(** Denotes tests referred overseas)

B. Helicobacter Pylori

Test Name	Use(s)	Special Considerations
Antibody Detection	Detect current and prior infection	➢ False positives may occur in prior infection. ➢ False negatives may occur if sample collected prior to seroconversion or if antibody levels are too low. ➢ Sample type – serum.
** Antigen Detection	1. Diagnose current infection 2. Assess treatment response 3. Document cure	➢ Causes for false positives unknown. ➢ False negatives may occur if antigenic levels are very low, with proton pump inhibitors, antibiotics & bismuth-containing compounds. ➢ Sample type - stool.

C. Human Papilloma Virus (HPV) DNA

Test Name	Use(s)	Special Considerations
** HPV, DNA, High Risk	1. To determine the need for colposcopy in individuals with ASCUS Pap test results 2. Used as adjunct to cervical cytology in women ≥ 30 yrs to assist in guiding patient management 3. To evaluate high risk male patients for HPV (anal-rectal swabs)	➢ Test detects 13 key types of HPV associated with intermediate/high risk of cervical cancer (Types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, and 68). ➢ CML will provide transport medium containing DNA collection device/brush/ cervical sampler or cervical broom. ➢ Cervical biopsy specimens accepted if placed in special transport media (supplied by CML). ➢ Liquid based Pap smear samples also acceptable (collection vial supplied by CML). ➢ Anal- rectal specimens collected with cytobrush and placed in special transport media (provided by CML).

(** Denotes tests referred overseas)

D. Hepatitis C Virus (HCV)

Test Name	Use(s)	Special Considerations
HCV, Antibody, EIA	First line screening test for detection of acute and chronic Hepatitis C	Window period between infection and seroconversion is highly variable (up to 12 months).
** HCV, Antibody, RIBA	Confirm infection if RNA result discrepant	Negative results required for re-entry into blood donor pool.
** HCV, Genotyping	Predict likelihood of therapeutic response & determine duration of treatment	Patients with non-type 1 HCV, respond better to interferon. Patients with type 1, HCV require extended duration of treatment.
** HCV, RNA, Qualitative	1. Detect acute infection prior to seroconversion 2. Confirmation of antibody test 3. Differentiate between active and resolved infection 4. Confirmation of disease resolution	Detects presence of hepatitis C virus circulating in the blood.
** HCV, RNA Quantitative	1. Detect early infection prior to seroconversion 2. Differentiate between treatment failure vs. partial response 3. Differentiate between active and resolved infection 4. Confirmation of antibody test 5. Confirmation of disease resolution	➢ Measures level of hepatitis C virus circulating in blood. ➢ Levels do not correlate with severity of disease.

(** Denotes tests referred overseas)

THROMBOPHILIA TESTING

A. Hereditary Thrombophilia

Test Name	Use(s)	Special Considerations
** Activated Protein C Resistance	1. Evaluation of patients with recurrent thrombotic episodes 2. Evaluation of symptomatic patients with positive family history of thrombosis	➢ False positive results may be seen in patients with lupus anticoagulant. ➢ Sample collected in light blue-top (citrate) tube.
** Antithrombin III Antigen & Activity	1. Evaluation of patients with recurrent thrombotic episodes 2. Evaluation of symptomatic patients with positive family history of thrombosis	➢ Oral anticoagulation therapy may interfere with testing. Prior to sample collection, convert patients from oral anticoagulants to heparin for 7-10 days, then discontinue heparin for 12-24 hrs, then collect sample. ➢ Sample collected in light blue-top (citrate) tube.
D- Dimer	1. Evaluation of patients with recurrent thrombotic episodes 2. Evaluation of symptomatic patients with positive family history of thrombosis	➢ Quantitation of D-Dimer assesses fibrinolytic activation and intravascular thrombosis as in DIC. ➢ Elevated levels associated with DVT, PE, DIC, myocardial infarction, surgery, trauma, sickle cell disease, sepsis, malignancy and inflammation. ➢ Sample collected in light-blue-top (citrate) tube.
** Factor V Leiden	1. Evaluation of patients with recurrent thrombotic episodes 2. Evaluation of symptomatic patients with positive family history of thrombosis	Sample collected in lavender-top (EDTA) tube.
** Homocysteine	1. Evaluation of patients with recurrent thrombotic episodes 2. Evaluation of symptomatic patients with positive family history of thrombosis	➢ Fasting for at least 8 hours is preferred. ➢ May be elevated in hypothyroidism, cigarette smokers and patients treated with corticosteroids and anticonvulsants. ➢ Sample collected in red-top tube.
** Protein C- Antigen and Activity	1. Evaluation of patients with recurrent thrombotic episodes 2. Evaluation of symptomatic patients with positive family history of thrombosis	➢ Oral anticoagulation therapy may interfere with testing. Prior to sample collection, convert patients from oral anticoagulants to heparin for 7-10 days, then discontinue heparin for 12-24 hrs, then collect sample. ➢ Oral contraceptives, pregnancy and estrogen replacement therapy contraindicates analysis. ➢ Sample collected in light blue-top (citrate) tube.

