



LABORATORY SERVICE GUIDE

Version 1.06

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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 (PIL) provides a diverse portfolio of high-quality diagnostic and analytical laboratory testing services catering to referring medical practitioners. We receive referrals from a broad spectrum of healthcare professionals, including general practitioners, specialists, medical clinics, medical centers, and major tertiary hospitals throughout Malaysia. Our reference core laboratory is located in Pantai Hospital Ampang.

The Laboratory User Guide aims to communicate the important steps in laboratory tests requisition, specimen requirements, 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 implications on the quality of the analytical results produced. Besides the usual regular preventive and service maintenance on the instruments and compliance with 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 involved in the reporting and managing the quality of our laboratory services. Under the active guidance of the consultants and with our management's commitment service excellence, 16 of our major branches are accredited with MS ISO 15189 by the Department of Standard Malaysia.

CONSULTANT PATHOLOGIST

Visit our website for more details:

<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

Level 21, TNB Dua Sentral,
No. 8, Jalan Tun Sambanthan,
Brickfields, 50470 Kuala Lumpur.
(T) +603 3345 7000

Customer Service Hotline

(T) +603 3385 4337
my.ppp.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			
Premier Integrated Labs Pantai Hospital Ampang (PHA) (Reference Core Laboratory (RCL)) LG Floor, Bangunan MOB, Pantai Hospital Ampang, Jalan Perubatan 3, 55100 Pandan Indah, Kuala Lumpur.	+603 4280 9115	+603 4296 4095	Mon - Fri : 8.30am - 5pm Sat : 8.30am - 1pm
Premier Integrated Labs Pantai Hospital Kuala Lumpur (PHKL) Level 2, Block A, Pantai Hospital Kuala Lumpur, No. 8, Jalan Bukit Pantai, 59100 Bangsar, Kuala Lumpur.	+603 2282 8795	+603 2287 2622	Mon - Fri : 9am - 5.30pm Sat : 9am - 1pm
Premier Integrated Labs Pantai Hospital Kuala Lumpur (PHKL) (Reference Specialized Lab (RSL)) Level 8, Block A, Pantai Hospital Kuala Lumpur, No. 8, Jalan Bukit Pantai, 59100 Bangsar, Kuala Lumpur.	+603 2282 8795 Ext: 209 / 210 (CMDL) 230 (Cyto) 138 (Histo)	+603 2287 2622	Mon - Fri : 9am - 5.30pm Sat : 9am - 5pm
Premier Integrated Labs Pantai Hospital Cheras (PHC) 11 & 11-1, Jalan 3/96A, Taman Cheras Makmur, 56100 Kuala Lumpur	+603 9131 7147	+603 9131 7141	Mon - Fri : 8.30am - 5pm Sat : 8.30am - 1pm

Premier Integrated Labs Gleneagles Hospital Kuala Lumpur (GHKL) 2nd Floor, Gleneagles Kuala Lumpur (Hospital Block), No. 286, Jalan Ampang, 50450 Kuala Lumpur.	+603 4141 3064	+603 4141 3065	Mon - Fri : 9am - 5pm Sat : 9am - 1pm
Premier Integrated Labs Prince Court Medical Centre (PCMC) Level 4A, Pathology Department, No. 39, Jalan Kia Peng, 50450, Kuala Lumpur.	+603 2160 0750	+603 2160 0760	Mon - Fri : 8.30am - 5pm Sat : 9am – 1pm
Premier Integrated Labs 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 : 8.30am - 9pm Sat : 9 am - 5pm
Premier Integrated Labs Hospital PICASO Level Ground (LG), No. 110, Jalan Professor Khoo Kay Kim, Seksyen 19, 46300, Petaling Jaya, Selangor.	+603 7932 5207 / 3793	-	Mon - Fri : 8.30am - 5pm Sat : 9am – 1pm
Premier Integrated Labs Axon Medical Ambulatory Centre (AMAC) 3rd Floor, Alpha Clinics Sdn Bhd Jalan PJU 5/6, Dataran Sunway Kota Damansara 47810 Petaling Jaya, Selangor.	+603 6144 6637	-	Mon - Fri : 8.30am - 5pm Sat : 9am – 1pm
Premier Integrated Labs Pantai Hospital Klang (PHK) 125, Ground Floor, Lebuh Turi Off, Persiaran Raja Muda Musa, 41200 Klang.	+603 3370 1315	+603 3370 1329	Mon - Fri : 9am - 5.30pm Sat : 9am - 1pm
Northern Region			
Premier Integrated Labs Pantai Hospital Sungai Petani (PHSP) Ground Floor & 1st Floor No.43, Lengkok Cempaka 2 Bandar Amanjaya, 08000 Sungai Petani, Kedah.	+604 441 2994	+604 441 3012	Sun -Thu: 8.30am - 5pm Fri : 8.30am - 1pm
Premier Integrated Labs Pantai Hospital Laguna Merbok (PHLM) 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

Premier Integrated Labs INS Medical Centre (INSMC) Ground Floor, INS Medical Centre, No. 639D, Jalan Pintu Sepuluh, 05100 Alor Setar, Kedah.	+604 730 8110	+604 730 8110	Sun -Thu: 8.30am - 5pm Fri : 8.30am - 1pm
Premier Integrated Labs Pantai Hospital Penang (PHP) 3rd Floor, Pantai Hospital Penang, No. 82, Jalan Tengah, Bayan Baru 11900 Bayan Lepas, Penang.	+604 646 5505	+604 646 6606	Mon - Fri : 8.30am - 5pm Sat : 8.30am - 1pm
Premier Integrated Labs Gleneagles Hospital Penang (GHP) 6th Floor, Block B, Gleneagles Hospital Penang, No. 1, Jalan Pangkor, 10050 Georgetown, Pulau Pinang.	+604 220 0838 / +604 210 8202	+604 210 6006	Mon - Fri : 9am - 5.30pm Sat : 9am - 1pm
Premier Integrated Labs Pantai Hospital Ipoh (PHI) 4th Floor, Pantai Hospital Ipoh, No. 126, Jalan Tambun, 31400 Ipoh, Perak..	+605 548 1279	+605 548 8044	Mon - Fri : 8.30am - 5pm Sat : 8.30am - 1pm
Premier Integrated Labs Hospital Ar-Ridzuan (HAR) (Collection Centre) A1, Jalan Dato' Seri Ahmad Said, Greentown Suria, 30450 Ipoh, Perak..	+605 242 1111	+605 241 1110	Mon - Fri : 8.30am - 5pm Sat : 8.30am - 1pm
Premier Integrated Labs Perak Community Specialist Hospital (PCSH) 277, Jalan Raja Permaisuri Bainun, 30250 Ipoh, Perak.	+605 241 9000	-	Mon - Fri : 8am - 6pm Sat : 8am - 1pm
Premier Integrated Labs KMC Medical Centre (KMCMC) Ground Floor, No. 20, Jalan Chung Thye Pin, 30250 Ipoh, Perak.	+605 253 1122	+605 253 5122	Mon - Fri : 8.30am - 5pm Sat : 8.30am - 1pm
Premier Integrated Labs Pantai Hospital Manjung (PHM) 1st Floor, Pantai Hospital Manjung, Jalan PPMP 1, Pusat Perniagaan Manjung Point, 32040 Seri Manjung, Perak.	+605 688 6608	+605 688 8058	Mon - Fri : 8.30am - 5pm Sat : 8.30am - 1pm
Southern Region			
Premier Integrated Labs Seremban Ground Floor, Oakland Commerce Centre, No. 55, Jalan Haruan 5/2, 70300 Seremban, Negeri Sembilan.	+606 601 6466	+606 601 6467	Mon - Fri : 9am - 5.30pm Sat : 9am - 1pm

Premier Integrated Labs Pantai Hospital Ayer Keroh (PHAK) Ground Floor, Pantai Hospital Ayer Keroh, No. 2418-1, Km 8, Lebuhraya Ayer Keroh, Melaka.	+606 231 7977	+606 231 7978	Mon - Fri : 8.30am - 5pm Sat : 8.30am - 1pm
Premier Integrated Labs Muar No. 6, Tingkat 1, Taman Perniagaan Jaya, Pusat Perniagaan Mas Jaya, Jalan Salleh, 84000 Muar, Johor.	+606 951 6095	+606 951 6139	Mon - Fri : 9am - 5.30pm Sat : 9am - 1pm
Premier Integrated Labs Pantai Hospital Batu Pahat (PHBP) No 134 & 136, Jalan Flora Utama 8, Taman Flora Utama, 83000 Batu Pahat, Johor.	+607 485 0068	-	Mon - Fri : 8.30am - 5pm Sat : 8.30am - 1pm
Premier Integrated Labs Kluang No 70, Jalan Kluang Perdana 1, Taman Kluang Perdana, 86000, Kluang, Johor.	+607 739 2534	+607 739 2504	Mon - Fri : 8.30am - 5pm Sat : 8.30am - 1pm
Premier Integrated Labs Gleneagles Hospital Johor (GHJ) Level 1, No. 2, Gleneagles Hospital Johor, Jalan Medini Utara 4, Medini Iskandar, 79250 Iskandar Puteri, Johor.	+607 560 1042 / 1043	+607 560 1050	Mon - Fri : 8.30am - 5pm Sat : 8.30am - 1pm
Premier Integrated Labs Kensington Green Specialist Centre (KGSC) Level 3A, No. 2, Jalan Ceria 20, Taman Nusa Indah, 79100 Iskandar Puteri, Johor.	+607 213 3893	-	Sun - Thu : 8am - 5pm Fri : 8am - 12pm
East Coast			
Premier Integrated Labs Kota Bharu PT 179 - 184, Jalan Sultan Yahya Petra, Lundang, 15200, Kota Bharu, Kelantan.	+609 743 3535	+609 743 3530	Sat-Thu: 8.30am-5.30pm Fri : 9am - 12pm
Premier Integrated Labs Kerteh Lot 50058, Tingkat 1, Jalan Kemaman - Dungun, 24300 Kerteh, Terengganu.	+609 826 2187	+609 826 1730	Sun-Thu:8.30am-5.30pm Sat : 8:30am - 1pm
Premier Integrated Labs KMI Kuala Terengganu Medical Centre (KMI KTMC) Ground Floor, Kuala Terengganu Medical Centre, Lot 3963, Jalan Sultan Mahmud, 20400 Kuala Terengganu, Terengganu.	+609 622 1241	+609 622 7801	Sun-Thu:8.30am-5.30pm Sat : 8:30am - 1pm

