Premier
Integrated Labs

LABORATORY SERVICE GUIDE

Version 1.05
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A supplementary to Premier Integrated Labs Sdn Bhd Price & Service Catalogue and Service Directories

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INTRODUCTION

Premier Integrated Labs Sdn Bhd has laboratories in the IHH Healthcare Malaysia hospitals, and non-hospital-based branches within Malaysia. Our reference core laboratory is located in Pantai Hospital Ampang. We serve the needs of inpatients and outpatients at the hospitals we are located, as well as other medical practitioners who practise within our area of service provision.

The Laboratory User Guide intends to communicate the important steps in laboratory tests requisition, specimen requirement, specimen collection, handling, and transportation. It also serves as a guide to the laboratory services available.

We provide quality laboratory services in the following disciplines:

- Allergy Testing
- Clinical Chemistry
- Cytopathology
- Drugs of Abuse Screening
- Endocrinology
- Fluids & Excretion Analysis
- Haematology
- Histopathology
- Immunology & Serology
- Microbiology
- Molecular Diagnostics
- Therapeutic Drugs Monitoring
- Transfusion Medicine
- Specialized Testing

The scope of our services includes specimen handling, specimen processing and analysis, reporting of test results, handling and delivery of supplies and test reports to our clients. Our internal quality audits, quality assurance and quality control programmes ensure the achievement of our quality service mission.

The integrity and reliability of the testing process have direct implication on the quality of the analytical results produced. Besides the usual regular preventive and service maintenance on the instruments and compliance to instrument calibration protocols, our laboratories also participate in many internal and external quality assurance programmes to monitor the testing processes.

We have more than 18 residents/visiting consultant pathologists from various disciplines involve in the reporting and managing the quality of our laboratory's services. Under the active guidance of the consultants and our management commitment towards service excellence with 16 major branches are accredited with MS ISO 15189 by Department of Standard Malaysia.

CONSULTANT PATHOLOGIST

Visit our website for more detail:
https://www.premierintegratedlabs.com.my/about-us/consultant-pathologist/

For pathologist advisory services kindly contact the respective laboratories.

OPERATION HOURS, LOCATION AND CONTACT NUMBERS

Corporate Office
4th Floor, Pantai Hospital Ampang
Jalan Perubatan 1,
55100 Pandan Indah, Kuala Lumpur
(T) +603 4297 9911 (F) +603 4296 5901

Customer Service Hotline
(T) +603 4280 9115 (F) +603 4297 4911
info@premierintegratedlabs.com.my

Dispatch Hotline
Core Laboratory
(T) +603 4280 2911 / +603 4280 5911
Bangsar
(T) +603 2282 2108

Table 1: Operation Hours, Location and Contact Numbers

LIST OF LABORATORY & ADDRESS	TELEPHONE NO.	FAX NO.	OPERATION HOURS
Central Region			
PIL @ Pantai Hospital Ampang (Reference Core Laboratory (RCL)) LG Floor, Bangunan MOB, Pantai Hospital Ampang, Jalan Perubatan 3, 55100 Pandan Indah, Kuala Lumpur.	03-4280 9115	03-4296 4095	Mon - Fri : 8.30am - 5pm Sat : 8.30am - 1pm
PIL @ Pantai Hospital Kuala Lumpur Level 2, Block A, Pantai Hospital Kuala Lumpur, No. 8, Jalan Bukit Pantai, 59100 Bangsar, Kuala Lumpur.	03-2282 8795	03-2287 2622	Mon - Fri : 9am - 5.30pm Sat : 9am - 1pm
PIL @ Pantai Hospital Kuala Lumpur (Reference Specialized Lab (RSL)) Level 8, Block A, Pantai Hospital Kuala Lumpur, No. 8, Jalan Bukit Pantai, 59100 Bangsar, Kuala Lumpur.	03-2282 8795 Ext 171 (CMDL), 176 (Cyto), 134 (Histo)	03-2287 2622	Mon - Fri : 9am - 5.30pm Sat : 9am - 1pm
PIL @ Pantai Hospital Cheras 11 & 11-1, Jalan 3/96A, Taman Cheras Makmur, 56100 Kuala Lumpur	03-9131 7147	03-9131 7141	Mon - Fri : 8.30am – 5.00pm Sat : 8.30am - 1pm
PIL @ Gleneagles Hospital Kuala Lumpur 2nd Floor, Gleneagles Kuala Lumpur (Hospital Block), No. 286, Jalan Ampang, 50450 Kuala Lumpur.	03-4141 3064	03-4141 3065	Mon - Fri : 8.30am - 5pm Sat : 8.30am - 1pm

PIL @ Prince Court Medical Centre (PCMC) Level 4A, Pathology Department, No. 39, Jalan Kia Peng, 50450, Kuala Lumpur.	03-2160 0750	03-2160 0760	Mon- Fri : 8am – 6pm Sat : 8am – 1.30pm
PIL @ PJ Integrated Centre for Advanced Surgery and Oncology (PICASO) Level Ground (LG), No. 110, Jalan Professor Khoo Kay Kim, Seksyen 19, 46300 Petaling Jaya, Selangor.	+603 7457 2888	-	Mon- Fri : 8.30am – 5pm Sat : 9am – 1pm
PIL @ Pantai Hospital Klang Ground Floor, Pantai Hospital Klang, Lot 5921, Persiaran Raja Muda Musa, 41200 Klang, Selangor.	03-3373 6252	03-3373 6271	Mon - Fri : 9am - 5pm Sat : 9am - 1pm
Klang Off-site, Selangor No.125, Ground Floor, Lebuh Turi Off Persiaran Raja Muda Musa 41200 Klang, Selangor.	03-33701315	03-33701329	Mon - Fri : 9am - 5pm Sat : 9am - 1pm
Northern Region			
PIL @ Pantai Hospital Sungai Petani Ground Floor, Pantai Hospital Sungai Petani, No.1, Persiaran Cempaka, Bandar Amanjaya, 08000 Sungai Petani, Kedah.	04-4412994	04-4413012	Sun - Thu : 8.30am - 5pm Fri : 8.30am - 1pm
PIL @ Pantai Hospital Laguna Merbok 2nd Floor, Pantai Hospital Laguna Merbok, C/O Amanjaya Specialist Centre Sdn. Bhd., No:1, Lorong BLM1/10, Bandar Laguna Merbok, 08000 Sungai Petani, Kedah	+604 441 0722	-	Sun - Thu : 8.30am - 5pm Fri : 8.30am - 1pm
PIL @ INS Medical Centre Ground floor, INS Medical Centre, No. 639D, Jalan Pintu Sepuluh 05100 Alor Setar, Kedah.	04-730 8110	04-730 8110	Sun - Thu : 8.30am - 5pm Fri : 8.30am - 1pm
PIL @ Pantai Hospital Penang 3rd Floor, Pantai Hospital Penang, No. 82, Jalan Tengah 11900 Bayan Baru, Penang	04-646 5505	04-646 6606	Mon - Fri : 8.30am - 5pm Sat : 8.30am - 1pm
Penang Off-Site 5-G-31 & 5-1-31, The Promenade, Persiaran Mahsuri, Bandar Bayan Baru, 11900 Bayan Baru, Penang.	04-611 8188	04-611 8788	Mon - Fri : 8.30am - 5pm Sat : 8.30am - 1pm

PIL @ Gleneagles Hospital Penang 6th Floor, Gleneagles Penang, No. 1, Jalan Pangkor, 10050 Georgetown, Pulau Pinang.	04-2200838 / 04-2108202	04-2106006	Mon - Fri : 9am - 5.30pm Sat : 9am - 1pm
PIL @ Pantai Hospital Ipoh 4th Floor, Pantai Hospital Ipoh, No. 126, Jalan Tambun, 31400 Ipoh, Perak.	05-548 1279	05-548 8044	Mon - Fri : 8.30am - 5pm Sat : 8.30am - 1pm
Ipoh Off-site 13, 13A & 13B, Pusat Perdagangan Canning 2, Pusat Perdagangan Canning, 31400 Ipoh, Perak.	05-543 0439 (office) / 05-543 0696 (Histo dept)	05-543 0150	Mon - Fri : 8.30am - 5pm Sat : 8.30am - 1pm
PIL @ Pantai Hospital Manjung 1st Floor, Pantai Hospital Manjung, Jalan PPMP 1, Pusat Perniagaan Manjung Point, 32040 Seri Manjung, Perak.	05-688 6608	05-688 8058	Mon - Fri : 8.30am - 5pm Sat : 8.30am - 1pm
Southern Region			
PIL @ Seremban Ground Floor, Oakland Commerce Centre, No. 55, Jalan Haruan 5/2, 70300 Seremban, Negeri Sembilan.	06-6016466	06-6016467	Mon - Fri : 9am - 5.30pm Sat : 9am - 1pm
PIL @ Pantai Hospital Ayer Keroh Ground Floor, Pantai Hospital Ayer Keroh, No. 2418-1, Km 8, Lebuh Ayer Keroh 75450 Ayer Keroh, Melaka.	06-231 7977	06-231 7978	Mon - Fri : 8.30am - 5pm Sat : 8.30am - 1pm
Ayer Keroh Off-site B7, B7-1, B8, B8-1 & B9-1 Jalan PKCAK 1, Pusat Komersial Cendana Ayer Keroh, Hang Tuah Jaya, 75450 Melaka.	06-231 3232	06-231 2277	Mon - Fri : 8.30am - 5pm Sat : 8.30am - 1pm
PIL @ Muar No. 6, Tingkat 1, Taman Perniagaan Jaya, Pusat Perniagaan Mas Jaya, Jalan Salleh, 84000 Muar, Johor.	06-951 6095	06-951 6139	Mon - Fri : 9am - 5.30pm Sat : 9am - 1pm
PIL @ Pantai Hospital Batu Pahat No 134 & 136, Jalan Flora Utama 8, Taman Flora Utama, 83000 Batu Pahat, Johor.	07-485 0068	-	Sun - Thu : 8.30am - 5pm Fri : 8.30am - 1pm
PIL @ Kluang No 70, Jalan Kluang Perdana 1, Taman Kluang Perdana, 86000, Kluang, Johor.	+607 739 2534	+607 739 2504	Sun – Thu: 9am – 5.30pm Fri : 9am – 1pm

PIL @ Gleneagles Hospital Johor Level 1, No. 2, Gleneagles Hospital Johor, Jalan Medini Utara 4, Medini Iskandar, 79250 Iskandar Puteri, Johor.	07-5601042	07-5601050	Mon - Fri : 8.30am – 5pm Sat : 8.30am - 1pm
East Coast			
PIL @ Kota Bharu Kota Bharu Medical Centre Sdn Bhd PT 179 - 184, Jalan Sultan Yahya Petra, Lundang, 15200, Kota Bharu, Kelantan.	09-7433535	09-7433530	Sat - Thu : 8.30am - 5.30pm Fri : 9am - 12pm
PIL @ Kerteh Lot 50058, Tingkat 1, Jalan Kemaman - Dungun, 24300 Kerteh, Terengganu.	09-826 2187	09-826 1730	Sun - Thu : 8.30am - 5.30pm Sat : 8:30am - 1pm
PIL @ Kuala Terengganu Specialist Hospital Ground Floor, Kuala Terengganu Specialist Hospital (KTSH), Lot 3963, Jalan Sultan Mahmud, 20400 Kuala Terengganu, Terengganu.	09-6221241	+609 622 7801	Sun - Thu : 8.30am - 5.30pm Sat : 8:30am - 1pm
PIL @ Kuantan A29, Ground Floor, Lorong Tun Ismail 10, Sri Dagangan, 25000 Kuantan, Pahang.	09-513 0886	09-513 0885	Mon - Fri : 9am - 5.30pm Sat : 9am - 1pm
East Malaysia			
PIL @ Gleneagles Hospital Kota Kinabalu 2nd Floor, Gleneagles Kota Kinabalu, Riverson@Sembulan, Block A-1 Lorong Riverson@Sembulan 88100 Kota Kinabalu, Sabah.	088-518908	-	Mon - Fri : 7.30am - 5pm Sat : 7.30am - 1pm
PIL @ Miri Lot 10602, Ground Floor and Second Floor, Pujut 7 Commercial Centre, Jalan Pujut 7, Sungai Merapa, Lutong, 98000 Miri, Sarawak.	085 491 725 Mobile: +60 12-245 6734	0 85 491 725	Mon - Fri : 9am – 5.30pm Sat : 9am - 1pm
PIL @ KMI Tawau Medical Centre Level 4, KMI Tawau Medical Centre TB 4551, Jalan Abaca, Bandar Tawau 91000 Tawau, Sabah.	08 977 1873, Ext: 125	-	Mon – Fri: 9.00am - 5.30pm. Saturday: 9am - 1pm
Satellite Laboratory			
PIL @ UKM Specialist Centre (UKMSC) 7th Floor, Clinical Block, UKM Medical Centre, Jalan Yaacob Latif, Bandar Tun Razak, 56000 Cheras, Kuala Lumpur.	03 - 9171 1748 / 1749	03 - 9171 1629	Mon - Fri : 8.30 am - 9pm Sat : 9 am - 5pm

PIL @ Perak Community Specialist Hospital (PCSH) 277, Jalan Raja Permaisuri Bainun, 30250 Ipoh, Perak.	05-241 9000	-	Mon - Fri : 8am - 6pm Sat : 8am - 1pm
PIL @ Kinta Medical Centre (KMC) Ground floor, No. 20, Jalan Chung Thye Pin, 30250 Ipoh, Perak.	05-2531122	05-2535122	Mon – Fri : 8.30am - 5pm Sat : 8.30am - 1pm
PIL @ Hospital Ar Ridzuan A1, Jalan Dato' Seri Ahmad Said, Greentown Suria, 30450 Ipoh, Perak.	05-242 1111	05-241 1110	Mon – Fri : 8.30am - 5pm Sat : 8.30am - 1pm
PIL @ Kensington Green Specialist Centre (KGSC) Level 3A, No. 2, Jalan Ceria 20, Taman Nusa Indah, 79100 Iskandar Puteri, Johor.	07- 213 3893	-	Sun – Thu : 8am - 5pm Fri : 8am - 12pm
PIL @ IIUM Medical Specialist Centre (IMSC) Kulliyah of Medicine IIUM, Kampus Kuantan, Bandar Indera Mahkota, 25200 Kuantan, Pahang.	+609 573 8150	-	Mon – Fri : 8.30am – 5.30am Sat : 9am – 1pm

INPATIENT ANCILLARY SERVICES

The hospital-based laboratory provides 24 hours clinical laboratory support for inpatient and emergency department.