** Protein S – Antigen and Activity	1. Evaluation of patients with recurrent thrombotic episodes 2. Evaluation of symptomatic patients with positive family history of thrombosis	➢ Oral anticoagulation therapy may interfere with testing. Prior to sample collection, convert patients from oral anticoagulants to heparin for 7-10 days, then discontinue heparin for 12-24 hrs, then collect sample. ➢ Oral contraceptives, pregnancy and estrogen replacement therapy contraindicates analysis. ➢ Sample collected in light blue-top (citrate) tube.

(** Denotes tests referred overseas)

B. Acquired Thrombophilia

Test Name	Use(s)	Special Considerations
** Cardiolipin Antibodies	1. Assess risk of thromboembolic disease 2. Assess risk of CVD	➢ Two positive tests, more than three months apart, are recommended for diagnosis of clinically significant antiphospholipid antibodies. ➢ Sample collected in light blue-top (citrate) tube.
Lupus Anticoagulant	1. Assess risk of thromboembolic disease 2. Evaluation of patients with recurrent arterial and venous thrombosis, and recurrent spontaneous abortion	➢ Two positive tests, more than three months apart, are recommended for diagnosis of clinically significant antiphospholipid antibodies. ➢ Oral anticoagulants may interfere with test and may give false positive result. ➢ Heparin therapy may contribute to erroneous result. ➢ Sample collected in light blue-top (citrate) tube.

(** Denotes tests referred overseas)

TOXICOLOGY

Test Name	Use(s)	Special Considerations
Amphetamine, * Qualitative	To detect exposure	Urine sample only.
Cannabis, * Qualitative and Quantitative	To detect exposure	Urine sample only.
Cocaine, *Qualitative and Quantitative	To detect exposure	Urine sample only.
Heroin, *Qualitative	To detect exposure	Urine sample only.
** Lead, Blood	To detect lead exposure and/or toxicity and to monitor course of treatment	Ensure that EDTA collection tube is certified as low in lead content.
Nicotine, *Qualitative and Quantitative	To detect exposure	Urine sample only.
** Mercury, Blood	To detect abnormal levels of exposure	Sample collected in EDTA or heparin tube.
** Mercury, Urine	To detect abnormal levels of exposure	Patients should refrain from eating predatory fish at least 3 days prior to sample collection. Sample collected in acid washed plastic urine containers.

(** Denotes tests referred overseas)

Note:
* Qualitative tests provide results that are reported as either positive or negative.
* Quantitative tests provide results that are reported as a numerical value, which enables monitoring of specific drug levels.