Premier Integrated Labs Kuantan A29, Ground Floor, Lorong Tun Ismail 10, Sri Dagangan, 25000 Kuantan, Pahang.	+609 513 0886	+609 513 0885	Mon - Fri : 9am - 5.30pm Sat : 9am - 1pm
Premier Integrated Labs IIUM Medical Specialist Centre (IMSC) Kulliyah of Medicine IIUM, Bandar Indera Mahkota, 25200 Kuantan, Pahang.	+609 573 8150	-	Mon-Fri : 8.30am-5.30pm Sat : 9am – 1pm
East Malaysia			
Premier Integrated Labs Gleneagles Hospital Kota Kinabalu (GHKK) 2nd Floor, Gleneagles Kota Kinabalu, Riverson@Sembulan, Block A-1, Lorong Riverson@Sembulan, 88100 Kota Kinabalu, Sabah.	+6088 518 908	-	Mon-Fri: 8.30am- 5pm Sat : 8.30am-12.30pm
Premier Integrated Labs KMI Tawau Medical Centre (KMI TAWAU) 1st Floor Unit 3, KMI Tawau Medical Centre, TB 4660, Jalan Abaca, Bandar Tawau, 91000 Tawau, Sabah.	+6089 763 979	+608-5491725	Mon-Fri: 8.30am- 5pm Sat : 8.30am-12.30pm
Premier Integrated Labs Miri Lot 10602, Ground Floor and Second Floor, Pujut 7 Commercial Centre, Jalan Pujut 7, Sungai Merapa, Lutong, 98000 Miri, Sarawak.	+6085 491 725 Mobile: +60 12-245 6734	+6085 491 725	Mon - Fri : 9am - 5.30pm Sat : 9am - 1pm
Premier Integrated Labs Timberland Medical Centre (TMC) Level 1, Lot 8305 & 8306, Block 16, KCLD, Wisma Soon Lien Hong, Jalan Sherip Masahor, 93250 Kuching, Sarawak.	+6082 243 342	-	Mon - Fri : 9am - 5pm Sat : 9am - 1pm

INPATIENT ANCILLARY SERVICES

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

All specimens sent for testing outside 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 to our outpatient department to ensure correct and adequate specimens are collected. Please refer to Table 1 for the operating hours. We are closed on public holidays.

SPECIMENS PICK UP SERVICES

Kindly call our service phone line provided for specimen pick up services.

Specimens pick up service is available during the operating hours listed below (except for a 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 supplies with Supply Request form shall be submitted to the laboratory personnel during office hours, 1 day in advance of the expected date of supply.

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

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

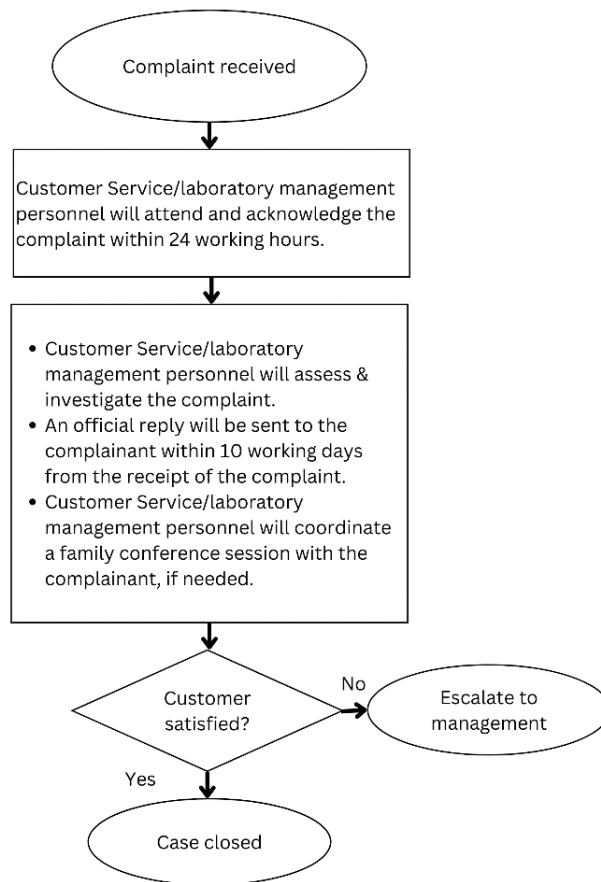
PRICING & PAYMENT POLICY

- 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 feedback or suggestion, please contact our Customer Service +603 3385 4337 or our respective branch or email to my.ppp.info@premierintegratedlabs.com.my

Customer Grievance Mechanism



GENERAL INFORMATION

Please refer to our Service Catalogue for the full range of examinations offered by the laboratory including, as appropriate, information concerning specimens required and primary specimen volumes. We will inform customers and users of any deviations from the Service Catalogue or service agreement that impact the examination results.

LABORATORY REQUISITION

TEST REQUISITION

All specimens shall be accompanied by a request form or by using e-Ordering System through HIS/I-Premier, 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)
- Nature / source of specimen
- Specimen Status (Fasting or non-fasting)
- Examination required

TYPE OF REQUEST FORMS

- Blood Transfusion Request Form
- Clinical Diagnostic 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 the box 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 the **URGENT** box.

- Send specimen in **URGENT Specimen Carrier Bag**.
- Provide email address on the request form if an email of the report is required.

ADD TEST

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

REFERRAL TEST

In some circumstances, our laboratory may refer the requested test to PIL-approved referral laboratories. These circumstances include:

- The Analysis or specialized tests requested requires special skills or instrumentation that are beyond the capacity of the in-house laboratory.
- Backup service for unscheduled or unanticipated situation.
- The laboratory will not be held responsible for tests sent to any laboratory other than PIL approved referral laboratories at the specific request of the requesting clinician.

SPECIMENS COLLECTION AND HANDLING

Proper specimen collection and handling are integral parts of obtaining a valid and timely laboratory test result. Specimens must be obtained using proper phlebotomy techniques, and collected in the appropriate container. 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 Bank Studies
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 sampling tubes must be drawn in a specific order to avoid cross-contamination of additives between tubes. The order of draw shall be as follows:

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 arise 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 shall 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 indwelling catheters, arterial line or infusion side** to prevent dilution of blood specimen.
- Ensure correct type of specimen container is 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 attending to the patient.

- Blood transfusion specimen must be labelled clearly and accurately at patient's bedside immediately after blood taking. **DO NOT** share blood transfusion specimen with other tests. Use only handwritten label and never use pre-printed label. The label shall include:
 - patient's full name
 - medical registration number (MRN) or NRIC number
 - Date and time of collection
 - Initial/ signature of the person who takes the blood
- Fill the citrate and EDTA specimens up to the volume mark indicated on the tube to ensure the correct anticoagulant to specimen ratio.
- Fill the Microtainer tube to the level between the lines indicated on the tube to reduce risk of micro clot formation.
- 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 zipper.
- Place the request form **with complete Patient's Information, clinical history and/or diagnosis** in the outer pocket of the specimen carrier bag (for "non-e-Ordering request").
- Send specimen(s) together with completed laboratory request form or electronically ordered through HIS/I-Premier to the laboratory for testing as soon as possible after collection to ensure best turnaround time and result accuracy. It is highly recommended that the specimen should arrive in the laboratory within the same day of collection.
- Separate or divide the primary specimen, when necessary, if delay in sending specimen(s) to the laboratory is anticipated.
- Specimen in formalin (e.g., histopathology) should be contained in a sealed container, preferably a screw cap container.
- Slides specimens shall be labelled on the frosted end (e.g., pap smear slides) and kept in appropriate slide holders.
- For drug abuse testing urine specimen collection, the collection site must be secure 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 transferring blood gently into appropriate blood sampling tubes.
 - If using vacutainer tubes, do not remove the cap.
 - Fill the blood specimen up to the mark indicated on the tube.
 - Do not shake the blood tube vigorously as this may cause haemolysis.
- Avoid clot formation by:
 - Ensuring smooth venepuncture and steady flow of blood into the syringe.
 - Transferring blood into anticoagulated tube up to the mark as soon as the blood has been drawn.
 - Mixing the capped blood tube immediately and gently by inverting the tube at least 5–10 times.

GENERAL SPECIMEN STORAGE

- Avoid exposing specimens to extreme heat or cold conditions.
- All specimen collected or obtained, except for those that require specific instructions as indicated in the "Preparation of Specimens" section of this guide, should be kept at room temperature in the clinics while awaiting pick-up by the despatchers.
- Do not keep the specimens overnight in the clinics, as this may lead to erroneous and misleading analytical results.

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 the laboratory via Pneumatic Tube Systems.
- To ensure timely and safe transportation of specimens, the following shall be followed:
 - proper packaging of specimen for transportation;
 - ensure the time between collection and receipt in the laboratory is appropriate for the requested examinations;
 - maintain the temperature interval specified for specimen collection and handling;
 - complies with any specific requirements to ensure integrity of specimen, e.g., use of designated preservatives;

SPECIMENS REJECTION

SPECIMENS REJECTION CRITERIA

To prevent any compromise in the quality of analytical results due to specimen quality, our laboratory personnel will inspect the appropriateness of the specimens and test requests upon receipt in the laboratory. Test requests or specimen that falls under the following Specimen Rejection Criteria will be rejected:

- Broken/leaking/split specimen.
- Clotted EDTA
- Clotted Citrate
- Grossly Haemolyzed serum
- Grossly Haemolyzed EDTA
- Grossly lipemic
- Discrepancy of patient information
- No request form accompanying with specimen (if applicable)
- No specimen received
- No handwritten label on crossmatch specimen
- Incomplete clinical history & diagnosis
- Incomplete date/time of specimen collection
- Incomplete Doctor's information/signature
- Incomplete Information of Nature/source/site 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 specimen collection site is suspected)
- Microbiology specimen without proper transport medium
- Microbiology specimen collected in non-sterile container
- Tissue block specimen contains 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

- Haemolyzed citrate
- Switched specimen tube cap (e.g., plain tube cap switch to EDTA tube cap)
- Specimens from more than one patient (>1) placed in one/same specimen bag

REJECTED SPECIMENS

- Specimen rejection will be communicated to the referring party by phone. If a physical notification is required, a rejection slip will also be issued.
- Corrective action to be taken will be suggested upon the notification of specimen rejection.