All specimens sent to for testing outside the normal office hours are subject to additional charges.

OUTPATIENT PHLEBOTOMY SERVICES

Phlebotomy services are available during the outpatient operating hours at our laboratories. Referring clinics shall issue a Laboratory Request Form for patients to bring along to our outpatient department to ensure correct and adequate specimens are collected. Please refer to Table 1 for the operating hours. We are close on public holidays.

SPECIMENS PICK UP SERVICES

Kindly call up our service call line provided for specimen pick up services.
Specimens pick up service is available during the below operating hours (except for few branches in Northern Region, East Coast and Southern Region):

- Monday to Friday 9.00 am to 5.30 pm
- Saturdays 9.00 am to 1.00 pm
- Sundays & Public Holidays Closed

For further details, please refer to Table 1: Operation Hours, Location and Contact Numbers. Extended hours are also available in some areas. Please enquire with your local branch for details.

SUPPLIES

We provide the following consumables within 2 working days upon receiving the Supply Request form from the client clinics:

- Request Forms
- Specimen Containers
- Sterile Swabs
- Cervical Smear Kit (Conventional and Liquid Based)
- Histopathology Specimen Containers
- Specimen Carrier Bags

Requisition of consumable supply with Supply Request form shall be submitted to the laboratory personnel during office hour 1 day in advance of the expected date of supply.

The collection of supply is strictly during normal office hours only.

Expired supplies shall be returned to us or being disposed at your end. Please give us a call for the arrangement.

PRICING & PAYMENT POLICY

- All prices are quoted in Ringgit Malaysia and subject to the implementation of the Goods and Services Tax.
- All cheque payment shall be payable to "Premier Integrated Labs Sdn Bhd" only.

Our Marketing and Despatch personnel are authorised to collect the cheques on behalf of the company.

FEEDBACK AND SUGGESTIONS

We value and welcome your feedback in relation to our services. If you have any comment or suggestion, please contact our Customer Service +603 4280 9115 or our respective branch or email to info@premierintegratedlabs.com.my

GENERAL INFORMATION

Please refer to our Service Catalogue for full range of examination offered by laboratory including, as appropriate, information concerning samples required and primary sample volumes. We will inform customer and user for any deviations from the Service Catalogue or service agreement that impact upon the examination results.

LABORATORY REQUISITION

TEST REQUISITION

All specimens shall be accompanied by a request form filled with the following particulars:

- Patient's Full Name & second identifier (Government ID or Passport No/Medical Record Number)
- Patient's age, date of birth & gender
- Date & time of specimen collection
- Diagnosis or Clinical History (Where Applicable)
- Name and signature of requesting doctor, clinic stamp and telephone number
- Billing mode (Cash, Clinic, Hospital and Employer/GL)
- Special attention if required (Urgent/Overtime/Phone/Fax No.)
- Nature / source of specimen
- Specimen Status (Fasting or non-fasting)
- Examination required

TYPE OF REQUEST FORMS

- Blood Bank/Transfusion Request Form
- Clinical Request Form
- Histopathology & Cytopathology Request Form

- Allergy Diagnostic Request Form
- PMCare Request Form
- Prudential Request Form
- Specialized Testing Request Form
- Microbiology Request Form

TEST ORDER

Tick at the column next to the test(s) to indicate the test(s) requested or name the test under the "**OTHER TEST**" column if it is not included on the printed test list.

"SPECIAL" TEST

Certain special test e.g., blood transfusion, HIV, Cytogenetic, DNA testing requires informed consent. It is the responsibility of the requester to ensure that consent is taken prior to testing. This consent should be kept in the patient's case note.

URGENT TEST

Tick on the **URGENT** box.

- Send specimen in **URGENT Specimen Carrier Bag.**
- Select/ Tick on phone/ email and provide phone/ email number on the request form if email of report is required.

ADD TEST

- Adding test to old specimen is subject to specimen availability, adequacy, and nature of specimen
- Overnight specimens are not suitable for biochemistry, haematology testing and microbiology.
- Please check with laboratory staff before adding new tests on same specimen. Do enquire with the local branch on the test listing with allowable time limits for requesting additional examinations or further examinations on the same primary sample.
- Oral/ verbal-request (regardless of new or additional test) is not acceptable. Additional tests to be added upon receiving the supplementary request form or upon receiving order from HIS/ e-Ordering system.

SPECIMENS COLLECTION AND HANDLING

Proper specimen collection and handling is an integral part of obtaining a valid and timely laboratory test result. Specimens must be obtained using proper phlebotomy techniques, collected in the proper container, correctly. It is the policy of the laboratory to reject specimens when there is failure to follow these guidelines. All specimens should be handled with universal precautions, as if they are hazardous and infectious.

TYPES OF CONTAINERS AND ANTICOAGULANT

Name	Cap	Type of Testing
Sodium Citrate	Blue	Coagulation
Plain	Red	Chemistry, Serology, Immunology, Endocrinology
Lithium Heparin	Green	Chemistry, Therapeutic Drugs
Sodium Heparin	Green	Karyotyping and FISH
EDTA	Purple	Haematology/ Blood banking & Crossmatch
Fluoride Oxalate	Grey	Glucose, Lactate

Refer to Appendix 1: BD Tube and Microtainer Tube Guide and Greiner Vacuette® Blood Collection Tubes and MiniCollect Guide

ORDER OF DRAW FOR BLOOD SPECIMENS

Blood collection tubes must be drawn in a specific order to avoid cross-contamination of additives between tubes. The recommended order of draw for plastic vacutainer tubes is:

1. Blood culture tubes (applying full aseptic technique)
2. Citrate Tube (Blue cap)
3. Plain Tube (Red cap)
4. Heparin Tube (Green cap)
5. EDTA Tube (Purple cap)
6. Fluoride Tube (Grey cap)

NOTE: Tubes with additives must be thoroughly mixed. Erroneous test results may be obtained when the blood is not thoroughly mixed with the additive.
Please refer to BD Vacutainer and Greiner Vacuette® Order of Draw for Multiple Tube Collections (Appendix 2)

GENERAL SPECIMEN PREPARATIONS

- Correct patient identification before specimen collection is extremely important. Identify the patient prior to specimen collection using **at least two patient identifiers**. Each specimen must be labelled with at least 2 identifiers which include the following information; and the information must tally with the form:
    - Patient's name AND
    - NRIC/ Passport Number for foreigner/Date of Birth (DOB)/Medical record number (MRN)

- **Avoid drawing blood below or from** the **indwelling catheters or arterial line or infusion side** to prevent dilution of blood specimen.
- Ensure correct type specimens in used. Select specimen containers according to the tests requested (Refer to Service Catalogue).
- Do not use expired collection container for specimen collection to ensure the integrity of specimens.
- Label specimen with waterproof ink at the point of specimen collection.
- Indicate the source of specimens on containers for anatomical pathology and microbiology specimens.
- Do not pre-label the empty specimen containers before attend to the patient.
- Blood bank specimen must be labelled clearly and accurately at patient's bedside immediately after blood taking. **DO NOT** share blood bank specimen with other tests. Use only handwritten label and never use pre-printed label or labelling specimen.
- Fill up the citrate and EDTA specimens to the volume mark available on the tube to ensure the correct anticoagulant to specimen ratio.
- Fill up the Microtainer tube to level between the lines to minimize the chance of microclot forming.
- Secure all specimen containers' caps to prevent leakage and cross contamination. All specimens should be properly sealed (e.g. capped firmly or screwed tightly) before transportation to the laboratory. Do not send specimen in syringes, regardless of whether the needles are attached or not.
- Place specimens in the inner pocket of the specimen carrier bag and seal the zip.
- Place the request form **with complete Patient's Information, clinical history and/or diagnosis** at the outer pocket of the specimen carrier bag.
- Send specimen(s) together with completed laboratory request form or electronic ordered through HIS.to the laboratory for testing as soon as possible after collection to ensure best turnaround time and most accurate results. It is highly recommended that the specimen should arrive in the laboratory within the same day of collection.
- Separate or divide the primary sample when necessary if foreseeing delay in sending specimen(s) to the laboratory.
- Specimen in formalin (e.g., histopathology) is contained in a sealed container, preferably a screw cap container.
- Slides specimens (e.g., pap smear slides) are kept in appropriate slide holders.
- For collection of urine specimen for drug abuse testing, collection site must be secure in order to eliminate the possibility of specimen tampering or adulteration.
- To prevent haemolysis:

- Allow alcohol on venepuncture site to dry before inserting needle into the vein.
- Use proper needle gauge size. A 21-gauge needle is recommended for collection of blood using non-vacutainer tubes. There is a greater likelihood of haemolysis with smaller gauge needles.
- Collection of blood using non-vacutainer tubes:
  - During venepuncture, the plunger of the syringe should be drawn back slowly, and the blood should flow freely.
  - After venepuncture, remove the needle before allocating blood into the blood tubes and expel blood gently into the correct collection container.
- If use vacutainer tubes, do not remove the cap
- Fill the blood sample up to mark on the tube
- Do not shake the blood tube vigorously as this may cause haemolysis

• Avoid clot formation by:
- Ensuring the smooth venepuncture and steady flow of blood into the syringe.
- Introducing the blood in the anticoagulated tube up to the mark as soon as the blood has been drawn.
- Immediately mix gently the capped blood tube by inverting the tube at least 5–10 times.

GENERAL SPECIMEN STORAGE

- Avoid exposing specimens to extreme heat or cold.
- All specimen collected or obtained, except for a few that require other specific instructions as indicated in the specimen types, are to be left at room temperature in the clinics while waiting for pick-up by the despatchers.

- Do not keep the specimens overnight in the clinics as these specimens may give erroneous and misleading analytical results to some tests reported, examples are urea, electrolytes, phosphate, glucose, etc.

TRANSPORT OF SPECIMENS

For clinic and wards situated within the hospital, the Pneumatic Tube System (if applicable) can be used to send blood, urine, and swab specimens to the laboratory. Blood culture, surgical tissue, body fluids, bone marrow specimens and amniotic fluid for cytogenetic examination shall NEVER be transported to laboratory via Pneumatic Tube Systems.

To ensure timely and safe transportation of specimens, the following shall be followed:

1. proper packaging of specimen for transportation;
2. ensure the time between collection and receipt in the laboratory is appropriate for the requested examinations;
3. maintain the temperature interval specified for sample collection and handling;
4. Any specific requirements to ensure integrity of sample, e.g., use of designated preservatives;

SPECIMEN REJECTION

SPECIMENS REJECTION CRITERIA

To ensure the quality of the analytical results provided are not compromised due to the quality of the specimens, our laboratory personnel will inspect the appropriateness of the specimens and test requests upon receiving in the laboratory. Inappropriate or inadequate specimens or test requests will be rejected according to the following Specimen Rejection Criteria:

- Broken/leaking/split specimen.
- Clotted EDTA
- Clotted Citrate
- Hemolyzed serum
- Grossly hemolyzed EDTA
- Grossly lipemic

- Discrepancy of patient information
- No request form accompanying with sample
- No specimen received
- No hand written label on crossmatch specimen
- Incomplete clinical history & diagnosis
- Incomplete date/time of specimen collection
- Incomplete Doctor's information/signature
- Incomplete Information of Nature/source of specimen
- Incomplete patient information
- Incorrect specimen type
- Insufficient specimen
- Unsuitable specimen
- Overfilled citrate specimen
- Underfilled citrate specimen
- Overnight/delayed specimen
- To rule out pre-analytical errors (wrong sample collection site is suspected)
- Microbiology specimen without proper transport medium
- Microbiology specimen collected in non-sterile container
- Tissue block specimen contain less than 10% of tumour for Molecular Oncology
- Collection swab has dried out for microbiology
- Specimen is grossly insufficient in proportion to the anticoagulant
- Inadequate histopathology/ cytopathology specimen
- Expired specimen container
- Test not available
- Specimen without label

REJECTED SPECIMENS

- Specimen rejection will be informed to the referring party by phone, followed by a Follow Up Specimen Request Form fax/send to the referring party.
- Corrective action to be taken will be suggested upon the notification of specimen rejection.
- Provide analysis or perform specialized tests which require special skills or instrumentation that are beyond the capacity of the in-house laboratory
- Provide analysis or perform tests that are requested infrequently
- Provide second opinion for histopathology, cytopathology, and related disciplines
- Provide backup service for unscheduled or unanticipated situation

The laboratory will not be held responsible for tests sent to a laboratory at the specific request of a requesting clinician if the respective referral laboratory:

- Is not an approved Outsource Referral Laboratory by Premier Integrated Labs Sdn. Bhd.

PREPARATION OF SPECIMENS

Preparation of specimens consists of the following:

1. Collecting A Clean Catch Urine
2. Collecting 24-hour Urine
3. Oral Glucose Tolerance Test
4. Urea Breath Test
5. Blood Gases pH
6. Semen Analysis
7. Neonatal Serum Bilirubin
8. Haematology Guidelines
9. Cytopathology Guidelines
10. Histopathology Guidelines
11. Microbiology Guidelines

COLLECTING A CLEAN CATCH URINE

Clean-catch urine specimens are collected in a sterile specimen cup or container. Instruction shall be provided to the patient prior to the specimen collection to facilitate a proper collection procedure.

Instruct the patient to wash hand thoroughly. The lid of the specimen container shall be removed and avoid touching the inside of the specimen container or lid. For a female patient, she shall spread her labia apart with one hand, keeping the folds separated for the rest of the procedure. Using disposable wipes, clean the area between the labia and around the urethra thoroughly from front to back. Use a new wipe for each stroke. If water is used in the cleaning, the same area shall be pat dry with clean paper towel. Men follow the same instructions but cleanse the outside of the penis before starting the urine stream. If the patient is not circumcised, he shall pull back the foreskin before starting the cleaning procedure.

The patient shall urinate a small amount into the toilet and start collecting the urine in the specimen container after 2 or 3 seconds. The patient shall avoid placing the container onto the perineal skin. A collection of about 30 ml of urine is sufficient for urinalysis and bacterial culture procedure. The lid of the container shall be secured before passing the urine specimen to the nurse.

A specimen that contains stool, vaginal discharge, or menstrual blood cannot be used.