TUMOR MARKERS

Test Name	Use(s)	Special Considerations
CA 125	1. Early detection of ovarian cancer recurrences 2. Therapeutic monitoring of ovarian cancers 3. Detection of residual disease in ovarian cancer	➢ May be elevated in breast, cervical, colorectal, endometrial, lung and pancreatic malignancies. ➢ May be elevated in pelvic inflammatory disease and pericarditis. ➢ Mild elevation in 1-2% healthy individuals.
** CA 15-3	Monitoring patients with advanced breast cancer	May be useful for monitoring patients with certain ovarian cancers.
** CA 19-9	1. Monitor therapy in patients with pancreatic cancer 2. Monitor therapy in selected patients with gastric and colon cancer	Blood levels may be increased modestly in patents with pancreatitis, biliary tract disease, inflammatory bowel disease and cystic fibrosis.
** CA 27-29	1. Therapeutic monitoring of patients with metastatic breast cancer 2. Early detection of recurrent breast cancer	➢ May be elevated in patients with ovarian, lung, liver and pancreatic cancer. ➢ May be elevated in patients with benign conditions e.g. lactating women, cirrhosis, chronic hepatitis & renal impairment.
** CA 72-4	Marker for gastrointestinal malignancies	➢ May be elevated in patients with lung, ovarian, breast and pancreatic cancer. ➢ May be elevated in benign disorders involving gastrointestinal tissues.
CEA	To monitor persistent, metastatic or recurrent adenocarcinoma of the colon	➢ May be elevated in smokers, patients with inflammatory disease of the GIT, liver diseases, advanced renal disease and fibrocystic disease of the breast. ➢ May be elevated in patients with breast, lung, hepatocellular and pancreatic carcinoma.
Alpha Fetoprotein	1. Distinguish between seminomations and non-seminomations testicular germ cell cancer 2. Monitor therapy and detect recurrence in patients with non-seminomations testicular germ cell cancer 3. Determine prognosis in patients with fulminant hepatitis 4. Monitor therapy in patients with hepatocellular carcinoma 5. Monitor hepatitis B carriers for evidence of liver cancer	May be elevated in patients with primary hepatocellular carcinoma.
** Neuron Specific Enolase	Monitor disease progression and therapy in patients with small cell lung cancer	May be elevated in patients with neuroblastoma, pancreatic islet cell carcinoma, medullary thyroid carcinoma and other neuroedocrine tumors.

(** Denotes tests referred overseas)

Note: The above-mentioned markers are not specific for malignancy or for any particular tumor type. These tests are not recommended for cancer screening or diagnosis as they may yield false negative or positive results. They may be used in conjunction with other clinical and pathological findings to assess response to therapy as well as likelihood of disease progression or recurrence.

TESTS REQUIRING SPECIAL COLLECTION/ HANDLING

Test	***Type of Specimen***	***Preservative/ Additive***	***Special Requirements/ Instruction***	***Storage and Handling***	***Rejection Criteria***
ACTH	*Plasma (purple top tube)*	*Liquid EDTA or freeze dried EDTA*	*Not Applicable*	*Serum must be immediately separated from clot and frozen.* *Serum should be sent to lab on ice.*	*Failure to comply with special requirements, storage and handling procedures.*
Cortisol	*Serum (red top tube)*	*None*	*AM sample should be taken preferably at 9:00 am. PM sample should be taken preferably at 5:00-6:00 pm.* *AM and pm samples should be taken on the same day.* *Serum samples should be clearly labeled as am or pm.*	*Not Applicable*	*Failure to comply with special requirements.*
Cortisol	*24 - hour Urine*	*None*	*1. On the morning of the test, the first urine voided should be discarded and the time noted.* *2. Following this, all urine voided in the next 24 hours should be collected in a clean container and poured into the bottle supplied by laboratory.* *3. Accurate collection is vital.*	*Not Applicable*	*Failure to comply with special requirements.*
Growth Hormone	*Serum (red tube top)*	*None*	*Not Applicable*	*Serum must be immediately separated from clot and frozen.* *Serum should be sent to lab on ice.*	*Failure to comply with special requirements, storage and handling procedures.*
5-HIAA	*24 -hr Urine*	*25 mls glacial acetic acid.*	*1. Foods such as pineapples, bananas, plums, avocadoes, tomatoes and egg plant should be avoided at least 48 hrs before urine is collected.* *2. On the morning of the test, the first urine voided should be discarded and the time noted.* *Following this, all urine voided in the next 24 hours should be collected in a clean container and poured into the bottle supplied by laboratory.* *3. Accurate collection is vital.*	*Not Applicable*	*Failure to comply with special requirements.*
Insulin	*Serum (red top tube)*	*None*	*Fasting specimen required.*	*Not applicable*	*Failure to comply with special requirements.*