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. Blood Bank Guidelines
10. Cytopathology Guidelines
11. Histopathology Guidelines
12. Microbiology Guidelines
13. Molecular Oncology Guidelines
14. Molecular Infectious Disease Guidelines
15. Cytogenetics Guidelines
16. Molecular Genetics 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 specimen collection to facilitate proper collection procedure.

Instruct the patient to wash hands thoroughly. The lid of the specimen container shall be removed and without 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 should 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 procedures. 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

PATIENT PREPARATION FOR URINE VANILLYLMANDELIC ACID (VMA)

1. **Appropriate Collection Supplies:** Ensure the patient receives the correct 24-hour urine collection container(s), with the appropriate preservative if required by the testing laboratory. The bottle contains strong acid (6N HCl). DO NOT DISCARD. Do not urinate directly into container.
2. **Dietary Restrictions:** Specifically listed foods and beverages should be avoided for 2-3 days before and during the 24-hour collection (e.g., soft drinks, ice creams, cookies, peppers, plums, kiwi, pineapple, avocado, tomato, brinjal, coffee, tea, chocolate, bananas, citrus fruits, vanilla, nuts, alcohol).
3. **Thorough Medication History:** Obtain a detailed and accurate medication history from the patient. Be acutely aware of medications known to interfere with VMA, Metanephrines, Catecholamine and 5-HIAA levels, such as:
 - Sympathomimetics (e.g., decongestants, some asthma medications)
 - Levodopa
 - Tricyclic antidepressants
 - Some antihypertensives (e.g., labetalol) Advise on necessary adjustments or temporary cessation based on the potential for interference and the clinical necessity of the VMA test.
 - Acetaminophen (Tylenol), Alpha-methyldopa (Aldomet), Buspirone (BuSpar, Apo or Novobuspirone, Codeine, Isoproterenol (Isuprel), Mandelamine, MAO inhibitors, Metoclopramide (Maxeran), Cimetidine, Dihydrocaffeic acid, Dihydrophenylacetic acid, Fluorouracil, Gentisic acid, Melphalan, 3-Indoxysulfate

INSTRUCTION FOR 24 HOURS URINE COLLECTION

1. Note the time before collecting urine.
2. Empty bladder completely upon waking up and discard this urine.
3. Collect all subsequent urine specimens passed during the next 24 hours in the container provided with the suitable preservative in it. (Urinate into a clean, dry container and transfer it into the 24 hours urine container provided).
4. Mix the contents thoroughly after each addition of urine if a preservative is used.
5. At the end of the collection period (approximately the same time the following day), empty bladder completely.
6. Include the last urine specimen in the total collection.
7. Send the specimen as soon as possible to the laboratory / Consultant suite.
8. 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 in the request form, if creatinine clearance is requested.

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 maintain normal dietary intake (containing at least 150g of carbohydrate daily) and regular 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 any factors that may influence the 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. The patient shall remain seated and consume nothing except water throughout the test. The test shall be discontinued 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 enable the laboratory to differentiate between the fasting and post-glucose load specimens.

UREA BREATH TEST

UREA BREATH TEST (PYtest)

For accurate test results, please adhere to the following:

- 4 hours before: No food or drinks (except plain water).
- 1 week before: Avoid all proton pump inhibitors
- 2 weeks before: Discontinue all cyto-protective medicines such as sucralfate.
- 1 month before: Discontinue all antibiotics and bismuth containing products

This is because such medications will decrease the DPM readings and may give false-negative results.

PYtest Administration & Analysis in 3 Easy Steps:

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 needs to be mailed or air-freighted

Step 2

The Patient swallows a PYtest® capsule (containing a small amount of ¹⁴C-labelled urea) with 2/3 full cup of water using the paper cup provided. Wait for 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.

Step 3

Ten (10) minutes after ingesting the capsule, a breath specimen is collected in a special metalized mylar balloon. The balloon containing the breath specimen sent to laboratory for analysis.

UREA C13 BREATH TEST KIT-HELIFORCE™

For accurate test results, please adhere to the following:

- 2 hours before: No food or smoking.
- 4 weeks before: Avoid all antibiotics and antibacterial medications.
- 2 weeks before: Discontinue Proton Pump Inhibitors (PPIs) and H₂ Receptor Antagonists, such as Amoxicillin, Bismuth tricitrate, Omeprazole, Lansoprazole, Cimetidine, and Nizatidine.

The Urea C13 Breath Test Kit-Heliforce™ should be opened up and all components laid such as C13 Urea Granule, 2 breath collection bags for 00-Min and 30-Min.

Urea C13 Administration & Analysis in 4 Easy Steps:

Step 1

Two (2) 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 specimen bag 30-Min. Send both breath collection bags to the laboratory for analysis.

HEADWAY ¹⁴C-UREA BREATH TEST

For accurate test results, please adhere to the following:

- Fast for at least 2 hours before the test, and preferably overnight.
- Pregnant and breastfeeding women should not undergo this test.
- Do not take any antibiotics for 4 weeks prior to the test.
- Avoid bismuth preparations for 4 weeks before the test.
- Do not take Proton Pump Inhibitors (PPIs) for 2 weeks prior to the test.
- Swallow the capsule whole; do not crush or chew it.

Preparation of test:

- ¹⁴C-Urea Breath Test Kit
- Drinking Water

Specimen collection:

- Take one ¹⁴C-Urea capsule with water.
- Sit calmly for 15 minutes.
- Unwrap the mouthpiece and collection card body.
- Blow reposefully through the mouthpiece, as long as possible.
- Patient can exchange breath during blowing. Do NOT inhale from the mouthpiece.
- Blow continuously for 1 to 3 minutes until the indicator of the collection card turns from orange to yellow. If the color doesn't fully change after 3 minutes, stop blowing.
- Discard the mouthpiece into dustbin.
- Send the sample card to 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 using heparinized syringe. While collecting the blood gases specimen, ensure 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. Abstain from sexual intercourse or masturbation for between 3 to 5 days.
2. Produce the specimen by masturbation without using any artificial lubricants. Do not use condom, as condoms contain spermicidal agents.
3. Collect the specimen into the clean, wide mouth container supplied. Ensure the entire ejaculate is collected. If any portion is missed, label the container as "incomplete."
4. Record the time of ejaculation and the number of days of sexual abstinence.
5. Deliver the specimen to the lab within 1 hour of collection, keeping it warm (at body temperature).

NEONATAL SERUM BILIRUBIN

Fill the capillary tube to approximately 80% capacity. After specimen collection, seal both ends of the tube with wax or clay.

The specimen must be protected from light (cover it) and sent to the lab urgently.

Please refer to Appendix 3 for detailed Capillary Blood Sampling instructions.

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 may be 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 up to the indicator line on the tube to ensure correct amount of blood is collected.
- Send blood to the laboratory as soon as possible.
- Note down the exact blood collection time.
- If haematocrit is >0.55, contact laboratory for a sodium citrate tube with adjusted anticoagulant volume.

LUPUS ANTICOAGULANT TEST (CODE: LUPAC)

1. Patient preparation

The patient should not be on anticoagulant therapy prior to specimen collection.

- 3 days before: Avoid Heparin, direct Xa (Xarelto /rivaroxaban, Eliquis /apixaban, Savaysa /edoxaban), thrombin inhibitor therapies (Pradaxa /dabigatran, Acova/argatroban) or tPA (tissue plasmin activator).
- 2 weeks before: Avoid warfarin (Coumadin®) therapy

2. Specimen collection & preparation

- Specimen 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 specimen 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. 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 freeze the specimen within 1 hour of collection time or maximum within 4 hours of collection time.

3. Transportation

- Specimen should be frozen below -20°C. If possible, send collected plasma with dry ice. Specimen must arrive frozen.

4. Stability

- 4 hours at 20°C ± 5°C
- 1 month at -20°C

5. Rejection criteria

- Severe hemolysis
- Improper labeling
- Clotted specimen
- Specimen diluted with IV fluids
- Specimens thawed in transit
- Improper specimen type
- Specimen out of stability

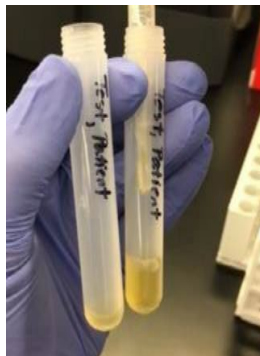
6. Double Centrifugation Instructions for Special Coagulation Testing

All specimens submitted for special coagulation testing **must** be prepared using the following “Double Centrifugation” technique to ensure the specimen 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.

BLOOD TRANSFUSION GUIDELINES

SPECIMEN COLLECTION AND LABELING PROCEDURE

1. The doctor/ nurse/ phlebotomist shall ensure that the patient is correctly identified by asking the patient to state his/her full name and IC number (the use of at least 2 identifiers) in open ended questions. The answer given must be checked against the information stated on patient's identification wristband and/or case note.
2. If it is not possible to identify the patient in above manner (e.g., unconscious patients, paediatric patients or in cases of emergencies), the phlebotomist/technical personnel/nurse taking blood must identify the patient by asking the relative to name the patient and then check the answer given against the information stated on patient's wristband and/or case note.
3. Blood taking procedure shall be carried out as one process by one person at the bedside. Only one patient shall be attended to at any one time till completion.
4. The specimen shall be labelled clearly and accurately at patient's bedside immediately after blood taking.
5. Use only handwritten label and use of pre-printed label is not advisable. The label shall include:
 - a) patient's full name
 - b) medical registration number (MRN) or NRIC number
 - c) Date and time of collection
 - d) Initial/ signature of the person who takes the blood
6. The doctor or phlebotomist shall initial on the request form with date and time of blood collection to indicate that he/she has ensured that the specimen has been accurately identified.
7. Never label 2 or more patient's specimens at the same time.