COLLECTING 24 HOUR URINE

Instruction for 24 Hours Urine Collection

1. Note time before collecting urine.
2. Empty bladder completely.
3. Discard this urine specimen.
4. Collect all subsequent urine specimens passed during the next 24 hours in the container provided with the suitable preservative in it. (Urinate into a small container and transfer it into the 24 hours urine container provided).
5. Mix the contents thoroughly after each addition of urine if a preservative is used.
6. At the end of the collection period (approximately the same time the following day), empty bladder completely.
7. Include the last urine specimen in the total collection.
8. Send the specimen immediately to the laboratory / Consultant suite.
9. Please do not urinate directly into the bottles as it contains preservative that are caustic and harmful to the skin.

Note: Please include the height and weight of patient if creatinine clearance is being done.

Patient Preparation for urine VMA

Many Laboratories restrict food. Such as coffee, tea, bananas, and other foods. Some ask for no drugs use (except for digitalis) for 2 weeks before the test. Aspirin, Peroxidane, Levodopa, Amoxicilin, Cardidopa, Reserpine and Disulfiram commonly interfere.

Monoamine oxidase inhibitor decrease VMA excretion.

For an infant, thoroughly wash the area around the urethra. Open a urine collection bag (a plastic bag with an adhesive paper on one end) and place it on the infant. For males, place the entire penis in the bag and attach the adhesive to the skin. For females, place the bag over the labia. Diaper as usual over the secured bag.

This procedure may take a couple of attempts -- lively infants can move the bag, causing the urine to be absorbed by the diaper. The infant should be checked frequently, and the bag changed after the infant has urinated into the bag. Drain the urine from the bag into the container provided by your health care provider.

Deliver it to the laboratory or your health care provider as soon as possible upon completion.

ORAL GLUCOSE TOLERANCE TEST

The oral glucose tolerant test (OGTT) is used for the diagnosis of gestational diabetes mellitus, type 1 and type 2 diabetes mellitus.

Patient shall be advised to resume normal diet intake (containing at least 150g of carbohydrate daily) and usual physical activity for at least 3 days prior to the test. The patient must fast overnight (8-14 hours) with only plain water is allowed. Smoking is not permitted during the test and the presence of factors that influence interpretation of the results shall be recorded (for example: medications, inactivity, infection, etc.).
A fasting venous blood specimen will be taken prior to the consumption of 75g anhydrous glucose. Paediatric patient will be given 1.75 g/kg body weight up to 75g for the glucose load. Patient shall be remained seated and consume nothing but water throughout the test. The test shall be abandoned if the patient vomits during the test.

For general patients who are not pregnant, a fasting and 2-hour post glucose load venous blood specimen shall be obtained for blood glucose testing; for OGTT performed on pregnant ladies, an additional 1-hour post glucose load specimen is required besides the fasting and 2-hour post glucose load specimens (Recommendation on the diagnosis and classification of hyperglycaemia in pregnancy by International Association of Diabetes).

Specimens for OGTT shall be clearly labelled with the time of collection to allow the laboratory to differentiate between the fasting and post glucose load specimens and report accordingly.

UREA BREATH TEST

PYtest Administration & Analysis in 3 Easy Steps
The patient should have fasted for 4 hours prior to completing the test. The patient should not have taken antibiotics and bismuth containing products for 1 month, proton pump inhibitors for 1 week and cyto-protective medicines such as sucralfate for 2 weeks prior to the test. This is because such medications will decrease the DPM readings and may give false-negative results.

Step 1

The PYtest® Kit should be opened and all components laid out.
PYtest Kit Includes:

- 2 paper cups
- PYtest® balloon
- PYtest® capsule
- A straw
- A courier/mailbox for the balloon should the breath specimen need to be posted or air-freighted

Step 2

The Patient swallows a PYtest® capsule (containing a small amount of 14C-labelled urea) with 30mls of water using paper cup provided. Wait 3 minutes then swallow the second cup of water and wait for another 7 minutes before proceeding to Step-3. When the 14C-urea comes into contact with *H. pylori* in the stomach, it is hydrolysed into 14C-carbon dioxide and ammonia. The 14C-carbon dioxide (14CO2) enters the bloodstream and is carried to the lungs via the circulatory system and is exhaled by the patient.

Step3

Ten minutes after ingesting the capsule, a breath specimen is collected in a special metalized mylar balloon. The balloon containing the breath specimen may be analysed on-site or sent to a pathology laboratory for analysis.

UREA C13 BREATH TEST KIT-HELIFORCE^{tm}

The patient should have fasted and no smoking for 2 hours prior for completing the test. The patient should not have taken Antibiotic/ Antibacterial at least 4 week, Proton Pump Inhibitor and H2 Receptor Antagonists at least 2 week such as Amoxcycilin, Bismuth tricitrtate, Omeprazole, Lansoprazole, Cimitidine and Nizatidine.

The Urea C13 Breath Test Kit-Heliforce[tm] should be opened up and all component laid sich as C13 Urea Granule, 2 breath collection bag for 00-Min and 30-Min.

Step 1
Two breath collection bags will be given. Remember to label with patient's Name and Date of collection. Indicate one as 00-Min and another as 30-Min.

Step 2
For collection the 00-Min, remove pull-off cap from mouthpiece. Ask the patient to breath normally and exhale into mouthpiece of the bag until it bloated. Replace the cap of the mouthpiece of the bag.

Step 3
Dissolve the C13 Urea Granule 80-100ml purified, room temperature water and mix well. Then, the patient drink the solution and set time for 30 minute.

Step 4
After 30 minutes taking the C13 ure granule solution, collect breath again using the sample bag 30-Min. Send both breath collection bags to the laboratory for analysis.

BLOOD GASES AND pH
The measurement of blood gases and pH are used to evaluate oxygen and carbon dioxide exchange, respiratory function, and acid-base balance. Arterial blood is preferred for these determinations due to its superior uniformity throughout the body, but venous pH is extremely similar in most situations and is more easily obtained.

The blood gases specimen shall be collected by using heparinized syringe. While collecting the blood gases specimen, be sure that no air bubbles are aspirated into the syringe. After adequate specimen volume is obtained, quickly remove the needle, and apply pressure on the puncture site.

The specimen shall be sealed immediately and placed on ice. It is important to keep the specimen airtight and watertight and immediately transport the specimen to the Intensive Care Unit for testing. The testing shall be performed within 10 – 15 minutes from the time of specimen collection.
Mode of oxygen delivery (whether the patient is breathing room air, oxygen, or ventilated) and patient's temperature must be indicated. Fever and assisted oxygen or breathing alters test interpretation.

The cause of specimen rejection includes clots in specimens, specimen left at room temperature for more than 15 minutes and specimen is not properly sealed before analysing**.**

SEMEN ANALYSIS
1. Refrain from sexual intercourse or masturbation for between 3 to 5 days.
2. Produce the specimen by masturbation without artificial lubricants. Do not use condom, as condoms contain spermicidal agents.
3. Collect the specimen into the clean, wide mouth container supplied. It is important that the whole ejaculate is collected. If not, the specimen should be labelled as incomplete.
4. Record time of ejaculation and the number of day of sexual abstinence.
5. The specimen must be delivered to the lab within 1 hour once been collected without any delay. Keep the specimen warm at body temperature during the transportation.

NEONATAL SERUM BILIRUBIN

The capillary tube shall be fill up 80% of tube and seal both end with wax or clay after sample has been collected.
Neonatal Serum Bilirubin specimen must be cover to protect from sunlight and shall be send Urgently.
Please refer to Appendix 3- Capillary Blood Sampling

HAEMATOLOGY GUIDELINES

Guideline for Coagulation Test

- Good specimen collection e.g., clean venepuncture with minimal stasis, not from indwelling catheters or arterial lines.
- Recommended to use a 21-gauge needle or butterfly. 19 gauge maybe used in adults with good veins: 23 gauge maybe required for infants.
- Do not use heparin-contaminated venous lines. If unavoidable, flush the lines with crystalloid and discard first few millilitres of blood.
- Correct ratio 1 part of sodium to part 9 of blood is essential. Collect blood to the indicator line on the tube to ensure correct amount of blood collected.
- Keep the blood (in collection tube) in ice.
- Send blood to the laboratory immediately
- Note down exact time blood is collected.
- If haematocrit is >0.55, contact laboratory for a sodium citrate tube with adjusted volume of anticoagulant.

CYTOPATHOLOGY GUIDELINES

Table 2: Specimen Collection and Handling for Cytopathology Specimens

SPECIMEN TYPE	COLLECTION & HANDLING GUIDELINES
BRONCHIAL BRUSHINGS	• Roll brush over clean, dry slide. • Fix immediately the labelled slides with spray fixative or 95% ethyl alcohol. • The brush used to prepare bronchial brushing slides may be swished in a container of Cytolyte solution to dislodge remaining specimen. • Label containers/ slides with at least 2 identifiers (e.g., patient's name, IC, passport number or MRN) • Submit to the laboratory using one request form.
FINE NEEDLE ASPIRATION (FNA)	• Advanced booking is required for FNA by Consultant Cytopathologist as well as when assistance is required by MLT. • A signed consent from the patient shall be obtained by the person performing the procedure. *Refer Appendix 6 for sample of the consent form.* • Fix 2 to 3 slides immediately (within a few seconds) using Cytopathology spray fixative or immerse in 95% ethyl alcohol for 15-30 minutes. • Provide another 2 to 3 air dry slide without fixative. • Fluid obtained with a needle pass shall be expressed into a sterile container. • Label containers with at least 2 identifiers (e.g., patient's name, IC, passport number or MRN) and indicate nature of the specimen. • Label slides as (A) to indicate air dried and (F) for alcohol fixed smears. • Submit to the Laboratory using one request form.
FLUIDS	• Including CSF, bronchial washing, colonic washing, pelvic washing, effusion, etc. • Collect in a sterile container, label with at least 2 identifiers (e.g., patient's name, IC, passport number or MRN) and indicate nature of the specimen and send immediately to the laboratory.
GYNAECOLOGY SMEAR	• Ideal sampling date is two weeks after the first day of the last menstrual period. Avoid sampling during normal menses. • Avoid use of vaginal medication, vaginal contraceptives, or douches for 48 hours prior to examination. • Information needed in the request form should include the following: i) Last Menstrual Period (LMP) ii) Previous surgery (GYN) iii) Hormonal/Oral Contraceptive (OCP)

Liquid Based (ThinPrep/PathTezt)

- To obtain an adequate sample from the cervix, insert the central bristles of the broom into the endocervical canal deep enough to allow the shorter bristles to fully contact the ectocervix. Push gently and rotate the broom in a clockwise direction 5 times.
- Rinse the broom in the preservative solution vial by pushing the broom into the bottom of the vial 10times, forcing the bristles apart. Swirl the broom vigorously to further release the material. Discard the broom.
- Tighten the cap so that the torque line on the cap passes the torque line on the vial.
- Label the test vial with at least 2 identifiers (e.g., patient's name, IC, passport number or MRN).
- Submit to the laboratory using one request form.
- Refer to Appendix 4: ThinPrep® quick reference guide.
- Refer to Appendix 5: PathTezt quick reference guide.

Conventional

- Label the slide with at least 2 identifiers (e.g., patient's name, IC, passport number or MRN).
- Smear preparations shall be fixed immediately after collection:

Fixative	Duration
95% ethyl alcohol	15 – 30 minutes
spray fixatives	10 minutes

- Fixed smears should be allowed to dry for 10 minutes prior to placing into slide carrier for dispatch to the laboratory.
- Submit to the laboratory using one request form.

HISTOPATHOLOGY GUIDELINES

HANDLING OF SPECIMEN

- Routine specimens should be fixed in 10% buffered formalin unless otherwise stated.
- Ensure volume fixative 10:1 ratio of fixative to tissue. Fixative volume shall be at least 10 times of the specimen size.
- Unfixed biopsy specimens for immunofluorescence shall be sent to laboratory immediately.
- Unfixed and fresh specimen for frozen sections shall be delivered to laboratory immediately.
- All specimens shall be labelled with patient's 2 unique identifiers and nature of specimens.
- All histopathology specimens shall be sent in containers with proper labelling.
- Large specimen shall be sent in double-bagged plastic bag to prevent leakage.
- Multiple small specimens, such as gastrointestinal biopsies, shall be mounted on a piece of filter paper and properly labelled. E.g.: specimen site.
- For specimens where orientation is important, mark or tag the specimen e.g., axillary tail of mastectomy specimens, surgical margin.
- Specimens from different anatomical sites should be sent in separate containers, labelled, and itemized in the same Histopathology Request Form.
- Specimens will be charged according to the number of containers, size and nature of specimens, complexity of specimens and not depending on the size of containers.

FROZEN SECTION

- At least one day advance booking is required.
- Contact Histopathology Department for enquiry.
- Specimen for frozen sections should be fresh specimen without fixative.
- An additional 100% surcharge will be imposed for frozen section request done after office hours.
- Courier service charge for waiting and pickup specimen.

IMMUNOFLUORESCENCE (IMF) (Renal or Skin)

- At least one day advance booking is required.
- 2 containers of specimen required:
  i. Fresh unfixed specimen for Renal OR Skin biopsy shall place on filter paper wet /soaked with saline.
  For outside Klang Valley - Kindly keep the fresh specimen in “Mitchel Fluid”.
  Kindly request one week before procedure.
  ii. Specimen in 10% buffered formalin.

SPECIAL STAINS & IMMUNOHISTOCHEMISTRY (IHC) STAINS

- Special stains employ staining techniques to identify suspected pathogens or demonstrate specific cellular components that aid pathologist in the evaluation of disease states.
- Immunohistochemistry stains (IHC):
  - To give clear picture of cancer invasion & metastasis
  - To decide appropriate line of therapy
  - In prognosis and response to treatment
  - In patient selection for targeted therapies
- Attending clinician will be informed of the additional test (Special stain or Immunohistochemistry stain) and charge will occur for further staining, kindly contact Histopathology laboratory for quotation.

RADIOACTIVE BIOLOGICAL SPECIMEN

- All biological specimens obtained from patients who have recently received radioactive material for the purposes of therapy or diagnosis are regarded as hazardous.
- All radioactive specimens should be sealed into containers and labelled with:
  - Radioactive label: “Caution Radioactive Material”
  - Type of radioisotope
  - Date and time the patient received radioisotope
- The requesting clinician must ensure to state that the specimen is radioactive and specify the radionuclide in the request form.
- Ensure double packaging of the radioactive specimens to prevent any potential leakage and do not use Pneumatic delivery system for radioactive specimens.