Test	***Type of Specimen***	***Preservative/ Additive***	***Special Requirements/ Instruction***	***Storage and Handling***	***Rejection Criteria***
17 Ketosteroids/ 17 Ketogenic steroids	*24- hr Urine*	*10 mls concentrated hydrochloric acid*	*1. On the morning of the test, the first urine voided should be discarded and the time noted.* *2. Following this, all urine voided in the next 24 hours should be collected in a clean container and poured into the bottle supplied by laboratory.* *3. Accurate collection is vital.*	*Not Applicable*	*Failure to comply with special requirements.*
PTH	*Serum* *(red top)*	*None*	*Fasting specimen required.*	*Serum must be immediately separated from clot and frozen.* *Serum should be sent to lab on ice.*	*Failure to comply with special requirements, storage and handling procedures.*
VMA *(vanillymandelic acid)*	*24- hr Urine*	*10 mls concentrated hydrochloric acid*	*1. Foods containing vanilla extract, bananas, chocolates, tea and coffee should be avoided at least 48 hrs before urine collection.* *2. On the morning of the test, the first urine voided should be discarded and the time noted.* *Following this, all urine voided in the next 24 hours should be collected in a clean container and poured into the bottle supplied by laboratory.* *3. Accurate collection is vital.*	*Not Applicable*	*Failure to comply with special requirements.*

SAMPLES REQUIRING SPECIAL COLLECTION/ HANDLING

Samples	***Type of Specimen***	***Preservative/ Additive***	***Special Requirements/ Instruction***	***Storage and Handling***	***Rejection Criteria***
Endocervical swab *– Chlamydia Screening* *(See* **Appendix 1**, *page 35)*	*Dry swab specimen (provided by CML)*	*None*	1. *Visualize the cervix using a speculum without lubricant.* 2. *Remove mucus and secretions from the cervix with swab and discard the swab.* 3. *Firmly yet gently sample the endocervical canal with a newly obtained sterile swab.*	*Transport to lab within 2 hours at room temp.* *Maximum holding time ≤ 24 hours at room temp.*	*Failure to comply with special requirements and storage and handling procedures.*
Sputum *Lower respiratory tract cultures*	*Sterile wide mouth container* *Minimum amount required: 5-10 ml*	*None*	*Prior to collecting specimen, instruct patient to do the following: -* 1. *Rinse mouth with tap water prior to expectorating.* 2. *Patient should inhale deeply on three occasions then cough deeply to produce a lower respiratory specimen (not post nasal fluid).* 3. *Place sputum immediately into container to reduce dilution by saliva.*	*Transport to lab within 2 hours at room temp.* *Maximum holding time ≤ 24 hours, refrigerated.*	*Non-representative sample e.g. saliva.*
Sputum *Tuberculosis cultures*	*Sterile wide mouth container* *Minimum amount required: 5-10 ml*	*None*	1. *Collect specimen under the direct supervision of a nurse or physician.* 2. *Instruct patient to cough deeply to produce a lower respiratory specimen (not postnasal fluid). Collect in sterile container.* 3. *Collect sputum on 3 consecutive early mornings and submit each to lab. Do not pool samples.*	*Transport to lab within 2 hours at room temp.* *Maximum holding time ≤ 24 hours, refrigerated.*	*Non-representative sample e.g. saliva.*