BLOOD SPECIMEN REQUIREMENT FOR TRANSFUSION

		Infant up to 4 months old	Older than 4 months old
Blood specimens for red cell transfusion	First time red cell transfusion	Infant: 1.5 - 2ml blood specimen in EDTA tube. Mother: 3 – 5ml blood specimen in EDTA tube. Both infant's and mother's specimens shall be sent to the blood bank together under a single request.	3 – 5ml blood specimen in EDTA tube accompanied by one request form.
	Repeated red cell transfusion	No further specimen is required for repeated transfusion for the same admission, provided there are no unexpected maternal red cell antibodies in the maternal / infant plasma and the infant's Direct Antiglobulin Test (DAT) is negative when first tested. If either the antibody screen or the DAT (or both) are positive, further specimen may be necessary for serological investigation of full compatibility testing. However, infant's specimen is required for subsequent transfusion if another set of paedipack is going to be issued.	If a patient requires repeated red cell transfusion during the same admission, each request for red cells shall be accompanied by a new blood specimen of 3 – 5ml of blood in EDTA tube.

Blood specimen for blood components (other than red cells) transfusion	A new request shall be accompanied by a blood specimen taken in EDTA tube. For a patient who has at least two previous blood grouping records at the hospital Blood Bank, a new blood specimen need not send together with the request for blood component.
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REQUEST FORM

1. Blood Transfusion Request Form shall be completely filled.
2. The following information should be clearly stated on the request form:
 - a) Patient's details and history:
 - i. Full name of patient (preferably patient's admission sticker label),
 - ii. Hospital registration number (MRN) and Identity Card (NRIC) number,
 - iii. Gender
 - iv. clinical diagnosis,
 - v. blood group (if known),
 - vi. previous transfusion history and the date of last transfusion if have
 - b) Indication of transfusion
 - c) Name and Initial of person who take the blood from patient
 - d) Type of request: Emergency, Urgent, Routine / GSH
 - e) Type, quantity of blood products and the time when the blood products are required
 - f) Name/ Stamp and signature of requesting doctor

TYPE OF REQUEST**Group, Screen and Hold (GSH)**

1. GSH is a procedure that consists of ABO and RhD blood grouping, and antibody screening on patient's specimen.
2. The patient's plasma is subsequently retained up to 72 hours in blood bank so that it is available for use if crossmatched blood is required within this period.
3. No crossmatched blood is reserved for patient.
4. GSH is recommended in cases where the likelihood of blood transfusion is low. It should be used for elective cases in conjunction with the Minimum Surgical Blood Ordering Schedule (MSBOS).
5. In the presence of unexpected red cell antibody(ies) detected by Indirect Antiglobulin Test, the requesting doctor who made the request will be informed whether to proceed for antibody identification, which is sent PIL referral lab.

Group and Crossmatching (GXM)

1. GXM consists of checking ABO and RhD blood grouping, antibody screening on patient's specimen and crossmatching patient's blood with donor unit for compatibility.
2. GXM shall be requested for cases with highly certainty for transfusion at that time.
3. The full procedure takes about 2 hours to be completed for a routine request.
4. When a clinically significant red cell antibody is identified, every effort shall be made to provide blood that is antigen negative (with respect to the identified antibody). This is to avoid risks of haemolytic transfusion reaction or anamnestic response.
5. Crossmatched blood will reserved in blood bank for a minimum of 48 hours, and those that have not been issued shall be released into stock after 72 hours, unless a request for reservation extension is made.
6. Elective cases
 - a) Request shall be sent to Blood Bank at least 24 hours before the blood is required, except for rare blood groups and/or RhD Negative where the hospital Blood Bank shall be informed at least 7 days in advance prior to the procedure.
 - b) The notification is essential to provide sufficient time for the blood bank to source the required blood and ensure that the blood units are available in a timely manner.

7. Urgent Crossmatch

- a) The request shall be indicated clearly on Blood Transfusion Request Form. Tick at the checkbox "Urgent (within 60 minutes)" column. This would alert technical personnel on duty to attend to the case urgently.
- b) Blood products will be available after the completion of full crossmatch within 60 minutes.

8. Emergency Uncrossmatched Group O (Safe O)

- a) In cases of emergency or life-threatening bleeding, uncrossmatched Group O RhD Positive packed cells (Safe O) can be used for resuscitation in dire emergency while waiting for group specific or crossmatched blood to be available.
- b) Any decision on the use of Safe O shall only be made after the clinician has carefully assessed the urgency of the patient's need for blood. The requesting doctor shall clearly state the reasons for the transfusion in patient's record and on the request form.
- c) The request shall be indicated clearly on Blood Transfusion Request Form. Tick at the checkbox "Emergency Uncrossmatched Group O (Safe O)" column.
- d) The personnel responsible for deciding the usage of Safe O shall sign on the request form.
- e) All requests for emergency cases shall be accompanied by a phone call to the blood bank to facilitate the process.
- f) A specimen of the patient's blood shall be taken before the transfusion of Safe O and sent together with the request form to blood bank, for the purpose of determining the patient's actual blood group and for subsequent management.
- g) The full crossmatch will be continued after the blood unit is issued.
- h) The requesting doctor will be informed to stop the transfusion if any incompatibility is encountered.

9. Emergency Crossmatch (Immediate Spin)

- a) If blood transfusion is required urgently, i.e., patients with polytrauma or those with massive bleeding and could not wait for the full crossmatching process, blood can be issued within 30 minutes by performing a saline crossmatch.
- b) The request shall be indicated clearly on Blood Transfusion Request Form. Tick at the checkbox "Emergency Crossmatched Blood (Immediate Spin)" column.
- c) The personnel responsible for deciding the usage of emergency crossmatch shall sign on the request form.
- d) All requests for emergency crossmatch shall be accompanied by a phone call to the blood bank to facilitate the process.
- e) A specimen of the patient's blood shall be taken before the transfusion and sent together with the request form to blood bank.
- f) The full crossmatch will be continued after the blood unit is issued.
- g) The requesting doctor will be informed to stop the transfusion if any incompatibility is encountered.
- h) Nevertheless, immediate spin crossmatch will only detect ABO incompatibilities. Full compatibility cannot be guaranteed, as it cannot detect other unexpected red cell antibodies. Hence, close monitoring of patient is recommended if blood is transfused after immediate spin crossmatch.

ISSUE/ COLLECTION, TRANSPORTATION AND STORAGE OF BLOOD/ COMPONENTS

1. Blood units must be collected by Staff Nurse or trained ward personnel when required.
2. Blood units should be collected from the blood bank only when it is ready to be transfused immediately.
3. Only one unit of red cell can be issued for a patient at one time with exceptions for:
 - a) Patient care units or locations that have a controlled blood product storage refrigerator.
 - b) Extreme emergency when multiple units may be transfused simultaneously, such as in the emergency department, intensive care units and operation theatre.

4. In the event that a staff nurse or trained personnel needs to collect blood units for multiple patients at the same time, the following requirements shall be fulfilled:
 - a) A maximum of 2 patients' blood unit(s) can be collected from Blood Bank at the same time.
 - b) Separate insulated box for each patient is required (i.e., one insulated box for one patient) during blood collection from Blood Bank.
5. Staff Nurse or trained ward personnel who come to collect blood units from the Blood Bank shall bring along:
 - a) Blood Collection Form (must be completely filled)
 - b) Group and Cross Match Report
 - c) Insulated box
6. Staff Nurse or trained ward personnel together with the technical personnel on duty in the blood bank, shall check that all particulars on the blood unit, blood pack card and Group and Cross Match Report are correctly indicated.
7. Staff Nurse or trained ward personnel shall transport the issued blood units to the ward without delay. Transportation shall be carried out at an appropriate temperature.
8. Issued blood units shall be transfused without undue delay. In the event where delay is inevitable, the Staff Nurse or trained ward personnel shall return the blood unit(s) to the blood bank immediately and this must be done within 30 minutes from the blood collection time.
9. Storage and Transportation Temperature of Blood/ Components as follow:

Component	Temperature		Transport Boxes
	Storage	Transportation	
Red cell	2 - 6°C	2 - 10°C	• Insulated box with ice pack • Direct contact with ice shall be avoided.
Platelet	20 - 24°C	20 - 24°C	• Insulated box without ice.
Frozen Products (FFP/ Cryoprecipitate/ Cryosupernatant)	< -25°C	< -25°C	• Insulated box. • If temperature rises > -25°C, the shelf life will be shortened to 3 months.
Thawed FFP/ Cryosupernatant	To be issued out immediately (Can be stored at 2 - 6°C up to 120 hours*)	2 - 10°C	• Insulated box with ice pack. • Direct contact with ice shall be avoided.
Thawed cryoprecipitate	Room temperature up to 4 hours		

(Reference: i) *Transfusion Practice Guidelines for Clinical and Technical Personnel, National Blood Centre, Ministry of Health Malaysia, 4th Edition, 2016.* ii) *Handbook on Clinical Use of Blood, 3rd Version 2020*)

10. The ward shall inform the blood bank if any of the unused blood returned has not complied with the storage or transportation temperature.
11. The blood pack card shall be correctly and fill up completely, packed separately and returned to the blood bank together with used blood bag within 24 hours.

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 the labelled slides immediately with spray fixative or 95% ethyl alcohol. - The brush used to prepare bronchial brushing slides may be swished in a container of CytoLyt 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 technical staff assistance is required. - A signed consent from the patient shall be obtained by the person performing the procedure. <i>Refer Appendix 6 for sample of the consent form.</i> - Fix 2 to 3 slides immediately (within a few seconds) using Cytopathology spray fixative or immerse in 95% ethyl alcohol for 15minutes. - Provide another 2 to 3 air dried slides without fixative. - Fluid obtained with a needle pass shall be expressed into a sterile, leak-proof 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) 'Dry' to indicate air dried and (F) 'Fixed' 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, leak-proof 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 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) - Avoid using lubricants during specimen collection, as they can interfere with the test results. If unavoidable, use a small amount of water-soluble, carbomer-free lubricant sparingly on the outer portion of the speculum only, avoiding the tip. - To obtain an adequate specimen 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. - For Thin Prep, rinse the broom in the preservative solution vial by pushing the broom into the bottom of the vial 10 times, forcing the bristles apart. Swirl the broom vigorously to further release the material. Discard the broom. - For Pathtest, disconnect the entire brush from the stem into the preservative solution vial. - Tighten the cap.