Table 3: Histopathology Specimen and Code

TEST NAME	TEST CODE	SPECIMEN
Uncomplicated specimen	HSS	1. Appendix 2. Fallopian tubes (1 Side) 3. Vas (1 Side) 4. Tonsils (1 Side) 5. Adenoids 6. Sebaceous cyst 7. Nasal polyp 8. Heart valve 9. Endocervical polyp 10. Endometrial curetting 11. Endometrial sampling/ pipelle 12. Doughnut (rectum)
Biopsy	BX	1. Wedge biopsy 2. Punch biopsy 3. Tru-cut biopsy (breast, 1 site) 4. Tru-cut biopsy (prostate – for 3 strips) 5. Tru-cut biopsy (bladder, lung etc.) 6. Antral biopsy 7. Gastric/ Stomach biopsy 8. Colon biopsy

		9. Cervical biopsy 10. PNS/NPC 11. Skin Lesion 12. Skin tag 13. Skin Biopsy 14. Liver biopsy 15. Lung biopsy
Medium Complicated Specimen	HMS	1. Eye 2. Salivary gland 3. Thyroid lobe (1 side) 4. Breast lump (1 Site) 5. Gallbladder 6. Prostatic chips (<3cm) 7. Splenectomy 8. Simple hysterectomy (prolapse) 9. Ovarian cyst/mass (<10cm) 10. Excised diabetic ulcer 11. Excised tumour (<10cm) 12. Lipoma (<5cm) 13. Omentum (<5cm) 14. POC 15. Mole with skin 16. Ovary (1 side <10cm) 17. Skin with tumour
Large complicated specimen	HLS	1. Lipoma (>5cm) 2. Omentum (>5cm) 3. Simple mastectomy 4. Breast hook-wire with margin 5. Breast WLE (<5cm) 6. Cone biopsy/ LLETZ/LEEP 7. Excised tumour (>10cm) 8. Hemicolectomy specimen 9. Prostatic chips (>3cm) 10. Ovary (1 side >10cm) 11. Axillary tail 12. Axillary lymph node 13. Lymph node 14. Fibroid 15. Molar/ Ectopic pregnancy 16. Placenta 17. Total abdominal hysterectomy and bilateral salphingoopherectomy (TAHBSO), without lymph node
Radical specimen	HRS	1. Laryngectomy 2. Pneumonectomy 3. Gastrectomy 4. Gut resection 5. Amputated limb (except for diabetes) 6. Total thyroidectomy 7. Total prostate 8. Bladder 9. Kidney 10. Breast WLE (>50mm) 11. Total colectomy 12. Ovarian mass 13. Femur

		14. Total abdominal hysterectomy and bilateral salphingoopherectomy (TAHBSO), with lymph node 15. Radical neck dissection 16. Mastectomy with axillary clearance 17. Whipple's (pancreaticoduodenectomy) 18. Wertheim's hysterectomy 19. Vulvectomy with lymphadenectomy 20. Any other radical dissections requiring margins and lymph node status
Immunofluorescence	IF	Renal/ Skin
Special stain	SS1	Histochemical stain
Single Immunohistochemistry (IHC) marker/ antibody	IHC	1 IHC marker/ antibody
Immunohistochemistry (IHC) Package	IHC	Package of 3 IHC markers/ antibodies ** Except for all IHC markers/ antibodies under Category 2 & Special Category
Frozen Section (Non-Neuro Cases)	FS	Please call lab at least 3 working days in advance to make appointment ** Only available in Klang Valley, Penang, Ipoh, Melaka, Johor Bahru & Kota Kinabalu
2nd opinion	H218	Second opinion by In-house pathologist
Photograph	PHOTO	Photograph of gross tissue specimen in report
Slide	BS	Request for 2 unstained slides or 1 H&E-stained slide
Tissue Block	TBL	Release request for 1-unit FFPE block

Note: Please contact histopathology lab for assistance.

MICROBIOLOGY GUIDELINES

GENERAL PRINCIPLES

- Whenever possible, specimens shall be collected before antibiotic therapy is commenced.
- Avoid contaminating the specimen. Maintain aseptic or sterile techniques.
- Specimens for bacterial culture should be representative of the disease process.
- Sufficient specimen must be collected to ensure an accurate examination.
- Transport specimens quickly to the laboratory to prevent desiccation of the specimen and death of the microorganisms.
- Submit fluid specimens collected. Do not submit fluids on swabs.
- Patient's recent antimicrobial therapy and brief clinical history shall be provided.

SPECIAL PRECAUTIONS

- Specify specimen collection site in the test order to ensure optimal recovery of micro-organisms.
- Specimen for urine culture shall be sent to the laboratory immediately after collection. Otherwise, it shall be refrigerated.

• CSF specimens shall be transported to the laboratory immediately after collection. Refrigeration is strictly prohibited as fastidious bacteria do not withstand refrigeration.

Table 5: Specimen Collection, Handling and Rejection Criteria for Microbiology Specimens

Specimen Type	Container and Amount	Storage and Transport	Precaution	Rejection Criteria
Abscess - needle aspiration - Drained abscess - Swab	Sterile leak-proof container Swab in Amies transport media	Transport as soon as possible at ambient temperature. If > 24 hours, refrigerate at 4 to 8°C	Avoid sampling the surface area. (Aspirate, if possible or pass a swab deep into the lesion and firmly sample the lesion's advancing edge) Remove surface exudates by wiping with sterile saline before collection.	Dry specimen in container Swab not in transport medium Received >24 hours after collection
Skin scraping/ Biopsy, Bone or Tissue	Sterile leak-proof container	Ambient temperature. If > 24 hours, refrigerate at 4 to 8°C Skin scrapping: transport to the laboratory in a cardboard mailer.	Cleanse the area with sterile saline. For skin scrapping, scrape area at the active margin of the lesion. Do not draw blood. Submit specimen in sterile container **without formalin**. Specimen may be kept moist with 0.85% sterile saline	Specimen submitted in formalin.
Blood Culture	Blood Culture Bottle Adult: 6-10 ml Aerobic blood culture bottle and 8-10 ml Anaerobic blood culture bottle Children or infants: 1-4 ml Paeds bottle	Transport upright in a rack in transport box. Ambient temperature if able to reach the lab within 24 hours.	An aseptic technique is critical to proper blood culture collection. Refer to Appendix 7 Do not keep Blood culture bottles in the refrigerator. Use Aerobic Blood culture bottles (6-10ml) for isolation of yeast/ fungal.	Broken blood culture bottles. Wrong container
Faecal Specimen or Rectal Swab	Clean, dry leak-proof screw cap containers or Appropriate bacteriology transport media or Swab in Amies transport media (rectal swab) 5ml liquid (a teaspoonful)	at 4 to 8°C	For rectal swab - pass the tip of a sterile swab approximately one inch beyond the anal sphincter. Carefully rotate the swabs to specimen the anal crypts for at least 10 seconds before withdrawing the swab. For bacterial isolation, need to process within 1 to 2 days of collection.	Leaking specimens Insufficient specimen Dry rectal swab or not visibly stained with faeces

	or 5g solid (peanut sized)			
Nail	Clean, dry leak-proof screw cap containers	Ambient temperature	Wipe nail with sterile saline. Clip away the affected areas and collect material under the nail	NA
Pernasal/ nasopharyngeal Swab	Swab in transport medium Calcium alginate swab in transport medium (for pertussis) Swab must be fully immersed in the transport medium	Ambient temperature	NA	Swabs not in transport medium
Sputum **Bronchial Lavage (BAL)** **Tracheal aspirate** **Nasopharyngeal aspirate**	Plain sterile container Sufficient amount depending on the number of tests requested	Transport in sealed container as soon as possible Bacteria – Ambient temperature. If > 24 hours, refrigerate at 4 to 8°C	Instruct patient to gargle or rinse mouth with water. Instruct patient to cough deeply to produce a specimen from the lower respiratory tract and not saliva.	Saliva, instead of sputum
Sterile Body Fluids	Plain sterile container Blood culture bottles Sufficient amount depending on the number of tests requested	Ambient temperature. If > 24 hours, refrigerate at 4 to 8°C	Clinicians obtain specimen via percutaneous needles aspiration or surgery. **Fluid specimens are preferable than swab culture.**	Insufficient specimen Received >24 hours after collection
Wound swab / pus	Swab with transport medium Swab must be fully immersed in the transport medium	Ambient temperature. If > 24 hours, refrigerate at 4 to 8°C	Disinfect surface of the wound with sterile saline. If swab is used, obtain specimen at the time of incision or drainage of wound. Avoid sampling of the surface area as it may contaminate the specimen with flora not involved in the infection.	Swab without transport medium Received >24 hours after collection
Throat Swab	Swab with transport medium Swab must be fully immersed	Ambient temperature.	Depress tongue with a sterile tongue depressor.	Swab without transport medium Received >24 hours

	in the transport medium	If > 24 hours, refrigerate at 4 to 8°C	Specimen inflamed area, exudates and/or lesions with the suitable swab for the test.	after collection
Vaginal And Urethral Swab	Swab in transport medium Swab must be fully immersed in the transport medium	Ambient temperature. If > 24 hours, refrigerate at 4 to 8°C	Avoid collection from the areas of normal flora. Please notify if *Neisseria gonorrhoe*a is suspected.	Swab without transport medium Received >24 hours after collection
CSF	Plain sterile bottle Minimum 0.5ml each in 3 different bottles	Transport in sealed containers as soon as possible. Bacteria – Ambient temperature. If > 24 hours, keep at 37ºC (incubator)	**Do not refrigerate specimen**	Insufficient specimen
Urine	Clean, screw-top specimen transport container Minimum 1ml	Transport to laboratory within 2-3 hours or store at 4 to 8°C not more than 24 hours	Avoid overnight specimens.	Insufficient specimen >4 hours after collection and left at room temperature >24 hours after collection if refrigerated sample
Urine from indwelling catheter	Clean, screw-top specimen transport container	Transport to laboratory within 2-3 hours or store at 4 to 8°C not more than 24 hours	Disinfect the catheter collection port with 70% alcohol. Use a needle and syringe to aseptically collect 5-10ml of urine. Transfer the urine to a sterile container	Foley catheter tips
QuantiFERON® – TB Gold Plus	1 ml for each tube collected in Nil control (Grey), TB1 antigen (Green), TB2 antigen (yellow) and Mitogen control tubes (purple).	Transport to laboratory within 16 hour after collection. Room temperature	Collect 1 ml blood for each QFT® blood collection tube according blood tube collection order (Grey-Green-Yellow-Purple). Follow the black mark on the side of the tube to ensure 1 ml fill volume.	Insufficient/ overfill specimen Received >16 hour after collection

Our routine Culture & Sensitivity of Bacterial Pathogen procedure identify and report the susceptibility pattern of a wide range of organisms as the laboratory uses the state-of-the-art technology in bacterial identification system.

Our routine Stool Culture procedure identifies and reports the susceptibility pattern of *Salmonella*, *Shigella* and *Vibrio*, *Aeromonas, Plesiomonas* and *Enteropathogenic E.coli.*

NOTE: For others special request please indicate on the request form if least common pathogens are sought or anaerobic culture is required.

MOLECULAR ONCOLOGY GUIDELINES

SAMPLE REQUIREMENTS FOR REAL TIME PCR OR SEQUENCING

- Tissue should be fixed in 10% Neutral Buffered formalin and not exposed to decalcification solution.
- The paraffin block should contain no less than 3 mm or at least 10% area of tumour for Real-Time PCR and at least 30% for Sequencing
- The laboratory accepts tissue sections. At least fifteen (15) paraffin sections are required for each test and to be kept in a microcentrifuge tube or mount on unstained slides.
- One H&E slide should be provided.
- Block or slide/ tube should be properly labelled with a block ID that matches the surgical pathology specimen number on the surgical pathology report.
- Block or slide/ tube should be sent at room temperature in proper storage containers (e.g., plastic slide boxes) to protect them during transport/shipment.
- A surgical pathology report and completed request form must accompany all specimens.

SAMPLE REQUIREMENTS FOR TISSUE FISH

- The recommended sample fixation for FISH is 6-48 hours in 10% Neutral Buffered Formalin.
- The laboratory accepts tissue sections. The optimal thickness for all sections is 3-4µm. Please clean microtome blade and water bath thoroughly before cutting sections to avoid cross-contamination and false positive results.
- The first few sections should always be reserved for FISH testing. Sections should be mounted on positively charged slides.
- Please label all slides clearly with AT LEAST TWO unique patient identifiers, e.g., name and pathology number (Block ID).
- For paraffin sections, send five (5) slides per FISH test requested in a protected container together with a completed request form, corresponding H&E slide with the relevant area marked (even if 100% is tumour tissue) and your own Histopathology report.
- If you prefer to send FFPE block, this will need to be cut and the sections marked by a histopathologist prior to testing.

Slides and blocks should be posted at room temperature packaged in a cushioned and sturdy outer package. A fine absorbent pad should be used to protect tissue face of the paraffin block from damage during transportation.

WHOLE BLOOD FOR LIQUID BIOPSY (***Refer Appendix 8***)

- Whole blood in two (2) 10 mL Cell-Free DNA (cfDNA) BCT Tubes provided or please contact Premier Integrated Labs at +603 2282 8795 ext. 209/210 for further information. (TUBES MUST BE IDENTIFIED WITH THE SAME NUMBER AS THAT REGISTERED IN THE ATTACHED REQUEST FORM AND MUST BE SENT TO THE LAB AS SOON AS POSSIBLE AT AMBIENT TEMPERATURE) After collection, immediately and gently invert the tubes 10 times. Inadequate or delayed in mixing may result in inaccurate test result.
- After 10 times inverted, store at room temperature (15°C to 30°C).
- Specimen must be reached at RSL, Premier Integrated Labs Sdn Bhd. Within 3 working days.
- Please contact Premier Integrated Labs Sdn Bhd. for collection of specimens.

MOLECULAR INFECTIOUS DISEASE GUIDELINES

GENERAL PRINCIPLES

- Handle the specimen with care and avoid steps that may cause contamination to the specimen.
- Sufficient specimen must be collected to ensure an accurate examination.
- Transport specimens quickly to the laboratory according to the requirement.
- Indicate anatomical collection site of the specimen and clinical diagnosis in the requested form.