Stool *Ova & Parasites*	*Clean wide mouth container*	*O&P preservative (10% formalin)*	*1. Pass directly into clean, dry container.* *2. Transfer about a cubic inch of stool into container with preservative.* ***Mix sample well.*** *3. If sample can not be received by CML within 24 hours of collection, freeze overnight and send frozen.*	*Transport to lab within 2 hours at room temp.* *Maximum holding time ≤ 24hours, refrigerated.*	*Patient should not take any medication containing mineral oil, barium, bismuth, magnesium, kaolin, and antibiotics for at least 5 days prior to specimen collection.*
Urine -Catheter *Indwelling for C&S*	*Sterile urine container* *Minimum amount required: ≥ 3ml*	*None*	*1. Disinfect the catheter port with 70% alcohol.* *2. Use needle and syringe to aseptically collect 5- 10 mls of urine.* *3. Transfer to sterile container.*	*Maximum holding time ≤ 24 hours, refrigerated.*	*Failure to comply with special requirements and storage and handling procedures.*
Urethrogenital Swab - *Male Urethra* *(See* **Appendix 1**, *page 35)*	*Swab/ culturette in transport media*	*None*	*1. A special small-tipped swab with wire shaft is used to collect specimen.* *2. Insert a urethrogenital swab 2 to 4 cm into the urethral lumen .* *3. Rotate swab, and leave it in place for at least 2 seconds to facilitate absorption.*	*Transport to lab within 2 hours at room temp.* *Maximum holding time ≤ 24 hours at room temp.*	*If the sample is taken from a lesion of the penis (external to the urethra), treat as a superficial wound.*
Vaginal Secretions *- Vaginitis and Bacterial Vaginosis*	*Swab in transport media*	*None*	*1. Wipe away excessive secretions or discharge.* *2. Obtain secretions from the mucosal membrane of the vaginal vault with a sterile swab.*	*Transport to lab within 2 hours at room temp.* *Maximum holding time ≤ 24 hours at room temp.*	*Delay in transportation may yield a false negative result for Trichomonas vaginalis.*

GENERAL INFORMATION

** Overseas Tests

Through linkages with local and overseas specialist laboratories, CML is able to provide a comprehensive range of services. For these services, patients should ideally be send to our collection centers for specimen collection except in cases where non-routine samples such as amniotic fluid or biopsy specimens are required. In these cases the specimen should be collected by the requesting doctor in consultation with CML's Laboratory Director who will provide information on requirements for sample collection.

These tests attract shipping and handling charges (paid in JA dollars), in addition to the cost of the test, which is to be paid in US$ dollars.

Results for overseas tests have variable turn-a –round times ranging between one to three weeks depending on the nature of the test.

Cross Matching of Blood and Blood Products

From time to time the laboratory is requested to perform crossmatching of Blood for patients with particular illnesses or for patients undergoing various medical or surgical procedures.

There are three important factors related to this service which you MUST note:

- The actual crossmatching and supply of blood is performed by the National Blood Transfusion Services (National Blood Bank), whom in addition, are our sole providers of Blood and Blood products. This entire process is facilitated by CML.

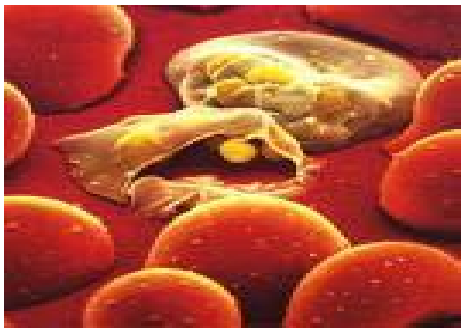
- It is recommended that Blood be donated on the patient's behalf prior to the date for use.

- Crossmatching of Blood attracts a service charge per unit. This charge is related to the preparation and testing of the units provided by the National Blood Bank. Each unit is screened for Hepatitis B, Hepatitis C, HTLV, HIV and Syphilis as well as undergoes compatibility testing. There is **NO** charge for the Blood or Blood product itself. This service charge is non-refundable even in the event that the patient does not receive the transfusion, as it represents the cost to process the unit.

Malaria Testing

Malaria is a potentially fatal blood disease caused by a parasite that is transmitted to human and animal hosts by the *Anopheles* mosquito. The human parasite, *Plasmodium falciparum,* is dangerous not only because it digests the red blood cell's hemoglobin, but also because it changes the adhesive properties of the cell it inhabits. This change in turn causes the cell to stick to the walls of blood vessels. It becomes especially dangerous when the infected blood cells stick to the capillaries in the brain, obstructing blood flow, a condition called cerebral malaria.