	- 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: <table border="1"> <tr> <th>Fixative</th><th>Duration</th></tr> <tr> <td>95% ethyl alcohol</td><td>15 – 30 minutes</td></tr> <tr> <td>spray fixatives</td><td>10 minutes</td></tr> </table> - 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.	Fixative	Duration	95% ethyl alcohol	15 – 30 minutes	spray fixatives	10 minutes
Fixative	Duration						
95% ethyl alcohol	15 – 30 minutes						
spray fixatives	10 minutes						
ANAL PAP	- Patient should refrain from receptive anal intercourse, avoid the use of rectal suppositories or enemas, any creams, lubricants or medications at the anus at least 24 hours prior to specimen collection. - Collect adequate specimens from approximately 5-6cm into anal canal (necessary in order to collect both rectal columnar and anal squamous cells) using cytobrush. Once inserted deep enough into the anus, the brush should be pulled out, applying some pressure to the wall of the anus, rotating the brush 3 times in a spiral motion along the way. - Rinse the brush as quickly as possible in the preservative solution by rotating the brush in the solution 10 times while pushing against the vial wall. Swirl the brush vigorously to further release material. Discard the brush. - Tighten the cap. - Label the test vial with at least 2 identifiers (e.g., patient's name, IC, passport number or MRN). - Place the vial and requisition form in a specimen bag for transport to the laboratory.						

Table 3: Sample Requirements

Sample Type	Temperature Range	Container	Transport Time	Special Instructions	Specific Requirements
Liquid-Based (ThinPrep and PathTezt)	2°C to 30°C	Sealed, labelled sample bag	Within 7 days	Ensure the sample is sealed properly and label the bag clearly. Avoid freezing.	Use designated preservatives to maintain sample integrity.
Conventional Pap Smear	15°C to 25°C (Room Temperature)	Fixed and labelled slide container	Within 7 days	Transport in a rigid slide holder to prevent breakage.	No additional preservatives required.
Bronchial Washings	2°C to 8°C	Sterile, leak-proof container	Within 24 hours	Refrigerate immediately after collection.	No additional preservatives required.
Body Fluids (e.g., pleural, peritoneal)	2°C to 8°C	Sterile, leak-proof container	Within 24 hours	Refrigerate immediately after collection.	Use designated preservatives if needed.

Urine Cytology	2°C to 8°C	Sterile, leak-proof container	Within 24 hours	Refrigerate immediately after collection.	Use designated preservatives if needed.
Sputum Cytology	2°C to 8°C	Sterile, leak-proof container	Within 24 hours	Refrigerate immediately after collection.	Use designated preservatives if needed.
Fine Needle Aspiration (FNA)	15°C to 25°C (Room Temperature)	Sealed, labelled sample bag or slide container	Within 24 hours	Ensure slides are fixed and transported in a rigid holder. Sample in CytoLyt medium acceptable as a preservative medium for cell block request.	Ensure no contamination during slide preparation. For smear, prepare at least a pair of FNAC smears; 1. FNAC smear must be fixed immediately for Papanicolaou staining method. The smear needs to fix in 95% alcohol for 15 minutes or spray with Cytospray fixative. Label 'Fixed' on the frosted-end slide. 2. For MGG staining method, the smear needs to be air dried. Label and place the smear in the slide mailing container. Label 'Dry' on the frosted-end slide.
Cerebrospinal Fluid (CSF)	2°C to 8°C	Sterile, leak-proof container	Within 2 hours	Transport to the lab as soon as possible. Refrigerate immediately if delayed.	Use designated preservatives if required to prevent degradation.
Anal ThinPrep Cytology	2°C to 30°C	Sealed, labelled sample bag	Within 7 days	Ensure the sample is sealed properly and label the bag clearly. Avoid freezing.	Use designated preservatives to maintain sample integrity.
Body Fluid for ThinPrep Cytology	2°C to 30°C	Sealed, labelled sample bag	Within 7 days	Ensure the sample is sealed properly and label the bag clearly. Avoid freezing.	Use designated preservatives to maintain sample integrity.
Gastric and Esophageal	2°C to 8°C	Sterile, leak-proof container	Within 24 hours	Refrigerate immediately after collection.	Use designated preservatives if needed.
Washings Gastric	2°C to 8°C	Sterile, leak-proof container	Within 24 hours	Refrigerate immediately after collection.	Use designated preservatives if needed.
Esophageal Brushing Breast Nipple Secretions	2°C to 8°C	Sterile, leak-proof container	Within 24 hours	Refrigerate immediately after collection.	Use designated preservatives if needed.

REFERENCES

1. ThinPrep (Liquid-Based):

- Hologic Inc. "ThinPrep Pap Test Collection and Transportation Guide." [Online] Available at: Hologic
- Mayo Clinic Laboratories. "ThinPrep Pap Test (Liquid-Based Pap Smear)." [Online] Available at: Mayo Clinic Laboratories

2. Conventional Pap Smear:

- American Society for Colposcopy and Cervical Pathology (ASCCP). "Pap Smear Collection Techniques." [Online] Available at: ASCCP
- Centers for Disease Control and Prevention (CDC). "Pap Test (Pap Smear) Information." [Online] Available at: CDC

3. Bronchial Washings, Body Fluids, Urine Cytology, Sputum Cytology:

- College of American Pathologists (CAP). "Collection and Handling of Cytology Specimens." [Online] Available at: CAP
- The Bethesda System for Reporting Cytopathology. "Guidelines for Collecting and Processing Cytology Specimens." [Online] Available at: Bethesda System

4. Fine Needle Aspiration (FNA):

- National Cancer Institute (NCI). "Fine Needle Aspiration Cytology: Techniques and Guidelines." [Online] Available at: NCI
- Hologic Inc. "CytoLyt Solution for Preservative Medium." [Online] Available at: Hologic

5. Cerebrospinal Fluid (CSF):

- World Health Organization (WHO). "Laboratory Guidelines for CSF Collection and Handling." [Online] Available at: WHO

6. Anal ThinPrep Cytology, Body Fluid for ThinPrep Cytology, Gastric and Esophageal Washings, Gastric and Esophageal Brushing, Breast Nipple Secretions:

- Clinical and Laboratory Standards Institute (CLSI). "Guidelines for the Collection and Handling of Cytology Specimens." [Online] Available at: CLSI
- Hologic Inc. "Additional Specimen Collection and Handling Instructions." [Online] Available at: Hologic

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. ***The use of prefilled-formalin containers is recommended.***
- Unfixed biopsy specimens for immunofluorescence shall be sent to the laboratory immediately.
- Unfixed and fresh specimen for frozen sections shall be delivered to the laboratory immediately.
- Please record the Cold Ischaemic Time (the period from tissue excision to fixation) in the appropriate section of the request form.
- 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.
- Containers of specimen required:
 - Fresh unfixed specimen for Renal OR Skin biopsy shall be placed 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.
 - 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 a charge will be incurred 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 4: 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) 13. Hemorrhoids/ piles (<3cm 14. Ethmoid 15. Fistula tract
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. Lung biopsy
Medium Complicated Specimen	HMS	1. Liver biopsy 2. Eye 3. Salivary gland 4. Thyroid lobe (1 side) 5. Breast lump (1 Site) 6. Gallbladder 7. Prostatic chips (<3cm) 8. Splenectomy 9. Simple hysterectomy (prolapse) 10. Ovarian cyst/mass (<10cm) 11. Excised diabetic ulcer 12. Excised tumour (<10cm) 13. Lipoma (<5cm) 14. Omentum (<5cm) 15. POC 16. Mole with skin

		17. Ovary (1 side <10cm) 18. Skin with tumour 19. Adrenal gland 20. Hemorrhoids/ piles (>3cm)
Large complicated specimen	HLS	1. Breast lump (with or w/o hook-wire) with margins 2. Lipoma (>5cm) 3. Omentum (>5cm) 4. Breast hook-wire with margin 5. Cone biopsy/ LLETZ/LEEP 6. Excised tumour (>10cm) 7. Hemicolectomy specimen Simple colectomy 8. Prostatic chips (>3cm) 9. Ovary (1 side >10cm) 10. Axillary tail 11. Axillary lymph node 12. Lymph node 13. Fibroid 14. Molar/ Ectopic pregnancy 15. Placenta 16. Total abdominal hysterectomy and bilateral salphingoopherectomy (TAHBSO)
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) (>5cm) 11. Total/ complicated colectomy 12. Ovarian mass 13. Femur 14. Total abdominal hysterectomy and bilateral salphingoopherectomy (TAHBSO) 15. Radical neck dissection 16. Mastectomy 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	SIHC	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
2 nd 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 OF SPECIMEN COLLECTION AND TRANSPORT

- Whenever possible, specimens shall be collected before antibiotic therapy is commenced.
- Avoid contaminating the specimen with naturally occurring bacterial flora by maintaining aseptic techniques during specimen collection.
- Sufficient amount of specimen must be collected to ensure result accuracy.
- Tissue, body fluids and pus aspirates specimens are preferred rather than specimens collected on swabs for optimal recovery of microorganisms.
- Transport specimens as soon as possible to the laboratory to prevent desiccation of the specimen and death of the microorganisms.
- If a delay in transit is anticipated, kindly contact the lab to find out more information on the required sample storage and transport condition.
- Specify specimen collection site (source), date and time of collection in the test order.
- Provide patient's current antimicrobial therapy and brief clinical history.
- For other special request(s), please specify the suspected microorganism(s) on the request form as these may require specialised/additional media for culture.