SPECIAL PRECAUTIONS

- CSF specimens shall be transported to the laboratory immediately after collection. Refrigeration is strictly prohibited.

Specimen Type	Container	Storage and Transport	Precaution	Rejection Criteria
Nasal/Nasopharyngeal / Throat/ Oropharyngeal Swab	Viral Transport Medium (VTM)	Recommended at 2°C-8°C Ambient is acceptable	NA	NA
Sputum, BAL, Bronchial washing, Semen Urine, and other body fluid (except CSF)	Sterile Leak-Proof Container	Recommended at 2°C-8°C Ambient is acceptable	Ensure to collect 1st void urine	Salivary sample
Plain Serum/EDTA Plasma	2x Plain Tube/EDTA Tube	Refrigerate serum/plasma at 2°C-8°C for 3 days. Freeze in -20°C or cooler if store more than 3 days	NA	Lysed specimen
Fresh tissue	Sterile Leak-Proof Container	Recommended at 2°C-8°C Ambient is acceptable	NA	NA
Urethral/ Vaginal/ Endocervical / Cervical/ Penile/ Anorectal swab	Dry/Cotton Swab	Recommended at 2°C-8°C Ambient is acceptable	Avoid collection from the areas of normal flora.	NA
Liquid Base Cytology	Thinprep, Surepath or Pathtezt	Ambient	NA	NA
FFPE Block/Cell Block	Block Container	Ambient	Avoid high temperature during transportation	NA
CSF	Sterile Leak-Proof Container	Ambient	Do not refrigerate/ freeze	NA

CYTOGENETICS GUIDELINES

PERIPHERAL BLOOD (KARYOTYPE)

- Proper specimen collection and sterile handling are critical for cytogenetic studies.
- Draw 5-10 mL (paediatric: 2-5 mL) peripheral blood in sodium heparin or lithium heparin collection tube (green cap).
- Ensure the tube is tightly capped to prevent sample leakage during transportation to the laboratory.
- Collection containers must be closed tightly to prevent leakage of sample during transportation to the laboratory.
- Label specimen tube with patient's name and a second identifier (ex: DOB, MRN).
- All requests should be accompanied with the request form signed by the respective medical officers / consultants.
- Indicate The REFERRAL REASON(S) for the test (compulsory requirement). Clinical reference, diagnosis, and/or intended purpose of the investigation allows us to select the exact culture regime or mode of analysis most appropriate for the clinical scenario.
- Specimens should be received by the laboratory as soon as possible (ideally within 24 hours). It is generally recommended that specimens be maintained at ambient temperature during transit. Extreme temperatures should be avoided. Never freeze, add fixative or preservative.
- If it is not possible to process samples as soon as they arrive, they should be stored at 2-8°C.
- Only the specimen collect with sodium heparin or lithium heparin media will be attempted for cytogenetic studies.
- Specimens that are clotted, haemolysed and/or added in wrong anticoagulant tube will be rejected and informed to the ward or clinic immediately.
- Suboptimal specimens;
    - For partially clotted or haemolysed blood, or in which the log time before receipt by the laboratory is more than 24 hours, karyotyping studies may be attempted. However, the procedure is less likely to be successful.

    - Metaphase spreads may obtain from the sample collected in lithium heparin; however, sodium heparin is preferred since lithium heparin may cause toxicity to cells.
- Do not use expired collection containers or transport media for specimen collection.

BONE MARROW (KARYOTYPING)

- Proper specimen collection and sterile handling are critical for cytogenetic studies.
- Aspirate 1-5 mLs of a first draw of bone marrow aspirate into a sodium heparin tube and mix well to prevent clotting.
- Collection containers must be closed tightly to prevent leakage of sample during transportation to the laboratory.
- Label specimen tube with patient's name and a second identifier (ex: DOB, MRN).
- All requests should be accompanied with the request form signed by the respective medical officers / consultants.
- Indicate the REFERRAL REASON(S) for the test (compulsory requirement). Clinical reference, diagnosis and/or intended purpose of the investigation allows us to select the exact culture regime or mode of analysis most appropriate for the clinical scenario.
- Specimens should be received by the laboratory as soon as possible (ideally within 24 hours). It is generally recommended that specimens be maintained at ambient temperature during transit. Extreme temperatures should be avoided. Never freeze, add fixative or preservative.
- If it is not possible to process samples as soon as they arrive, they should be stored at 2-8°C.However, since delays affect quality, cultures should be initiated as soon as possible.
- Only the specimen collect with sodium heparin media will be attempted for cytogenetic studies.
- Specimens that are clotted, haemolysed and/or added in wrong anticoagulant tube will be rejected and informed to the ward or clinic immediately.
- Suboptimal specimens;
    - For partially clotted or haemolysed blood, or in which the log time before receipt by the

laboratory is more than 24 hours, karyotyping studies may be attempted. However, the procedure is less likely to be successful.
- Metaphase spreads may obtain from the sample collected in lithium heparin; however, sodium heparin is preferred since lithium heparin may cause toxicity to cells.

- Do not use expired collection containers or transport media for specimen collection.

AMNIOTIC FLUID (KARYOTYPE)

- Proper specimen collection and sterile handling are critical for prenatal cytogenetic studies.
- Informed consent from patients shall be obtained for all prenatal requests.
- Collect 15-25 ml of amniotic fluid at 15 weeks of gestation or greater in a sterile syringe.
- Discard the first 2-3ml of aspirated fluid to avoid maternal cell contamination.
- Transfer the remaining specimen into 2 sterile conical tubes (10mlx2) provided by the lab.
- The amniotic fluid should be refrigerated at 2-8°C if there is a delay in transportation to the lab.
- The specimen should be transported to the lab at room temperature.
- Label specimen tube with patient's name and a second identifier (ex: DOB, MRN).
- All specimen shall be accompanied with a request form complete with patient's particular such as clinical diagnosis and weeks of gestation, and signed and stamped by the respective medical officers / consultants.
- Specimen should be received by the laboratory as soon as possible to avoid culture failure.
- If it is not possible to process the sample upon arrival, sample should be refrigerated at 2-8°C.

Result will be ready between 6 to 14 working days, depending on the progress of cell growth.

FLUORESCENCE IN SITU HYBRIDIZATION (FISH)

- If FISH is done in conjunction with chromosome analysis, no additional specimen is required.
- Requirement for type of specimen to be sent:
  - 3ml bone marrow or peripheral blood in sodium heparin tube (green top). (Only FISH test is requested).
  - Label specimen tube with patient's name and a second identifier (ex: DOB, MRN).
  - Maintain at room temperature and transport to the Lab as soon as possible.
  - These studies may also be performed on paraffin embedded tissue.

MOLECULAR GENETICS (FETAL, MATERNAL & REPRODUCTIVE) GUIDELINES

- Proper specimen collection and aseptic handling are critical for molecular genetic studies.
- All specimens must be accompanied by a completed requisition form signed by the requesting medical practitioners or consultants
- Informed consent from patients shall be obtained for all prenatal requests.
- Do not use expired collection containers or transport media for specimen collection.
- Specimen not fulfilling the requirement will be either notified to the requesting medical practitioners for follow up actions or rejected by the laboratory

AMNIOTIC FLUID (DNA EXTRACTION, QF-PCR, THALASSEMIA)

- Collect 15-20 mL of amniotic fluid at $\geq$15 weeks of gestation in a sterile syringe.
- Discard first 2-3 mL of aspirated fluid to avoid maternal cell contamination.
- Transfer the remaining specimen into 2 sterile falcon tubes (10 mL x 2) provided by the lab.
- Specimen label must contain patient's name and a second identifier (ex: DOB, MRN).
- Collection tubes must be closed tightly to prevent sample leakage during transportation.
- Specimen should be transported in ambient temperature (25-30°C) from external clients to the lab.
- Specimen should be refrigerated (2-8°C) if there is a delay in the transportation.
- Do not freeze the specimen. A cool pack can be used to assure that specimens are not exposed to temperature exceeding 30^{o}C.

- Specimens should arrive at Cytogenetics and Molecular Diagnostics Lab (CMDL) Premier Integrated Labs within 24-48 hours from time of collection.
- If it is not possible to process the specimen on the same day of arrival, the specimen should be refrigerated (2-8°C).
- For maternal cell contamination study, include 3 mL of maternal blood collected in a lavender-top (EDTA) collection tube.

PERIPHERAL BLOOD (DNA EXTRACTION, QF-PCR, THALASSEMIA, MATERNAL CELL CONTAMINATION, Y MICRODELETION)

- Fresh blood specimens are preferred.
- Draw 3 mL of peripheral blood (paediatric: 1-2 mL) in a lavender-top (EDTA) collection tube and mix gently by inverting the tubes to prevent clotting.
- Specimen label must contain patient's name and a second identifier (ex: DOB, MRN).
- Collection tube must be closed tightly to prevent sample leakage during transportation.
- Specimen should be transported in ambient temperature (25-30°C) from external clients to the lab.
- If there is a delay in the transportation, the specimen should be refrigerated at 2-8°C.
- Do not freeze the specimen. A cool pack can be used to assure that specimens are not exposed to temperature exceeding 30^{o}C.
- Specimens should arrive at Cytogenetics and Molecular Diagnostics Lab (CMDL) Premier Integrated Labs within 24-48 hours from time of collection
- Specimens that are clotted, haemolysed and/or added in wrong anticoagulant tube will be rejected and informed to the ward or clinic immediately

CHORIONIC VILLUS, CVS (DNA EXTRACTION, QF-PCR, THALASSEMIA)

- For chorionic villus specimens, careful examination should be carried out to reduce the risk of maternal cell contamination (villi free from maternal decidua, blood vessels and unidentified tissue).
- Collect 15-20 mg of cleaned chorionic villi between 10-12 weeks of gestation in a sterile transport culture medium tube provided by the lab.
- Label the specimen tube with patient's name and a second identifier (ex: DOB, MRN).
- Specimen tubes must be closed tightly to prevent sample leakage during transportation.
- Specimen should be transported in ambient temperature (25-30°C) from external clients to the lab.
- If there is a delay in the transportation, the specimen should be refrigerated at 2-8°C.
- A cool pack can be used to assure that specimens are not exposed to temperature exceeding 30^{o}C.
- Specimens should arrive at Cytogenetics and Molecular Diagnostics Lab (CMDL) Premier Integrated Labs within 24-48 hours from time of collection.
- If it is not possible to process the specimen on the same day of arrival, the specimen should be refrigerated at 2-8°C.
- For maternal cell contamination study, include 3 mL of maternal blood collected in a lavender-top (EDTA) collection tube.

PRODUCTION OF CONCEPTION (DNA EXTRACTION, QF-PCR, THALASSEMIA)

- Fetal tissues and placenta are used for molecular studies in case of therapeutic termination, multiple miscarriages and fetal demise.
- Aborted fetal tissues or placenta are collected aseptically in a sterile saline container.
- Label the specimen container with patient's name and a second identifier (ex: DOB, MRN).
- Specimen container must be closed tightly and sealed with a masking tape to prevent sample leakage during transportation.
- Specimen should be transported in ambient temperature (25-30°C) from external clients to the

lab.
- If there is a delay in the transportation, the specimen should be refrigerated at 2-8°C.
- A cool pack can be used to assure that specimens are not exposed to temperature exceeding 30ºC.
- If fresh tissue is not available, formalin fixed paraffin embedded (FFPE) tissue blocks are accepted for DNA extraction and molecular studies.
- Specimens should arrive at Cytogenetics and Molecular Diagnostics Lab (CMDL) Premier Integrated Labs within 24-48 hours from time of collection.
- If it is not possible to process the specimen on the same day of arrival, the specimen should be refrigerated at 2-8°C. FFPE blocks should be kept at room temperature.
- For maternal cell contamination study, include 3 mL of maternal blood collected in a lavender-top (EDTA) collection tube.

RESULTS REPORTING

REPORTING OF LABORATORY RESULTS
- Quantitative results will be reported together with reference ranges.
- Comments will be included for all results with poor specimen quality that may interfere with the accuracy of the testing.
- Preliminary reports which are crucial to patient management will be issued to requesting clinician.
- Completed reports will be delivered or printed to the requesting clinician and not to patient.
- All laboratory personnel are strictly adhering to Personal Data Protection Act and code of ethics of private and confidentiality of result.

REPORTS FROM THE EXTERNAL REFERRAL LABORATORIES
The laboratory is responsible to channel the entire original report from the outsource referral laboratory to the requesting clinician without alteration. Reference will be made to any work that referred to a referral laboratory or consultant.
If transcription is required, the transcribed results shall be legible without mistake and verified by key personnel.

URGENT RESULTS
Urgent results will be reported to the requesting doctor via fax/phone provided the fax/phone number is provided on the request form. However, faxing of urgent reports are recommended instead of verbal reports to ensure the accuracy of results conveyed.

TURNAROUND TIME
Laboratory reports are usually completed within 24hours upon receipt of the specimen except for the tests that are outsourced, requires long period of incubation (e.g., Bacteria culture), run in batches and involved clinical interpretation (e.g., Histopathology, Molecular and Cytopathology)
Occasionally, the laboratory may not be able to meet the defined turnaround time for test that are routinely performed in-house e.g., equipment breakdown, LIS/Server down or where the second opinion required. If there is a delay in reporting results which may compromise patient care, lab will notify affected requesting doctor/client accordingly.

Further inquiries regarding Turnaround Time, can be made by calling respective Premier Integrated Labs Branch and/marketing personnel.

CRITICAL / PANIC VALUES
Critical or panic values are life threatening results that indicates an imminent life-threatening condition whereby therapy of immediate actions is required promptly.

Test results which fall within the critical value will be informed to the requesting doctor with record maintained. The doctor shall read back the patient's identity and critical value informed before the end of the conversation as a precautionary step to ensure correct information had been conveyed and received.