Malaria in the Blood



There are four species of the genus plasmodium responsible for the malarial parasite infection that commonly infects man, P. falciparum, P. vivax, P. malariae and P. ovale. Of these P. falciparum is the most significant as it can be rapidly fatal and is responsible for the majority of malaria related deaths.

Blood Film Preparation

Thick Films

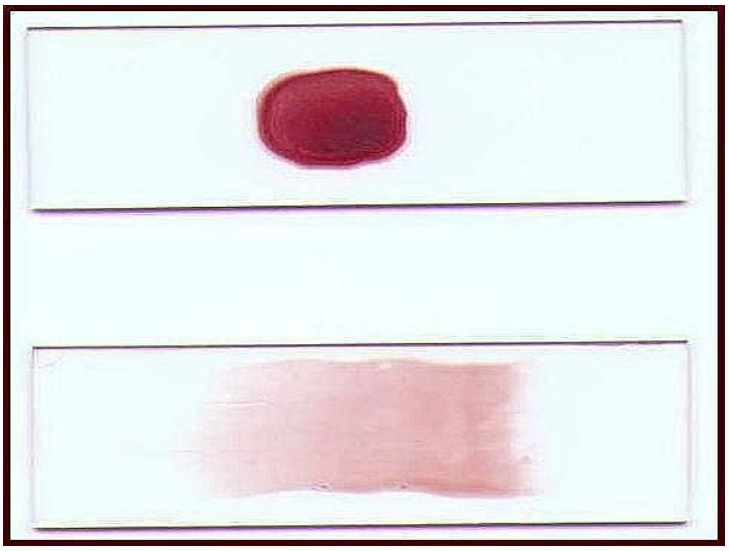
Place a drop of blood in the middle of a clean microscope slide and with the corner of a second slide spread the drop until it is about 10-15mm in diameter. The thickness should be such that it is just possible to see news print through it.

Thin Films

These films are made in the standard manner and allowed to air dry.

Thick Film

Thin Film



Rapid Diagnostic Tests (RDT's)

Rapid diagnostic tests are becoming an increasingly important method for detecting malaria. These tests have the potential of enhancing the speed and also the accuracy of diagnosing P. falciparum, particularly in non-specialized laboratories where inexperienced staff may be involved. RDT's may also be very useful for screening or confirmation, especially when there is difficulty in identifying scanty ring forms on blood films. Some RTD's can detect only one species (P. falciparum), while others detect additional species of the parasite. Blood for the test is commonly obtained from a finger-prick.

Pap Smears

The cervical smear or Pap test is a screening test that has been used successfully over many decades to detect pre-cancerous cells of the cervix.

Sample preparation is one of the most important fundamentals of an accurate cytological assessment. Key points to remember in preparing the specimen include:

1. Ensuring that the smear from cervix is placed on a clean glass slide *(Figure 1).*

2. Ensuring that the smear is applied as thin as possible.

3. Immediately spraying the glass slide with cytological fixative (within 10-15 seconds) to prevent excessive drying, which may impede accurate assessment *(Figure 2).*

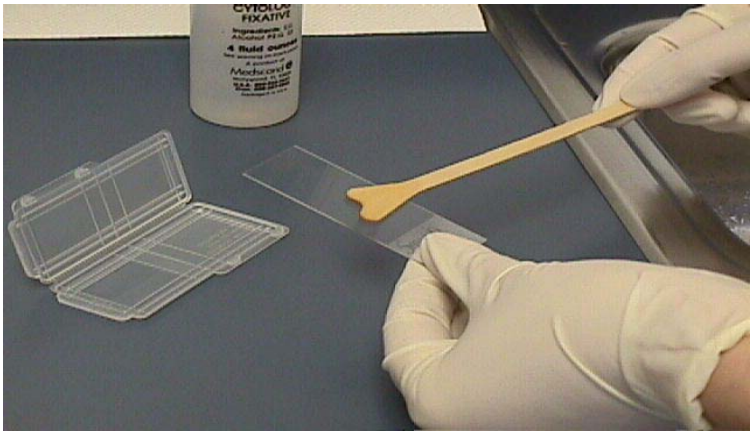


Figure 1.
Application of cervical smear to glass slide using Ayre spatula.
The combination of spatula and Cytobrush (image not shown) collects more endocervical cells than does the spatula alone and provides excellent results.