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/Note	Rejection Criteria
Body fluid specimen				
Sterile Body Fluids (Pericardial fluid, Peritoneal fluid and Joint fluid)	Sterile specimen container 2-5 ml <i>Alternative:</i> Inoculation into blood culture bottles	Transport as soon as possible at ambient temperature.	Obtain specimen via percutaneous needle aspiration or surgery. Fluid specimens are preferable than swab culture.	Insufficient specimen
Cerebral spinal fluid (CSF)	Sterile specimen container 1-3 ml	Transport as soon as possible at ambient temperature.	Do not refrigerate the specimen.	Leaking specimens Insufficient specimen
Blood Culture	Blood Culture bottles <u>Adult:</u> Aerobic bottle: 10 ml Anaerobic: 10 ml <u>Children and infants:</u> Paediatric bottle: 1-4 ml <u>For Fungal Culture:</u> Aerobic blood culture bottles: 10 ml Paediatric bottle: 1-4 ml	Transport as soon as possible at ambient temperature.	An aseptic technique is critical for proper blood culture collection. Refer to Appendix 7 Do not keep blood culture bottles in the refrigerator.	Broken/Expired blood culture bottles. Wrong container

Gastrointestinal specimen				
Stool specimen	2-5ml liquid (a teaspoonful) or 5-10g solid (peanut sized) Sterile specimen container or Appropriate bacteriology transport media	If the specimen is not transported immediately for bacterial culture, refrigerate it. If the specimen is to be submitted for <i>C. difficile</i> testing and a >48-h delay is anticipated, freeze the specimen or submit it at 4°C. Submit fresh specimens for parasite studies as soon as possible.	*Notify the laboratory if bacteria other than the routinely isolated pathogen is suspected.	Leaking specimens Insufficient specimen
Rectal swab	Swab with transport medium. Swab must be fully immersed in the transport medium	For <i>N. gonorrhoeae</i> , do not refrigerate the specimen. Transport as soon as possible at ambient temperature. For routine culture, refrigerate the transport medium if a delay in transit of 6 h or more is anticipated.	For rectal swab - pass the tip of a sterile swab approximately one inch beyond the anal sphincter. Carefully rotate the swabs to sample the anal crypts for at least 10 seconds before withdrawing the swab. *Notify the laboratory if bacteria other than the routinely isolated pathogen is suspected.	Dry rectal swab or not visibly stained with faeces
*Note: Routine stool culture and sensitivity procedures identifies and reports the antimicrobial susceptibilities of <i>Salmonella</i> , <i>Shigella</i> , <i>Vibrio</i> , <i>Aeromonas</i> , <i>Plesiomonas</i> , and <i>Enteropathogenic E.coli</i> .				
Genital specimen				
Vaginal And Urethral/Penile Swab	Swab with transport medium. Swab must be fully immersed in the transport medium	Transport as soon as possible at ambient temperature.	For HVS, please state if the following organism/diagnosis is suspected: i. <i>Neisseria gonorrhoeae</i> ii. Bacterial vaginosis	Swab without transport medium
Endocervical swab	Swab with transport medium. Swab must be fully immersed in the transport medium	Transport as soon as possible at ambient temperature.	Endocervical swab is the specimen of choice for gonorrhoea	Swab without transport medium

Vaginal wet smear for <i>Trichomonas vaginalis</i>	Swab immersed in 1 ml of 0.9 % normal saline OR Swab with transport medium. Swab must be fully immersed in the transport medium	Transport to lab within 2 hours after collection	Delay in transit decreases the ability to detect <i>T. vaginalis</i> , due to rapid loss of motility. Wet smear has low sensitivity of detection. An alternative is a nucleic acid testing which is highly sensitive and specific.	Dry swab without normal saline or transport medium
Respiratory specimen				
Per nasal/nasopharyngeal Swab	Swab with transport medium. Swab must be fully immersed in the transport medium	Transport as soon as possible at ambient temperature.	N/A	Swabs not in transport medium
Throat Swab	Swab with transport medium. Swab must be fully immersed in the transport medium	Transport as soon as possible at ambient temperature.	Specimen inflamed area, exudates and/or lesions with the suitable swab for the test.	Swab without transport medium
Sputum Bronchioalveolar Lavage (BAL) Pleural fluid Tracheal aspirate Nasopharyngeal aspirate	Sterile specimen container 2-5 ml	Transport as soon as possible at ambient temperature.	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
Urine specimen				
Urine	Sterile specimen container Minimum 1ml	Transport to laboratory within 2-3 hours. If delay is anticipated, keep the urine at 4-8°C.	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	Sterile specimen container Use a needle and syringe to aseptically collect 5-10ml of urine. Transfer the urine to a sterile specimen container	Transport to laboratory within 2-3 hours. If delay is anticipated, keep the urine at 4-8°C	Disinfect the catheter collection port with 70% alcohol.	Foley catheter tips

Wound specimen				
Abscess - Needle aspiration - Drained abscess - Swab	Sterile specimen container (1-3 ml) Swab with transport medium. Swab must be fully immersed in the transport medium	Transport as soon as possible at ambient temperature.	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 cleansing with sterile saline before collection.	Dry specimen in container Swab not in transport medium
Wound swab / pus	Swab with transport medium. Swab must be fully immersed in the transport medium	Transport as soon as possible at ambient temperature.	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
Others				
Skin scraping/ Biopsy, Bone or Tissue	Sterile specimen container	Transport as soon as possible at ambient temperature. Skin scraping: transport to the laboratory in a cardboard mailer.	Cleanse the area with sterile saline. For skin scraping, 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.
Nail	Sterile specimen container	Transport as soon as possible at ambient temperature.	Wipe nail with sterile saline. Clip away the affected areas and collect material under the nail	N/A

Vascular access devices (catheter-tip), arterial lines	Sterile specimen container Catheter tip is inclusive of the catheter segment near skin and tip end	Transport as soon as possible at ambient temperature.	Disinfect skin with 70% alcohol. Use sterile scissors to cut the catheter tip Peripheral blood culture to be collected simultaneously as it helps with the interpretation	Swab without transport medium
Eye and Ear swabs	Swab with transport medium. Swab must be fully immersed in the transport medium	Transport as soon as possible at ambient temperature.	Moisten the swabs with sterile distilled water	Swab without transport medium
Anaerobic Cultures -Pus aspirates -Empyema -Body fluid secretion	Sterile specimen container	Transport as soon as possible at ambient temperature.	Anaerobic organism is usually suspected based on clinical suspicion and or foul-smelling discharge Do not refrigerate	Swab without transport medium
QuantiFERON® – TB Gold Plus	QFT(R) Collection tubes: -Nil control (Grey) TB1 antigen (Green) -TB2 antigen (yellow) -Mitogen control (purple).	Transport to laboratory within 16 hours after collection. Room temperature	Collect 1 ml blood for each QFT® blood collection tube in the following order: i. Grey ii. Green iii. Yellow iv. Purple Follow the black mark on the side of the tube to ensure 1 ml of volume is being filled.	Insufficient/ overfill specimen. Received >16 hour after collection.

Our routine Culture & Sensitivity of Bacterial Pathogen procedure identifies and reports the susceptibility patterns of a wide range of organisms as the laboratory uses 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

SPECIMEN 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.

SPECIMEN REQUIREMENTS FOR TISSUE FISH

- The recommended specimen 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.
 - a) The first few sections should always be reserved for FISH testing. Sections should be mounted on positively charged slides.
 - b) 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 sent 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 inverting 10 times, store at room temperature (15°C to 30°C).
- Indicate the date and time of blood collection on the request form.
- The specimen must be reach RSL, Premier Integrated Labs Sdn Bhd within 3 working days.
- Please contact Premier Integrated Labs Sdn Bhd. for collection of specimens.

WHOLE BLOOD FOR GERMLINE TESTING

- Whole blood in two (2) 3 mL EDTA Tubes. After collection, immediately and gently invert the tubes 10 times. Inadequate or delayed in mixing may result in inaccurate test result.
- After inverting 10 times, tubes must be sent as soon as possible to lab, within 5 days at cold temperature (2°C to 8°C).
- Indicate the date and time of blood collection on the request form.

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 result.
- Transport the specimens quickly to the laboratory according to the requirement.
- Indicate anatomical collection site of the specimen and clinical diagnosis in the request 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 1 st void urine	Salivary specimen
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 Pathtest	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

EDTA Plasma (For HIV viral load)	EDTA tube	Whole Blood K2 EDTA: RT: 15–30 °C up to 8h; Refrigerate: 2–8 °C up to 3 days Plasma: RT: 15–30 °C up to 24h; Refrigerate: 2–8 °C up to 6 days; Frozen: ≤ -18 °C and ≤ -70 °C for up to 6 weeks	This test is volume sensitive. Kindly provide at least 2 EDTA tubes	Insufficient specimen. Specimen sent in blood collection tubes other than EDTA
EDTA Whole Blood (For HIV Qualitative test)	EDTA tube	2–8 °C for up to 96 hours or at 2–35 °C for up to 24 hours	This test is volume sensitive. A minimum of 100 µL of whole blood is required	Insufficient specimen. Specimen sent in blood collection tubes other than EDTA

CYTOGENETICS GUIDELINES

PERIPHERAL BLOOD AND BONE MARROW (KARYOTYPE)

- Proper specimen collection and sterile handling are critical for cytogenetic studies.
- Specimen collection:
 - **Peripheral blood:** Draw 5-10 mL (paediatric: 2-5 mL) of peripheral blood into sodium heparin or lithium heparin blood collection tube (green cap).
 - **Bone Marrow:** 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 specimen leakage 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.
- Only the specimen collected in sodium heparin or lithium heparin blood collection tubes 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 be obtained from the specimen 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 the specimen tube with patient's name and a second identifier (ex: DOB, MRN).
- All specimens 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.
- 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.
- Specimen type requirement:
 - 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

GENERAL PRINCIPLES

- 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 ≥ 15 weeks of gestation in a sterile syringe.
- Discard the 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 specimen leakage during transportation.
- Specimen should be transported in ambient temperature (25-30°C) 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°C.
- Specimens should arrive at Cytogenetics and Molecular Diagnostics Lab (CMDL) Premier Integrated Labs within 24-48 hours from the time of collection.
- 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 specimen leakage during transportation.
- Specimen should be transported in ambient temperature (25-30°C) 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°C.
- Specimens should arrive at Cytogenetics and Molecular Diagnostics Lab (CMDL) Premier Integrated Labs within 24-48 hours from the 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 specimen leakage during transportation.
- Specimen should be transported in ambient temperature (25-30°C) 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°C.
- Specimens should arrive at Cytogenetics and Molecular Diagnostics Lab (CMDL) Premier Integrated Labs within 24-48 hours from the time of collection.
- 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 masking tape to prevent specimen leakage during transportation.
- Specimen should be transported in ambient temperature (25-30°C) 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°C.
- 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 the time of collection.
- 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 the patient.
- All laboratory personnel strictly adhere 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 for channelling the entire original report from the external referral laboratory to the requesting clinician without alteration. Reference will be made to any work that referred to a referral laboratory or consultant.

URGENT RESULTS

Urgent results will be reported to the requesting doctor via email or via phone if requested by the doctors. However, emailing 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.