Table 6: Critical Values

CHEMISTRY	Critical Low	Critical High	Units
Sodium	≤ 125	≥ 155	mmol/L
Potassium	≤ 2.8	≥ 6.0	mmol/L
Bilirubin (1 month to 18 years old) (< 1 month old)	None None	≥ 400 ≥ 256 (PHSP & PHLM) ≥ 400 ≥ 256 (PHSP, PHLM, GKK) ≥ 300 (PHM)	µmol/L
Glucose (> 18 years old) (1 month to 18 years old, CSF)	≤ 2.8 ≤ 1.6	≥ 20.0 None	mmol/L mmol/L
Adjusted Calcium (> 18 years old) (1 month to 18 years old)	≤ 1.5 ≤1.7	≥ 3.00 ≥ 3.10	mmol/L mmol/L
Phosphate (> 18 years old) (1 month to 18 years old)	≤ 0.32 ≤ 0.40	≥ 2.87 ≥ 2.80	mmol/L mmol/L
Magnesium (> 18 years old) (1 month to 18 years old)	≤ 0.4 ≤ 0.5	≥ 2.00 ≥ 1.8	mmol/L mmol/L
Creatinine Kinase (CK)	None	≥ 600	U/L
Troponin T	None	> 50	ng/L
Troponin I	None	> 0.07	ng/ml
Creatinine (1 month to 18 years old)	None	≥ 330	µmol/L
Urea (1 month to 18 years old)	None	≥ 19.0 ≥ 10.0 (PHM)	mmol/L

Uric Acid (1 month to 18 years old)	None	≥ 0.50	mmol/L

HAEMATOLOGY	**Critical Low**	**Critical High**	**Units**
Haemoglobin (> 18 years old)	≤ 7.0 < 8.0 (PHM)	≥ 20.0	g/dL
(1 month to 18 years old)	≤ 7.0 < 8.0 (PHM)	≥ 20.0	g/dL
(< 1 month old)	≤ 8.0 ≤ 10.0 (PHM)	≥ 22.0	g/dL
Total White Cell (WBC) (1 month to 18 years old)	≤ 2.0	≥ 50.0	10^9 /L
Platelets (> 18 years old)	≤ 20 ≤ 50 (PHBP)	≥ 1000	10^9 /L
(1 month to 18 years old)	≤ 50 ≤ 100 (PHM) < 50 (GKK) (Paeds & neonate)	≥ 1000	10^9 /L
Fibrinogen (> 18 years old) (1 month to 18 years old)	≤ 1 ≤ 0.7	None None	g/L g/L
Prothrombin Time (PT)	None	≥ 40.0	seconds
Activated Partial Thromboplastin Time (APTT)	None	≥ 80.0	seconds
Malarial Parasite	None	Seen	Not Applicable
Limits must be referred to Clinical Pathologist for the presence of blast cells, plasma cells, indefinable cells, morphologically abnormal white cells, morphologically abnormal platelets: (In the absence of Clinical Pathologist, the section leader or laboratory manager must verify the slides)			

INFECTIOUS DISEASE	
Anti-HIV 1 & II	All Reactive

MOLECULAR INFECTIOUS DISEASE	
Zika	Positive
Mycobacterium TB PCR	Positive

BACTERIOLOGY	
Blood Culture	Positive Gram stain/ Culture ***Note: For blood culture detected out of Microbiology lab operating hours, the on-call staff should culture the positive bottle. Microbiology staffs should attend it urgently on the next working day.***
Acid Fast Bacilli (AFB)	Positive AFB stain/ Culture
Sterile Body Fluids (Cerebral spinal fluid (CSF), Pleural Fluid, Peritoneal fluid and Pericardial fluid)	Positive Gram stain/ Bacterial Antigen detection/ Culture
CSF bacteria antigen detection	Positive
High Alert Organisms	Extended-spectrum Beta Lactamase Producer (ESBL) Methicillin-Resistant *Staphylococcus aureus* (MRSA) Multi-drug Resistant Organisms (MDRO) Vancomycin -Resistant Enterococcus (VRE) Vancomycin- Resistant Staphylococcus aureus (VRSA) *Salmonella typhi* *Vibrio cholerae* *Shigella* *Corynebacterium diphtheriae* *Bordetella pertussis* *Leptospira* *Histoplasma* *Neisseria gonorrhoeae* *Neisseria meningitidis* *Burkholderia pseudomallei*

BLOOD BANK	
Direct Antiglobulin Test	Positive
Indirect Antiglobulin Test	Positive
Crossmatch	Incompatible (Especially after the release of un-crossmatched blood or emergency crossmatched blood.)

CYTOPATHOLOGY	
Gynaecology	All cases reported as: High Grade Squamous Intraepithelial Lesion (HSIL) High Grade Squamous Intraepithelial Lesion (HSIL) with suspicious of invasion Squamous Cell Carcinoma (SCC) Atypical Glandular Cell-Non otherwise specified (AGC-NOS) Atypical Glandular Cell (AGC) favour neoplastic Adenocarcinoma in-situ (AIS) Adenocarcinoma are categorized as critical results.
Non-gynae (body fluids) and Fine Needle Aspiration (FNA)	Unexpected malignancy

HISTOPATHOLOGY	
Malignancy in an uncommon / unexpected location or specimen type.	Unexpected or discrepant findings: a) Significant disagreement between frozen section and final diagnosis. b) Significant disagreement of tumour diagnosis with clinical diagnosis. c) Significant disagreement and / or change between diagnosis of primary pathologist and outside pathologist consultant. d) Mycobacterial, fungal or other significant infectious organism identified on special stain. e) Significant disagreement between biopsy and surgical specimen diagnosis by same pathologist.

Appendix 1: BLOOD COLLECTION TUBE GUIDE

BD Helping all people live healthy lives

BD Vacutainer® Venous Blood Collection
Tube Guide

For the full array of BD Vacutainer® Blood Collection Tubes, visit www.bd.com/vacutainer.
Many are available in a variety of sizes and draw volumes (for pediatric applications). Refer to our website for full descriptions.

BD Vacutainer® Tubes with BD Hemogard™ Closure	BD Vacutainer® Tubes with Conventional Stopper	Additive	Inversions at Blood Collection*	Laboratory Use	Your Lab's Draw Volume/Remarks
Gold	Red/ Gray	• Clot activator and gel for serum separation	5	For serum determinations in chemistry. May be used for routine blood donor screening and diagnostic testing of serum for infectious disease.** Tube inversions ensure mixing of clot activator with blood. Blood clotting time: 30 minutes.	
Light Green	Green/ Gray	• Lithium heparin and gel for plasma separation	8	For plasma determinations in chemistry. Tube inversions ensure mixing of anticoagulant (heparin) with blood to prevent clotting.	
Red	Red	• Silicone coated (glass) • Clot activator, silicone coated (plastic)	0 5	For serum determinations in chemistry. May be used for routine blood donor screening and diagnostic testing of serum for infectious disease.** Tube inversions ensure mixing of clot activator with blood. Blood clotting time: 60 minutes.	
Orange		• Thrombin-based clot activator with gel for serum separation	5 to 6	For stat serum determinations in chemistry. Tube inversions ensure mixing of clot activator with blood. Blood clotting time: 5 minutes.	
Orange		• Thrombin-based clot activator	8	For stat serum determinations in chemistry. Tube inversions ensure mixing of clot activator with blood. Blood clotting time: 5 minutes.	
Royal Blue		• Clot activator (plastic serum) • K_2EDTA (plastic)	8 8	For trace-element, toxicology, and nutritional-chemistry determinations. Special stopper formulation provides low levels of trace elements (see package insert). Tube inversions ensure mixing of either clot activator or anticoagulant (EDTA) with blood.	
Green	Green	• Sodium heparin • Lithium heparin	8 8	For plasma determinations in chemistry. Tube inversions ensure mixing of anticoagulant (heparin) with blood to prevent clotting.	
Gray	Gray	• Potassium oxalate/ sodium fluoride • Sodium fluoride/Na_2 EDTA • Sodium fluoride (serum tube)	8 8 8	For glucose determinations. Oxalate and EDTA anticoagulants will give plasma samples. Sodium fluoride is the antiglycolytic agent. Tube inversions ensure proper mixing of additive with blood.	
Tan		• K_2EDTA (plastic)	8	For lead determinations. This tube is certified to contain less than .01 µg/mL(ppm) lead. Tube inversions prevent clotting.	
	Yellow	• Sodium polyanethol sulfonate (SPS) • Acid citrate dextrose additives (ACD): **Solution A -** 22.0 g/L trisodium citrate, 8.0 g/L citric acid, 24.5 g/L dextrose **Solution B -** 13.2 g/L trisodium citrate, 4.8 g/L citric acid, 14.7 g/L dextrose	8 8 8	SPS for blood culture specimen collections in microbiology. ACD for use in blood bank studies, HLA phenotyping, and DNA and paternity testing. Tube inversions ensure mixing of anticoagulant with blood to prevent clotting.	
Lavender	Lavender	• Liquid K_3EDTA (glass) • Spray-coated K_2EDTA (plastic)	8 8	K_2EDTA and K_3EDTA for whole blood hematology determinations. K_2EDTA may be used for routine immunohematology testing, and blood donor screening.*** Tube inversions ensure mixing of anticoagulant (EDTA) with blood to prevent clotting.	
White		• K_2EDTA and gel for plasma separation	8	For use in molecular diagnostic test methods (such as, but not limited to, polymerase chain reaction [PCR] and/or branched DNA [bDNA] amplification techniques.) Tube inversions ensure mixing of anticoagulant (EDTA) with blood to prevent clotting.	
Pink	Pink	• Spray-coated K_2EDTA (plastic)	8	For whole blood hematology determinations. May be used for routine immunohematology testing and blood donor screening.*** Designed with special cross-match label for patient information required by the AABB. Tube inversions prevent clotting.	
Light Blue Clear	Light Blue	• Buffered sodium citrate 0.105 M (=3.2%) glass 0.109 M (3.2%) plastic • Citrate, theophylline, adenosine, dipyridamole (CTAD)	3-4 3-4	For coagulation determinations. CTAD for selected platelet function assays and routine coagulation determination. Tube inversions ensure mixing of anticoagulant (citrate) to prevent clotting.	
Clear	New Red/ Light Gray	• None (plastic)	0	For use as a discard tube or secondary specimen tube.	

Note: BD Vacutainer® Tubes for pediatric and partial draw applications can be found on our website.

BD Diagnostics
Preanalytical Systems
1 Becton Drive
Franklin Lakes, NJ 07417 USA

BD Global Technical Services: 1.800.631.0174
BD Customer Service: 1.888.237.2762
www.bd.com/vacutainer

* Invert gently; do not shake
** The performance characteristics of these tubes have not been established for infectious disease testing in general; therefore, users must validate the use of these tubes for their specific assay-instrument/reagent system combinations and specimen storage conditions.
*** The performance characteristics of these tubes have not been established for immunohematology testing in general; therefore, users must validate the use of these tubes for their specific assay-instrument/reagent system combinations and specimen storage conditions.

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ORDER OF DRAW

greiner BIO-ONE

VACUETTE®
Blood Collection Tubes

based on CLSI GP41-ED7

	ADDITIVES	TESTS DISCIPLINES	
	1 BLOOD CULTURE	PATHOGEN IDENTIFICATION	
	2 SODIUM CITRATE	COAGULATION	Mix well by inversion X 5
	3 SERUM with and without Separator	CHEMISTRY IMMUNOCHEMISTRY IMMUNOHEMATOLOGY (NO GEL) VIRAL MARKER (NO GEL) TDM'S	Mix well by inversion X 5
	4 HEPARIN with and without Separator	CHEMISTRY IMMUNOCHEMISTRY	Mix well by inversion X 5
	5 EDTA with and without Separator	HEMATOLOGY IMMUNOHEMATOLOGY MOLECULAR DIAGNOSTICS VIRAL MARKER	Mix well by inversion X 5
	6 POTASSIUM OXALATE SODIUM FLOURIDE	GLYCOLYTIC INHIBITOR GLUCOSE & LACTATE	Mix well by inversion X 5
	7 OTHER ADDITIVES		

RING INDICATOR

yellow - Gel Separation | black - Standard Draw | green - Sodium Heparin | white - Pediatric Draw

*If a winged blood collection set is used AND the coagualtion specimen is drawn first, a discard tube is recommended to be drawn prior to this tube to ensure proper anticoagulant-to-blood ratio.

**For complete clotting, 30 minutes minimum clotting time is required. Incomplete or delayed mixing may result in delayed clotting.

NOTE

Always follow general effective and safe working procedures and precautions during use and disposal of the products.

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HANDLING RECOMMENDATIONS

greiner BIO-ONE

MINICOLLECT®
Capillary Blood Collection System

1. 
Prewarm and disinfect the puncture site.

2. 
Remove the cap.

3. 
Carry out the puncture and **discard first drop of blood.**

4. 
Collect the blood sample.

5. 

Close the tube with the original cap.

6. 

Immediately after collection, invert the tube gently.

ORDER OF DRAW

ACCORDING TO CLSI GP42-ED7

Note: Always follow your facility's protocol for order of draw.

1. EDTA
2. Other additive tubes
3. Tubes without additive and Serum tubes

ADDITIONAL

MINICOLLECT®
Coagulation Tube

Intended only for use with venous blood.

1. 
Transfer venous blood into the tube.

2. 

Close the tube with the original cap.

3. 

Immediately invert the tube gently.

WIDE RANGE OF SAFETY LANCETS

MINICOLLECT® PIXIE
Heel Incision Safety Lancets

- light-green ● ↓0.65 mm
- orange ●● ↓0.85 mm
- yellow ●●● ↓1 mm

MINICOLLECT®
Safety Lancets
with needle

- lavender ● 28G / ↓1.25 mm
- orange ●● 23G / ↓2.25 mm

with blade

- pink ●●● ↓1 mm
- green ●●●● ↓1.5 mm
- blue ●●●●● ↓2 mm

MINICOLLECT®
Lancelino Safety Lancets
with needle

- light green ● 30G / ↓1.2 mm
- lavender ●● 25G / ↓1.5 mm
- blue ●●● 21G / ↓1.8 mm
- green ●●●● 21G / ↓2.4 mm

with blade

- yellow ●●●●● ↓2 mm

The volume of blood depends on the length of the lancet and is marked with blood drops

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Poster 980312 MiniCollect® Handling Recommendations en (rev.01, 07.2023)

Appendix 2: ORDER OF DRAW

BD Helping all people live healthy lives

BD Vacutainer® Order of Draw for Multiple Tube Collections

Designed for Your Safety

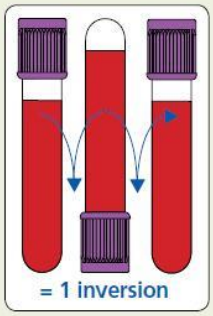
Reflects change in CLSI recommended Order of Draw (H3-A5, Vol 23, No 32, 8.10.2)

Closure Color	Collection Tube	Mix by Inverting
BD Vacutainer® Blood Collection Tubes *(glass or plastic)*		
	• Blood Cultures - SPS	8 to 10 times
	• Citrate Tube*	3 to 4 times
or	• BD Vacutainer® SST™ Gel Separator Tube	5 times
	• Serum Tube *(glass or plastic)*	5 times (plastic) none (glass)
	• BD Vacutainer® Rapid Serum Tube (RST)	5 to 6 times
or	• BD Vacutainer® PST™ Gel Separator Tube With Heparin	8 to 10 times
	• Heparin Tube	8 to 10 times
or	• EDTA Tube	8 to 10 times
	• BD Vacutainer® PPT™ Separator Tube K_2EDTA with Gel	8 to 10 times
	• Fluoride (glucose) Tube	8 to 10 times

* When using a winged blood collection set for venipuncture and a coagulation (citrate) tube is the first specimen tube to be drawn, a discard tube should be drawn first. The discard tube must be used to fill the blood collection set tubing's "dead space" with blood but the discard tube does not need to be completely filled. This important step will ensure proper blood-to-additive ratio. The discard tube should be a nonadditive or coagulation tube.