Figure 2.
Spraying of glass slide with cytological fixative.

*The Papanicolau technique described above has recently been modified by using liquid based media, also known as the "thin-prep". The thin prep is achieved by rinsing the collection device(s) in a preservative fluid to generate a suspension of cells that is processed to deposit a monolayer of cells on a microscope slide. The thin prep offers some advantages over the traditional Papanicolau technique, being somewhat easier to read, and is less affected by white and red cell contamination while retaining as good an accuracy if not better, than with the glass slide preparation. An additional advantage is that reflex HPV testing can be done in the event of an abnormal result (*see **HPV, DNA** in the Infectious Diseases section of **Clinical Guide to Select Specialized Tests Offered by CML).**

When using the thin-prep technique, follow the directions from the manufacturer of the liquid media-collecting jar, as this may vary from manufacturer to manufacturer.

Semen Analysis

Kindly instruct patients to adhere to the following guidelines for sample collection. These instructions are also available in a written format to be given to the patients.

- *Abstain from sexual intercourse for three (3) days.*
- *Collect semen by masturbation or interrupted sex.*
- *The specimen (semen) should be passed directly into a sterile container.*
- *Specimen should be kept warm (body temperature), until it gets to the laboratory (e.g. by keeping the specimen close to the body, in a breast pocket).*
- *Specimen must arrive at the laboratory as soon as possible, i.e. not later than one (1) hour after it is passed.*
- *Record the time the specimen is passed on the container and the time it is received at the laboratory.*

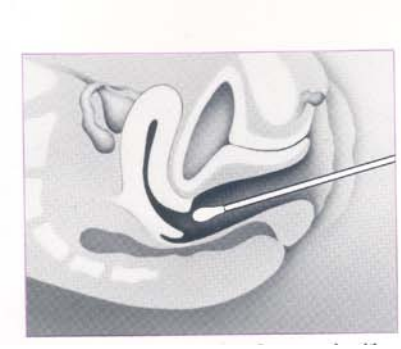
Semen specimens are only accepted on a Tuesday and Thursday between the hours of 8:00 am and 10:00 am at specific collection centres. Please contact CML (754-6199 to 6202, Kingston and 974-2614, Ocho Rios) for collection centres.

NOTE: Condoms <u>SHOULD NOT</u> be used to collect the specimen – they contain a spermicide, which will kill the sperms.

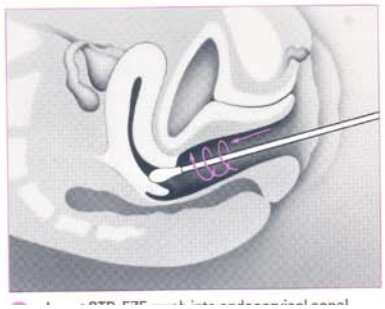
APPENDIX

RECOMMENDED SAMPLING TECHNIQUES IN SPECIMEN COLLECTION FOR CHLAMYDIA

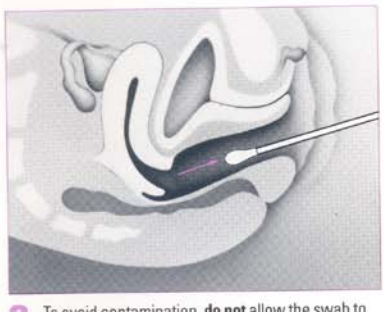
For Women:



1. **Remove excess mucous from the exocervix with a cotton ball or swab. Dispose of swab.**

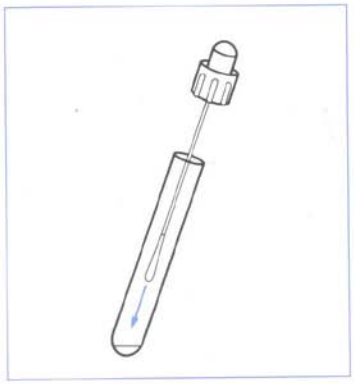


2. Insert sterile swab into endocervical canal until most of the tip is no longer visible. **Rotate** the swab for 15-30 secs. in the endocervix to ensure adequate sampling and adsorbtion by the swab.