Below is the **general turnaround time** for tests in each discipline:

DEPARTMENT	TURNAROUND TIME
Biochemistry	Within 24 hours upon receipt of specimen.
Immunology	Within 24 hours upon receipt of specimen (excluding reactive cases and cases that requires further investigation).
Microbiology	2 -3 days (except for Blood culture, fungal culture or other special cases).
Haematology	Within 24 hours upon receipt of specimen for FBC, ESR and basic Coagulation tests.
Serology	Within 24 hours upon receipt of specimen except for batch testing.
Blood Bank	24 hours upon receipt of specimen (except for Transfusion cases).
Allergy	2 to 3 working days upon receipt of specimen.
Cytogenetics and Molecular Diagnostics	Turnaround time varies according to test, as clinical interpretation is required.
Histology	Uncomplicated & Biopsy specimens: - Urgent : 3 working days Routine : 5 working days
	Medium, Large, Radical specimens: - Urgent : 5 working days Routine : 7 working days
	Frozen section: Verbal result within 30 minutes upon specimen arrival.
	Second Opinion, IHC, Immunofluorescence, Special Stain: 3 - 5 working days.
Cytology	Conventional Pap smear & liquid based cytology: - Urgent : 3 working days Routine : 5 working days
	Gynae cytology Co-Testing: 5 working days.
	HPV DNA Primary Screening/ Genotyping: working days.
	Non-Gynae Cytology (Swab/Body Fluid/ Aspirate): - Urgent : 3 working days Routine : 5 working days
	Fine Needle Aspiration Cytology (FNAC): - Urgent : 3 working days Routine : 5 working days
	Cell block: 5 working days.

Further inquiries regarding Turnaround Time, can be made by calling the 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 immediate clinical actions is required.

Test results which fall within the critical value will be informed to the requesting doctor via phone call and record is 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)	None	≥ 400 ≥ 256 (PHSP & PHLM)	$\mu\text{mol/L}$
(< 1 month old)	None	≥ 400 ≥ 256 (PHSP, PHLM, GKK) ≥ 300 (PHM)	
Glucose (> 18 years old)	≤ 2.8	≥ 20.0	mmol/L
(1 month to 18 years old, CSF)	≤ 1.6	None	mmol/L
Adjusted Calcium (> 18 years old)	≤ 1.5	≥ 3.00	mmol/L
(1 month to 18 years old)	≤ 1.7	≥ 3.10	mmol/L
Phosphate (> 18 years old)	≤ 0.32	≥ 2.87	mmol/L
(1 month to 18 years old)	≤ 0.40	≥ 2.80	mmol/L
Magnesium (> 18 years old)	≤ 0.4	≥ 2.00	mmol/L
(1 month to 18 years old)	≤ 0.5	≥ 1.8	mmol/L
Creatinine Kinase (CK)	None	≥ 600	U/L
Troponin T	None	> 50	ng/L
Troponin I	None	Above reference range	ng/ml
Creatinine (1 month to 18 years old)	None	≥ 330	$\mu\text{mol/L}$
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	≥ 20.0	g/dL
	< 8.0 (PHM)		
(1 month to 18 years old)	≤ 7.0	≥ 20.0	g/dL
	< 8.0 (PHM)		
(< 1 month old)	≤ 8.0	≥ 22.0	g/dL
	≤ 10.0 (PHM)		
Total White Cell (WBC) (1 month to 18 years old)	≤ 2.0	≥ 50.0	10^9 /L
Platelets (> 18 years old)	≤ 20	≥ 1000	10^9 /L
	≤ 50 (PHBP)		
(1 month to 18 years old)	≤ 50	≥ 1000	10^9 /L
	≤ 100 (PHM)		
	< 50 (GKK) (Paeds & neonate)		
Fibrinogen (> 18 years old)	≤ 1	None	g/L
(1 month to 18 years old)	≤ 0.7	None	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
<i>Mycobacterium</i> 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 <i>Staphylococcus aureus</i> (MRSA) Multi-drug Resistant Organisms (MDRO) Vancomycin -Resistant Enterococcus (VRE) Vancomycin- Resistant <i>Staphylococcus aureus</i> (VRSA) <i>Salmonella typhi</i> <i>Vibrio cholerae</i> <i>Shigella</i> <i>Corynebacterium diphtheriae</i> <i>Bordetella pertussis</i> <i>Leptospira</i> <i>Histoplasma</i> <i>Neisseria gonorrhoeae</i> <i>Neisseria meningitidis</i> <i>Burkholderia pseudomallei</i>

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



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 ₂ EDTA (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 ₂ EDTA (plastic)	8	For lead determinations. This tube is certified to contain less than .01 µg/mL (ppm) lead. Tube inversions prevent clotting.	
	 Yellow	• Sodium polyanethanol 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 ₂ EDTA (glass) • Spray-coated K ₂ EDTA (plastic)	8 8	K ₂ EDTA and K ₂ EDTA for whole blood hematology determinations. K ₂ EDTA 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 ₂ EDTA 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 ₂ EDTA (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	 Light Blue	• Buffered sodium citrate 0.105 M (±0.2%) glass • 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	 Clear	• 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

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 FLUORIDE	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 coagulation 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.

www.gbo.com

Greiner Bio-One GmbH / Bad Haller Straße 32 / 4550 Krefeldmünster / Austria
PHONE +43 7583 6791-0 / FAX +43 7583 6318 / E-MAIL office@gbo.com

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Axisbio Diagnostics Sdn. Bhd. (7902200-AJ)
 04-1, Seda Amanah, Jalan Seda Prima 8 U13/1, Bandar Seda Alam,
 Selangor U13, 40170, Shah Alam, Selangor Darul Ehsan, Malaysia.
 Tel: +603 33422770 Fax: +603 33422780
 Email: info@axisbio.com.my website: www.axisbio.com.my

HANDLING RECOMMENDATIONS



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 preferred order of draw.

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

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.

ADDITIONAL

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® Lancetino 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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PHONE +43 7583 6791-0 / FAX +43 7583 6318 / E-MAIL office@gbo.com

Poster 980302 MiniCollect® Handling Recommendations en (rev.01, 31.03.25)

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Selatayen U13, 40170, Shah Alam, Selangor Darul Ehsan, Malaysia.
Tel: +603 33422770 Fax: +603 33422780
Email: info@axisbio.com.my website: www.axisbio.com.my

Appendix 2 : Order of Draw

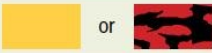
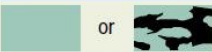
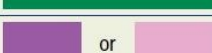
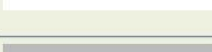


Helping all people
live healthy lives

BD Vacutainer® Order of Draw for Multiple Tube Collections

Designed for Your Safety

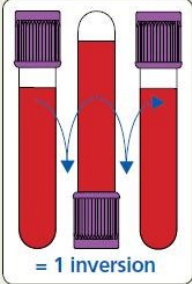
Reflects change in CLSI recommended
Order of Draw (H3-A5, Vol 23, No 32, 8.10.2)

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
	• 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
	• BD Vacutainer® PST™ Gel Separator Tube With Heparin	8 to 10 times
	• Heparin Tube	8 to 10 times
	• EDTA Tube	8 to 10 times
	• BD Vacutainer® PPT™ Separator Tube K ₂ EDTA 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 resheathing 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.



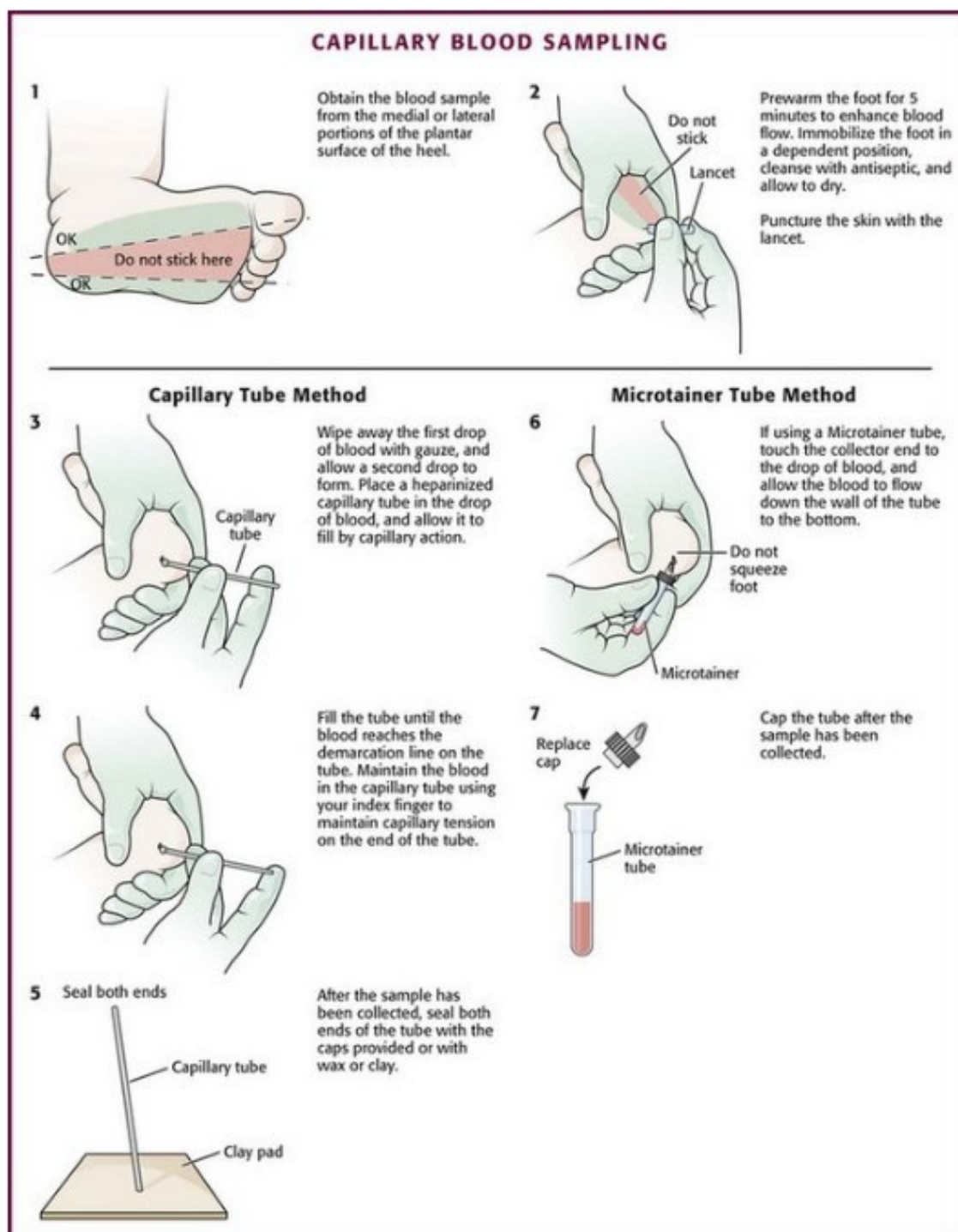
= 1 inversion

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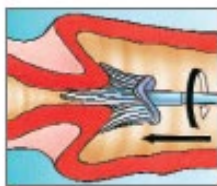
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Appendix 3: Capillary Blood Sampling



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 endocervical 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.