Note: Always follow your facility's protocol for order of draw

Handle all biologic samples and blood collection "sharps" (lancets, needles, luer adapters and blood collection sets) according to the policies and procedures of your facility. Obtain appropriate medical attention in the event of any exposure to biologic samples (for example, through a puncture injury) since they may transmit viral hepatitis, HIV (AIDS), or other infectious diseases. Utilize any built-in used needle protector if the blood collection device provides one. BD does not recommend reshielding used needles, but the policies and procedures of your facility may differ and must always be followed. Discard any blood collection "sharps" in biohazard containers approved for their disposal.



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www.bd.com/vacutainer

1 Becton Drive
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ORDER OF DRAW

FOR THE COMPLETE HANDLING INSTRUCTIONS

please refer to the Instructions for Use for each product at www.gbo.com.

VACUETTE®
Blood Collection Tubes

based on CLSI GP41-ED7

1. **BLOOD CULTURE**
2. **SODIUM CITRATE/CTAD***
3. **SERUM**
   with and without Separator
4. **HEPARIN**
   with and without Separator
5. **EDTA**
   with and without Separator
6. **GLYCOLYTIC INHIBITOR**
7. **OTHER ADDITIVES**

* If a winged blood collection set is used, the first tube in the series will be under-filled. Therefore, if a Sodium Citrate specimen is drawn first, a discard tube (e.g. No Additive) is recommended to be drawn prior to this tube to ensure the proper additive-to-blood ratio. In addition, even though studies have shown that PT and aPTT tests are not affected if drawn first in a tube series, it is advisable to draw a second tube for other coagulation assays, since it is not known whether or not these tests will be affected.

NOTE

Always follow general effective and safe working procedures and precautions during use and disposal of the products.

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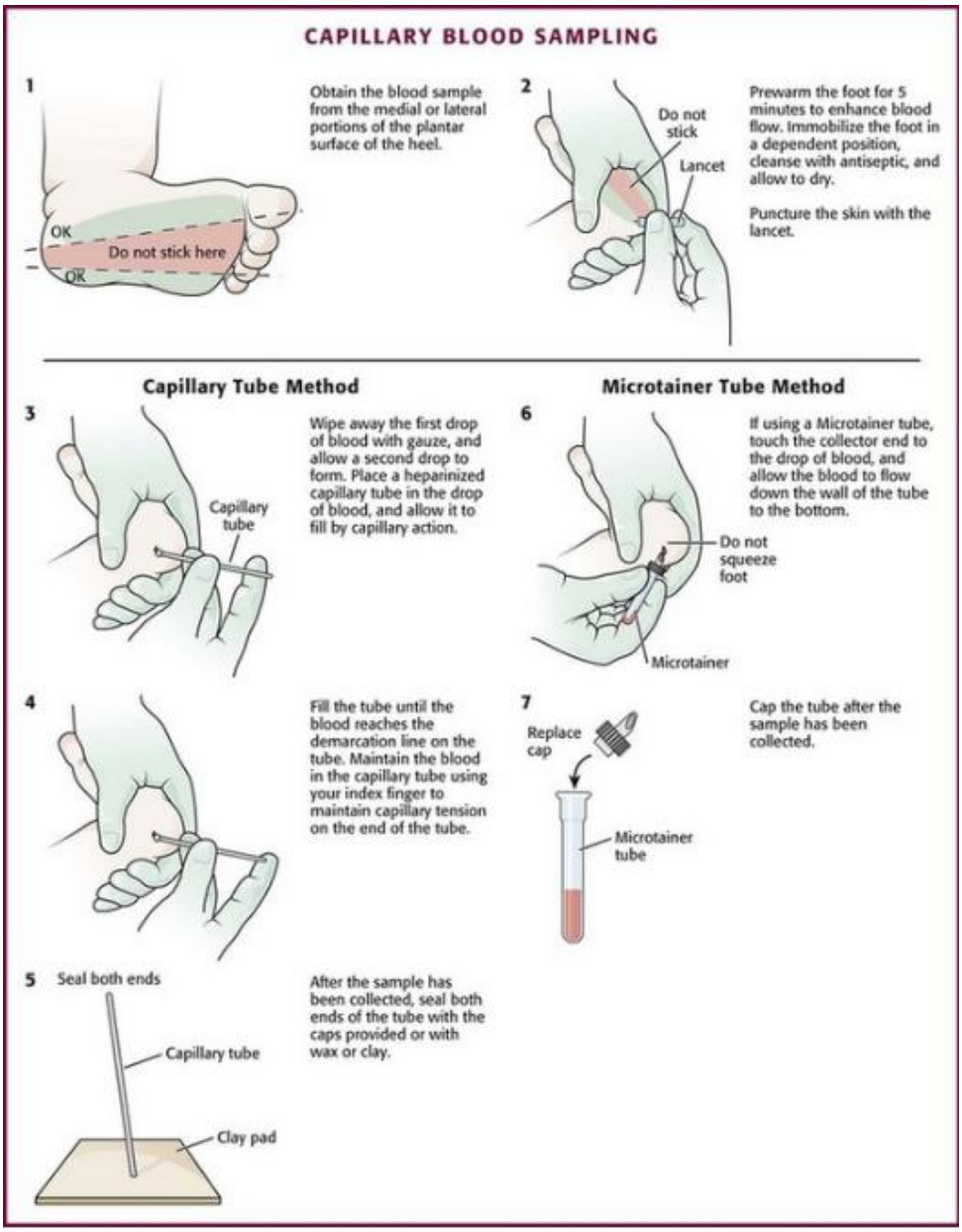
Poster Order of Draw en [rev.03, 04.2021]

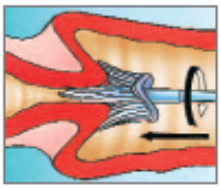
Appendix 3: CAPILLARY BLOOD SAMPLING



Appendix 4: THINPREP® QUICK REFERENCE GUIDE

ThinPrep® Pap Test Quick Reference Guide

Broom-Like Device Protocol



Obtain…

…an adequate sampling from the cervix using a broom-like device. Insert the central bristles of the broom into the endo-cervical canal deep enough to allow the shorter bristles to fully contact the ectocervix. Push gently, and rotate the broom in a clockwise direction five times.

Rinse…

…the broom as quickly as possible into the PreservCyt® Solution vial by pushing the broom into the bottom of the vial 10 times, forcing the bristles apart. As a final step, swirl the broom vigorously to further release material. Discard the collection device.

Tighten…

…the cap so that the torque line on the cap passes the torque line on the vial.

Record…

…the patient's name and ID number on the vial.

…the patient information and medical history on the cytology requisition form.

Place…

…the vial and requisition in a specimen bag for transport to the laboratory.

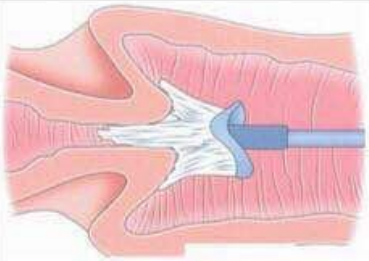
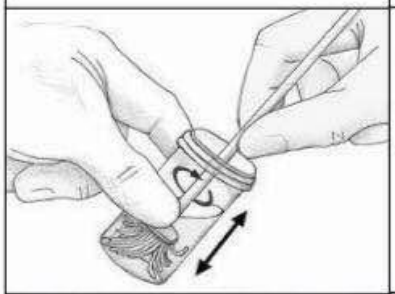
www.thinprep.com

THE ThinPrep PAP TEST

The Test You Trust

Appendix 5: PATH TEZT QUICK REFERENCE GUIDE

Intend To Use For Liquid Based Cytology

	**1. Cervical Sample Collection** Insert the Cervical brush into the endo-cervical canal. Apply gentle pressure until the bristles form against the cervix. Maintaining gentle pressure, hold the stem between the thumb and forefinger and rotate the brush five times in a clockwise direction.
	**2. Preserve the entire sample** Placing your thumb against the back of the brush pad, simply disconnect the entire brush from the stem into the ***Pathtezt®*** ***Preserve Cell Solution***
	**3. Cap and label vial** Place the cap on the vial and tighten. Label the vial and lab requisition form with patient name and/or number, physician name and date if desired.
	**4. Send vial to your lab** Place the vial and requisition into a specimen bag and send to the laboratory.

Appendix 6: CONSENT FORM FOR FINE NEEDLE ASPIRATION PROCEDURE

CONSENT FORM FOR FINE NEEDLE ASPIRATION PROCEDURE

I, _____NRIC_____
(Name of Patient)

of_____
(Address)
hereby consent to undergo the procedure of Fine-Needle Aspiration (FNA), where the nature, effects of which, and the risk of the proposed and alternative course of action have been explained to me by

Dr. _____ personally, to her/his best of ability.
(Name of Attending Doctor)

I also consent to such further or alternative operative measures or treatment as found necessary on medical grounds during the course of the procedure.

I further consent to any disposition deemed proper by the staff

or _____ of the parts/fluid/tissue removed in the process of
(Name of Hospital /Clinic)
performing this procedure.

Patient's signature _____/or thumbprint _____

Name _____

Date _____

I confirm having informed consent from the patient after having explained the nature and effect of this procedure and risks of both the proposed and alternative course of action.

Doctor's signature_____

Name_____

Date_____

Appendix 7: BLOOD CULTURE COLLECTION

BLOOD CULTURE COLLECTION: NEEDLE & SYRINGE

BLOOD CULTURE COLLECTION*

- → Do not use damaged or expired bottles.
- → Remove the "flip-cap". Disinfect & allow to air dry.
- → Collect 2-3 sets.
- → 10 mL of blood per bottle for an adult.
- → Volume based on weight for pediatric patients.**
- → Transport to the laboratory as quickly as possible.

RECOMMENDATIONS FOR BLOOD CULTURE COLLECTION

1 CHECK PATIENT ID & PREPARE MATERIAL

2 PREPARE BOTTLES FOR INOCULATION

Wash hands or use an alcohol hand rub.

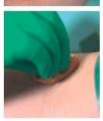
Remove the plastic "flip-cap".

Disinfect the bottle septum and **allow to air dry.**

3 PREPARE VENIPUNCTURE SITE

Palpate to find the vein.

Apply clean examination gloves.

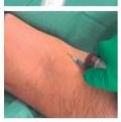


Disinfect the skin.

Allow the site to **air dry.**

4 COLLECT WITH NEEDLE AND SYRINGE

Assemble the needle and syringe.



To prevent contamination, **do not re-palpate**

Insert the needle into the prepared vein.

5 BOTTLE INOCULATION

Collect the **anaerobic bottle first.*****

Ensure the bottle **is correctly filled to the Fill-to Mark or target fill level, as shown.**

Repeat for **aerobic bottle.**

6 FINISH THE PROCEDURE

Record collection date, **time** and **site.**

Label bottles according to manufacturer's recommendations.

Transport inoculated bottles **as quickly as possible** at room temperature to laboratory for testing.

7 CORRECT LABELING

DO NOT

Leave cotton over the septum

Replace the plastic "flip-cap"

Position label in the wrong place

* Best practices for blood culture collection vary among countries and healthcare facilities: refer to guidelines applicable in your institution. This card is based on World Health Organization recommendations for phlebotomy (WHO guidelines on drawing blood: best practices in phlebotomy-2010-ISBN 978 92 4 159922 1).

** Pediatric bottles are available.

*** Fill the anaerobic bottle first if enough blood volume was collected to fill the aerobic blood bottle with the recommended volume.

CHECKLIST FOR NEEDLE & SYRINGE COLLECTION

- ☐ Approved skin disinfectant
- ☐ Blood culture set (ideally 2 to 3 sets; 1 set = 1 aerobic bottle + 1 anaerobic bottle)
- ☐ Needle and Syringe
- ☐ Blood collection tubes (if blood is needed for other laboratory tests)
- ☐ Blood collection tube adaptor (if required)
- ☐ Gloves
- ☐ Disposable underpad
- ☐ Tourniquet
- ☐ Gauze pads
- ☐ Bandage
- ☐ Waste collection container
- ☐ Pen to record collection date, time, and collection site

NOTE: If other blood tests are required, always collect blood cultures first.