3. To avoid contamination, **do not** allow the swab to touch any vaginal surfaces upon withdrawal.

(NB. If a gonorrhoea specimen is requested, collect before taking the Chlamydia sample using a separate swab.

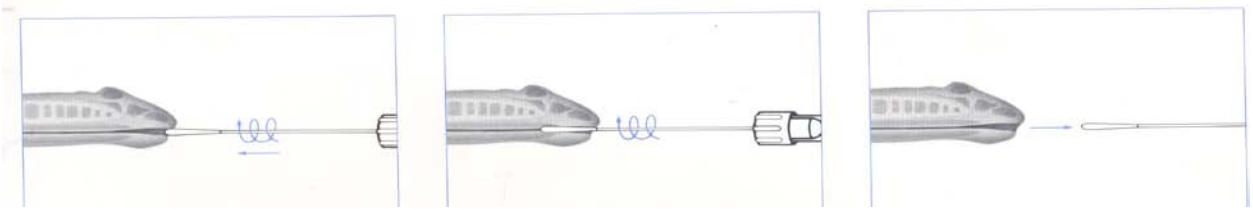


4. After collecting specimen remove tube top and insert swab to bottom of tube.

5. Push cap down tightly over outside of tube opening.

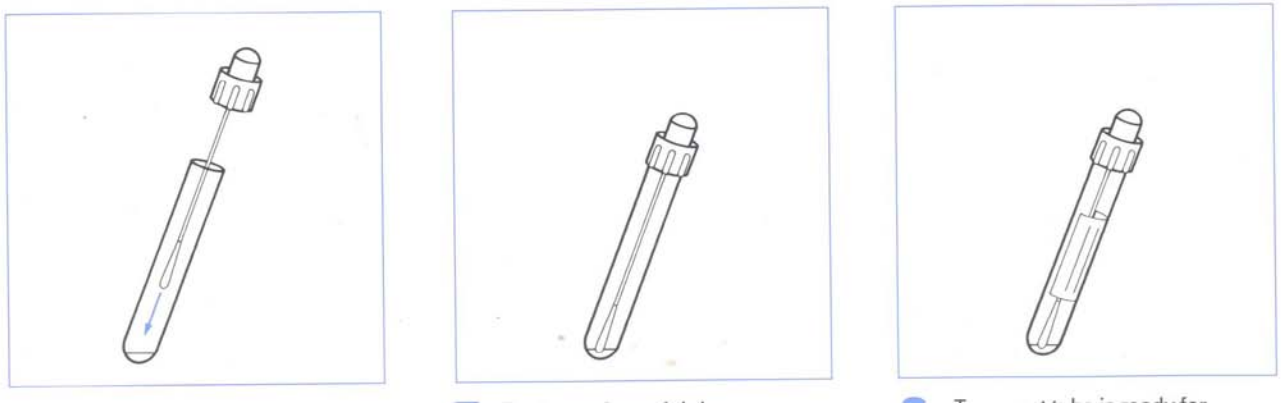
6. Transport tube is ready for patient identification (on outer label).

For Men:



1. **To ensure accurate test results, it is preferable to instruct the patient not to urinate for 1 hour prior to sampling.** Insert the swab 2-4 cm into the urethra. This may be facilitated by slightly rotating the swab during insertion.
2. Gently **rotate** swab, using sufficient pressure to ensure that the swab comes into contact with all urethral surfaces. Allow swab to remain inserted for 3-5 seconds.
3. Withdraw the swab.

.



4. After collecting specimen remove tube top and insert swab to bottom of tube.
5. Push cap down tightly over outside of tube opening.
6. Transport tube is ready for patient identification (on outer label).