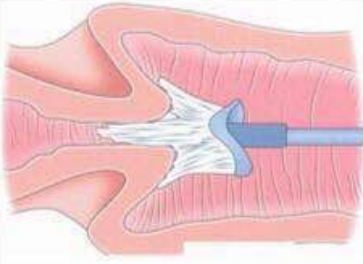
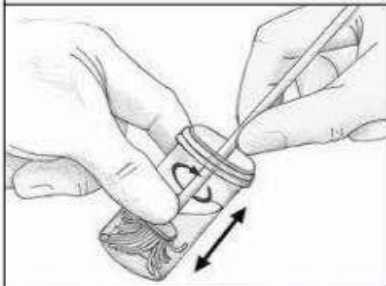
www.thinprep.com



The 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

RECOMMENDATIONS FOR BLOOD CULTURE COLLECTION

A SUMMARY OF GOOD PRACTICE

A) USING WINGED BLOOD COLLECTION SET (preferred method of collection)^{1,2,3}

1 PREPARE BLOOD COLLECTION KIT

Confirm the patient's identity and gather all required materials before beginning the collection process.

Do not use blood culture bottles beyond their expiration date, or bottles which show signs of damage, deterioration or contamination.

It is recommended to identify the Fill-to Mark or mark the target fill level on the blood culture bottle label about 10 ml above the media level.



2 PREPARE BOTTLES FOR INOCULATION

Wash hands with soap and water then dry, or apply an alcohol hand rub or another recognized effective hand rub solution.

Remove the plastic "flip-cap" from the blood culture bottles and disinfect the septum using an appropriate and recognized effective disinfectant, such as chlorhexidine in 70% isopropyl alcohol, 70% isopropyl alcohol, or tincture of iodine in swab or applicator form. Use a fresh swab/applicator for each bottle.

Allow bottle tops to dry in order to fully disinfect.



3 PREPARE VENIPUNCTURE SITE

If skin is visibly soiled, clean with soap and water. Apply a disposable tourniquet and palpate for a vein. Apply clean examination gloves (sterile gloves are not necessary).

Cleanse the skin using an appropriate disinfectant, such as chlorhexidine in 70% isopropyl alcohol or tincture of iodine in swab or applicator form. The venipuncture site is not fully clean until the disinfectant has fully evaporated.



4 VENIPUNCTURE

Attach a winged blood collection set to a collection adapter cap*.

To prevent contaminating the puncture site, do not re-palpate the prepared vein before inserting the needle. Insert the needle into the prepared vein.



5 CULTURE BOTTLE INOCULATION

Place the adapter cap over the aerobic bottle and press straight down to pierce the septum. Hold the bottle upright, below the level of the draw site, and add up to 10 ml of blood per adult bottle and up to 4 ml per pediatric bottle.** Ensure the bottle is correctly filled to the Fill-to Mark or target fill level. Once the aerobic bottle has been inoculated, repeat the procedure for the anaerobic bottle.



6 OTHER BLOOD TESTS

If blood is being collected for other tests, an insert placed into the adapter cap may be required. The insert is used to guide blood collection tubes onto the needle.

If other blood tests are requested, always collect the blood culture first.



7 FINISH THE PROCEDURE

Discard the winged collection set into a sharps container and cover the puncture site with an appropriate dressing. Remove gloves and wash hands before recording the procedure, including indication for culture, date, time, site of venipuncture, and any complications.

Ensure additional labels are placed in the space provided on the bottle label and do not cover the bottle barcodes, and that the tear-off barcode labels are not removed. If additional labels contain a barcode, they should be positioned in the same manner as the bottle barcode.

Inoculated bottles should be transported to the laboratory for testing as quickly as possible, preferably within 2 hours per CLSI.⁽⁴⁾ If delays are expected, it is important to refer to the manufacturer's Instructions for Use for guidance.



1. Applied Phlebotomy, Dennis J. Ernst, Lippincott Williams & Wilkins, 2005.

2. Essentials Of Medical Laboratory Practice, Linsecke C, et al. 2012.

3. Qemrudin A, et al. J Clin Pathol. 2008;61:509-13.

4. Principles and procedures for Blood Cultures, Approved Guideline, CLSI document M47-A, Clinical and Laboratory Standards Institute (CLSI); Wayne, PA. 2007.

* The use of blood collection sets without blood collection adapters is not recommended.

** Avoid holding the blood culture bottle in a horizontal or upside down position or drawing blood with a needle connected directly to the adapter cap, as fill level cannot be monitored during collection and there is a possible risk of media reflux into the bloodstream.

These recommendations illustrate the best practices for blood culture collection based on the World Health Organization recommendations (WHO guidelines on drawing blood: best practices in phlebotomy, 2010, ISBN 978 92 4 159922 1). Best practices may vary between healthcare facilities; refer to guidelines applicable in your facility.



RECOMMENDATIONS FOR BLOOD CULTURE COLLECTION

A SUMMARY OF GOOD PRACTICE

B) USING NEEDLE AND SYRINGE

Conventional needles and syringes should be replaced wherever possible with winged blood collection sets, which are safer.^(1,2,3)

They should only be used if prevention measures to Accidental Blood Exposure are strictly applied*. Needles must not be recapped, purposely bent or broken by hand, removed from disposable syringes or otherwise manipulated by hand.

1 PREPARE BLOOD COLLECTION KIT

Confirm the patient's identity and gather all required materials before beginning the collection process.

Do not use blood culture bottles beyond their expiration date, or bottles which show signs of damage, deterioration or contamination.

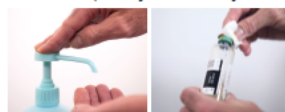
It is recommended to identify the Fill-to Mark or mark the target fill level on the blood culture bottle label about 10 ml above the media level.



2 PREPARE BOTTLES FOR INOCULATION

Wash hands with soap and water then dry, or apply an alcohol hand rub or another recognized effective hand rub solution.

Remove the plastic "flip-cap" from the blood culture bottles and disinfect the septum using an appropriate and recognized effective disinfectant, such as chlorhexidine in 70% isopropyl alcohol, 70% isopropyl alcohol, or tincture of iodine in swab or applicator form. Use a fresh swab/applicator for each bottle. Allow bottle tops to dry in order to fully disinfect.



3 PREPARE VENIPUNCTURE SITE

If skin is visibly soiled, clean with soap and water. Apply a disposable tourniquet and palpate for a vein. Apply clean examination gloves (sterile gloves are not necessary).

Cleanse the skin using an appropriate disinfectant, such as chlorhexidine in 70% isopropyl alcohol or tincture of iodine in swab or applicator form. The venipuncture site is not fully clean until the disinfectant has fully evaporated.



4 VENIPUNCTURE

Attach the needle to a syringe. To prevent contaminating the puncture site, do not re-palpate the prepared vein before inserting the needle.



5 CULTURE BOTTLE INOCULATION

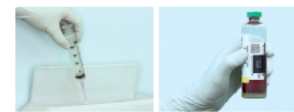
Collect the sample. Transfer the blood into the culture bottles, starting with the anaerobic bottle. Hold the bottle upright, and add up to 10 ml of blood per adult bottle and up to 4 ml per pediatric bottle. Ensure the bottle is correctly filled to the Fill-to Mark or target fill level. Once the anaerobic bottle has been inoculated, repeat the procedure for the aerobic bottle.



6 FINISH THE PROCEDURE

Discard the needle and syringe into a sharps container and cover the puncture site with an appropriate dressing. Remove gloves and wash hands before recording the procedure, including indication for culture, date, time, site of venipuncture, and any complications.

Ensure additional labels are placed in the space provided on the bottle label and do not cover the bottle barcodes, and that the tear-off barcode labels are not removed. If additional labels contain a barcode, they should be positioned in the same manner as the bottle barcode. Inoculated bottles should be transported to the laboratory for testing as quickly as possible, preferably within 2 hours per CLSI.⁽⁴⁾ If delays are expected, it is important to refer to the manufacturer's Instructions for Use for guidance.



* Refer to recognized guidelines such as those issued by the WHO or CDC:
http://www.who.int/infection_safety/plebs_final_screen_ready.pdf
<http://www.cdc.gov/hivstd/docs/2000-108/pdfs/2000-108.pdf>

These recommendations illustrate the best practices for blood culture collection based on the World Health Organization recommendations (WHO guidelines on drawing blood: best practices in phlebotomy, 2010. ISBN 978 92 4 159922 1). Best practices may vary between healthcare facilities; refer to guidelines applicable in your facility.

bioMérieux S.A. • 69280 Marcy l'Étoile • France
Tel.: +33 (0)4 78 87 20 00 • Fax: +33 (0)4 78 87 20 90
www.biomerieux.com • www.biomerieux-diagnostics.com



LABELLING BLOOD CULTURE BOTTLE

CORRECT LABELLING



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



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

LAB INTENDED USED
For Bottle Tracking



medigene



Horizontal
position



Covers the
bottom

WRONG LABELLING

Appendix 8 : Whole Blood for Liquid Biopsy

Cell-Free DNA BCT®



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 K₂EDTA 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 analytical 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

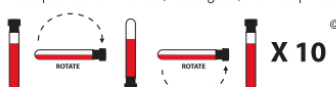
For a video demonstration, visit streck.com/mixing.

1. Collect specimen by venipuncture according to CLSI GP41¹.

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 GP41¹. 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.

Australia Patent AU2003254755

Canada Patent CA2,917,912

Europe Patent EP2228453B1; EP2626438A1; EP2814981; EP1816461

Germany Patent DE202010048559; DE60201322817.5

United States Patent US 9,657,227; US 9,926,590; US 10,144,955; US 10,294,513; US 10,091,984

Others Pending

See streck.com/patents for patents that may be applicable to this product.



Streck
7002 S. 109 Street, La Vista, NE 68128 USA

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