Blood Culture Safety
FIRST and ALWAYS

A Key Investigation for Diagnosis of Bloodstream Infections

Tips ' n' Hints

- Recommended blood to broth ratio is 1:5 to 1:10. As the volume of blood drawn is increased, the yield of positive cultures increases. Optimally, 20ml of blood should be drawn from adults (10ml per bottle).
- When labeling the bottles, do not cover the peel-off section of the barcode labels or the lot numbers. Attached the barcode in vertical direction at sample ID column
- For best volume control, mark fill level on side of bottle prior to collection.
- Do not overfill the bottles, as this may cause false positive readings.
- If very small quantity available (e.g. 5mL total) inoculate all into one aerobic bottle, and note "difficult venesection" on lab request.
- If less than 3mL (shocked patient, paediatric patient) inoculate all into a paediatric blood culture bottle.
- To avoid contamination of the blood culture sample, inoculate blood culture bottles first. Then fill additional blood collection tubes

Type of Bottles:

Bottle Type		Description	Specimen Type	Optimal Volume of Blood Sample
BacT/ALERT® FA Plus - Ref. 410851		Aerobic and Fungal	Blood or Sterile Body Fluid (SBF)	**6 mL to 10 ml**
BacT/ALERT® FN Plus - Ref. 410852		Anaerobic	Blood or SBF	**8 mL to 10 mL**
BacT/ALERT® PF Plus - Ref. 410853		Pediatric	Blood	**1mL to 4 mL**

Note : The range of blood volume is minimum 1 mL and maximum 10 mL

Recommended Incubation Time

Microorganisms	Days
Routine pathogens	5 Days
Fungal	14 Days

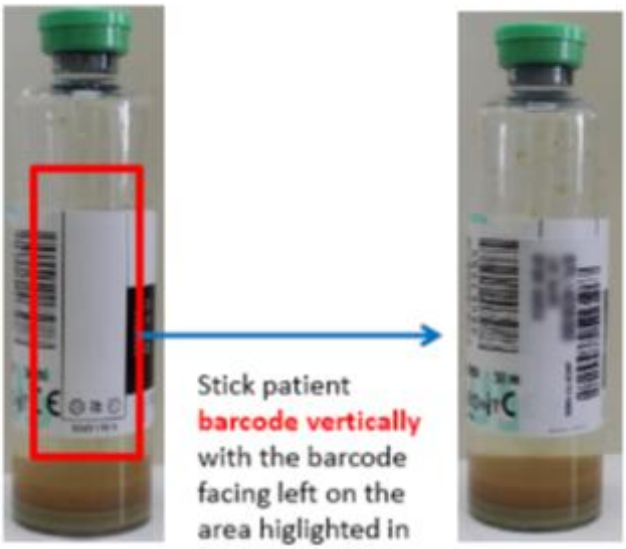
Bottle Storage Instruction

All BacT/ALERT cultures bottles are ready for use. Store in an upright position protected from direct sunlight at room temperature (15-30°C).

An expiration date is printed on each bottle label. Do Not use the culture bottles beyond the expiration date indicated.

LABELLING BLOOD CULTURE BOTTLE

CORRECT LABELLING



Stick patient **barcode vertically** with the barcode facing left on the area higlighted in red

Peel the sticker and stick onto the request form for bottle tracking

LAB INTENDED USED For Bottle Tracking

Horizontal position

Covers the bottom

WRONG LABELLING

BIOMÉRIEUX medigene

Appendix 8: WHOLE BLOOD FOR LIQUID BIOPSY

Cell-Free DNA BCT®

STRECK

INSTRUCTIONS FOR USE
Cell-Free DNA BCT® is a direct draw whole blood collection tube intended for collection, transport and storage of blood samples. **The product is For Research Use Only. Not for use in diagnostic procedures.**

SUMMARY AND PRINCIPLES
Cell-Free DNA BCT stabilizes cell-free plasma DNA as well as preserves cellular genomic DNA present in nucleated blood cells and circulating epithelial cells (tumor cells) found in whole blood.

Accurate analysis of cf-DNA can be compromised by sample handling, shipping and processing, causing lysis of nucleated blood cells and subsequent release of cellular genomic DNA. Additionally, degradation of cf-DNA due to nuclease activity can be problematic.

The preservative reagent contained in Cell-Free DNA BCT stabilizes nucleated blood cells, preventing the release of cellular genomic DNA, and inhibits nuclease mediated degradation of cf-DNA, contributing to the overall stabilization of cf-DNA. Samples collected in Cell-Free DNA BCT are stable for up to 14 days at temperatures between 6 °C to 37 °C, allowing convenient sample collection, transport and storage.

The preservative reagent contained in Cell-Free DNA BCT stabilizes circulating epithelial cells (tumor cells) in whole blood for up to 7 days at temperatures between 15 °C to 30 °C.

REAGENTS
Cell-Free DNA BCT contains the anticoagulant K_3EDTA and a cell preservative in a liquid medium.

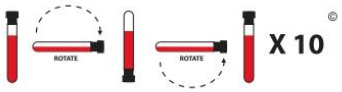
PRECAUTIONS
1. **For Research Use Only. Not for use in diagnostic procedures.**
2. Do not freeze specimens collected in glass Cell-Free DNA BCT.
3. Do not use tubes after expiration date.
4. Do not use tubes for collection of materials to be injected into patients.
5. Product is intended for use as supplied. Do not dilute or add other components to Cell-Free DNA BCT.
6. Overfilling or underfilling of tubes will result in an incorrect blood-to-additive ratio and may lead to incorrect analytic results or poor product performance.
   CAUTION
   a. Glass has the potential for breakage; precautionary measures should be taken during handling of glass tubes.
   b. All biological specimens and materials coming in contact with them are considered biohazards and should be treated as if capable of transmitting infection. Dispose of in accordance with federal, state and local regulations. Avoid contact with skin and mucous membranes.
   c. Product should be disposed with infectious medical waste.
   d. Remove and reinsert stopper by either gently rocking the stopper from side to side or by grasping with a simultaneous twisting and pulling action. A "thumb roll" procedure for stopper removal is NOT recommended as tube breakage and injury may result.
7. SDS can be obtained at streck.com or by calling 800-843-0912.

STORAGE AND STABILITY
1. When stored at 2 °C to 30 °C, empty Cell-Free DNA BCT is stable through expiration date.
2. Short-term storage at 2 °C to 40 °C is acceptable for empty Cell-Free DNA BCT for up to 14 days.
3. Do not freeze empty Cell-Free DNA BCT. Proper insulation may be required for shipment during extreme temperature conditions.
4. Sample storage/stability:

	Sample Type		
	Cell-Free DNA	Cellular Genomic DNA	Epithelial Cells (Tumor Cells)
Sample Stability	14 days	14 days	7 days
Sample Storage Temperature	6 °C to 37 °C	6 °C to 37 °C	15 °C to 30 °C

INDICATIONS OF PRODUCT DETERIORATION
1. Cloudiness or precipitate visible in reagent of empty tube.
2. If indications of product deterioration occur, contact Streck Technical Services at 800-843-0912 or technicalservices@streck.com.

INSTRUCTIONS FOR USE
For a video demonstration, visit streck.com/mixing.
1. Collect specimen by venipuncture according to CLSI GP41[1].
   Prevention of Backflow - Since Cell-Free DNA BCT contains chemical additives, it is important to avoid possible backflow from the tube.
   To guard against backflow, observe the following precautions:
   a. Keep patient's arm in the downward position during the collection procedure.
   b. Hold the tube with the stopper in the uppermost position so that the tube contents do not touch the stopper or the end of the needle during sample collection.
   c. Release tourniquet once blood starts to flow in the tube, or within 2 minutes of application.
2. Follow recommendations for order of draw outlined in CLSI GP41[1]. Cell-Free DNA BCT should be drawn after the EDTA tube and before the fluoride oxalate (glycolytic inhibitor) tube. If a Cell-Free DNA BCT tube immediately follows a heparin tube in the draw order, Streck recommends collecting a non-additive or EDTA tube as a waste tube prior to collection in the Cell-Free DNA BCT.
3. Fill tube completely.
4. Remove tube from adapter and immediately mix by gentle inversion 8 to 10 times. Inadequate or delayed mixing may result in incorrect analytical results or poor product performance. One inversion is a complete turn of the wrist, 180 degrees, and back per the figure below:



5. After collection, transport and store tubes within the recommended temperature range.

Note:
1. For best results, a 21G or 22G needle is advised. Slower fill times may be observed when using a smaller gauge needle.
2. When using a winged (butterfly) collection set for venipuncture and the Streck Cell-Free DNA BCT is the first tube drawn, a non-additive or EDTA discard tube should be partially drawn first in order to eliminate air or "dead space" from the tubing.
3. Cell-Free DNA BCT does not dilute blood samples; therefore, no dilution factor correction is necessary.
4. As in the case with most clinical laboratory specimens, hemolysis, icterus and lipemia may affect the results obtained on blood samples preserved with Cell-Free DNA BCT.

DNA EXTRACTION
Extraction of cell-free plasma DNA and cellular genomic DNA can be accomplished using most commercially available kits that include a Proteinase K treatment step.

Cell-Free Plasma DNA
Streck has qualified two separate plasma separation spin protocols for your convenience.

Double Spin Protocol 1
Step 1. To separate plasma, centrifuge whole blood at 300 x g for 20 minutes at room temperature.
Step 2. Remove the upper plasma layer and transfer to a new conical tube (not provided).
Step 3. Centrifuge the plasma at 5000 x g for 10 minutes.
Step 4. Isolate cell-free DNA per kit manufacturer instructions.

Double Spin Protocol 2 (for maximum plasma recovery)
Step 1. To separate plasma, centrifuge whole blood at 1600 x g for 10 minutes at room temperature.
Step 2. Remove the upper plasma layer and transfer to a new conical tube (not provided).
Step 3. Centrifuge the plasma at 16000 x g for 10 minutes.
Step 4. Isolate cell-free DNA per kit manufacturer instructions.

For optimal results, include a Proteinase K treatment step (≥ 30 mAU/mL digest) at 60 °C in the presence of chaotropic salts for 1 hour when extracting cell-free DNA.

Cellular Genomic DNA
Step 1. To separate the white blood cells, either lyse the red blood cells and wash, or centrifuge whole blood and collect the buffy coat layer.
Step 2. Isolate genomic DNA per kit manufacturer instructions.

For optimal results, include a Proteinase K treatment step (≥ 30 mAU/ml digest) at 60 °C in the presence of chaotropic salts for 2 hours when extracting cellular genomic DNA.

FREEZING AND THAWING
PLASMA
1. To Freeze: For long-term storage, after spinning, collect and transfer the upper plasma layer to a cryogenic tube (not provided) and freeze at -20 °C or -80 °C.
2. To Thaw: Thaw cryogenic tubes at appropriate temperature as specified in your protocol.
   Note: If cryoprecipitates form in the plasma, vortex the tube for 30 seconds after thawing. Do not centrifuge the plasma.

LIMITATIONS
1. For single use only.
2. Samples drawn in other anticoagulants or preservatives may cause coagulation in Cell-Free DNA BCT.
3. Specimen transport via pneumatic tube system is not advised.

REFERENCES
1. Clinical and Laboratory Standards Institute. GP41, Procedures for the collection of diagnostic blood specimens by venipuncture. Approved Standard - Seventh Edition.

ORDERING INFORMATION
Please call our Customer Service Department toll free 800-228-6090 for assistance. Additional information can be found online at streck.com.

GLOSSARY OF SYMBOLS
See the Instructions (IFU) tab under Resources on the product page at streck.com.

Streck
7002 S. 109 Street, La Vista, NE 68128 USA
350547-18
2020-08

Appendix 9: LUPUS ANTICOAGULANT TEST (CODE: LUPAC)

1. **Patient preparation**
   The patient should not be on anticoagulant therapy.
   Avoid warfarin (Coumadin®) therapy for two weeks prior to the test and heparin, direct Xa (Xarelto /rivaroxaban, Eliquis /apixaban, Savaysa /edoxaban), thrombin inhibitor therapies (Pradaxa /dabigatran, Acova/argatroban) or tPA (tissue plasmin activator) for about three days prior to testing.

2. **Specimen collection & preparation**
   - Sample collection must be in conformity with the recommendations for haemostasis test.
   - Blood is collected in 3.2% sodium citrate (3 tubes). Evacuated collection tubes must be filled to completion to ensure a proper blood to anticoagulant ratio. The sample should be mixed immediately by gentle inversion at least six times to ensure adequate mixing of the anticoagulant with the blood.
   - Upon receipt of the specimens in the lab, perform a “Double Centrifugation” technique. Centrifugation speed 1800g for 10 min (Eppendorf Centrifuge 5702). Collect the plasma supernatant and repeat the centrifugation step. (refer Double Centrifugation Instructions for Special Coagulation Testing)
   - The double-centrifuged plasma should be aliquoted (1 to 2 mL per aliquot) into clearly labeled plastic tubes. Specimen should be frozen immediately.
   - If the plasma is collected, ideally should take place within 1 hour of collection time. however, it must be completed within 4 hours of collection time

3. **Transportation**
   - Specimen should be frozen at below -20°C, if possible, sent collected plasma with dry ice. Specimen must arrive frozen.

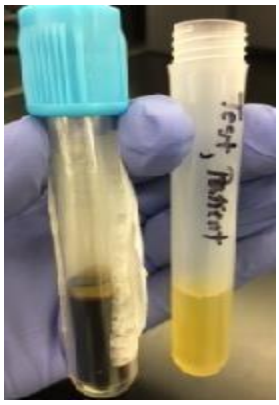
4. **Stability**
   - 4 hours at 20ºC ± 5ºC
   - 1 month at -20ºC

5. **Rejection criteria**
   - Severe hemolysis
   - Improper labeling
   - Clotted specimen
   - Specimen diluted with IV fluids
   - Samples thawed in transit
   - Improper sample type
   - Sample out of stability

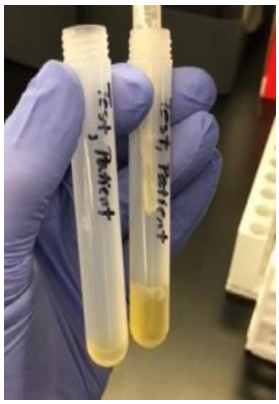
Double Centrifugation Instructions for Special Coagulation Testing

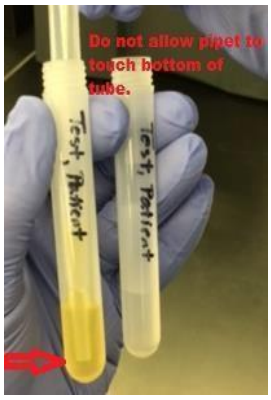
All specimens submitted for special coagulation testing **must** be prepared using the following “Double Centrifugation” technique to ensure the sample being tested is Platelet Poor Plasma.

- Centrifuge the Sodium Citrate tube at 1800g for 10 minutes.
- Transfer the plasma to a plastic tube with a plastic pipette, staying away from the buffy coat layer (the white layer made up of White Blood Cells and Platelets).



- Centrifuge the plasma portion again at 1800g for 10 minutes.
- With a new plastic pipette, transfer the plasma to another plastic tube, staying clear of the bottom of the tube where the platelets lie.





- Cap the second tube, label with patient's name, date of birth, date, and time of collection, and freeze.