LABORATORY SERVICE GUIDE

PANTAI
PREMIER PATHOLOGY

Version 1.02, Effective Date: 1st May 2018

A supplementary to Pantai Premier Pathology Sdn Bhd
Price & Service Catalogue and Service Directories

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INTRODUCTION

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

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

We provide quality laboratory services in the following disciplines:

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

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

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

We have more than 18 residents/visiting consultant pathologists from various disciplines involve in the reporting and managing the quality of our laboratories services. Under the active guidance of the consultants and our management commitment towards service excellence with 8 major branches are accredited with MS ISO 15189 by Department of Standard Malaysia.

Mission, Vision, Core Values & Brand Promise

Our Mission

Delivering quality healthcare services that exceed your expectations with a professional commitment to continuous improvement.

Our Vision

To be the trusted professionals of healthcare delivery.

Our Core Values

- Empathy
- Caring
- Progressive
- Professionalism
- Teamwork

Our Brand Promise

We are always there for you.
Because we care.

We serve. We heal. We deliver.
As individuals. And together.

We pioneer and innovate solutions.
We strive to be the finest in healthcare.

In the great cycle of life,
everyone will need medical attention sometime.

When we say that the patient comes first,
it is all about what we do best.

CONSULTANT PATHOLOGIST

Resident

No	Consultants	Discipline	Posting
1	Dr Nik Azizah binti Wan Kadir	• Histopathology • Cytopathology	Reference Specialised Lab, Bangsar Central Region
2	Dr Shahrin Iskandar bin Abdul Wahab	• Histopathology • Cytopathology	Reference Specialised Lab, Bangsar Central Region
3	Dato Dr. Sharifah Noor Akmal binti Syed Husain Shahabuddin	• Histopathology • Cytopathology • Cytogenetic & Molecular Pathology	Gleneagles Kuala Lumpur branch Reference Specialised Lab, Bangsar Central Region
4	Dr Lee Bang Rom	• Histopathology • Cytopathology	Gleneagles Kuala Lumpur branch Reference Specialised Lab, Bangsar Central Region
5	Dr Krishnan Ramanathan	• Histopathology • Cytopathology	Gleneagles Penang Branch Northern Region
6	Dr Chan Kai Soon	• Histopathology • Cytopathology	Ipoh Branch Northern Region
7	Dr Rosli bin Ismail	• Histopathology • Cytopathology	Ayer Keroh Branch Southern Region

Visiting

No	Consultants	Discipline	Posting
1	Dr Peh Suat Cheng	• Histopathology • Cytopathology	Reference Specialised Lab, Bangsar Central Region
2	Dr Julia Munchar binti Munchar Jaluli	• Histopathology • Cytopathology	Gleneagles Kuala Lumpur branch Reference Specialised Lab, Bangsar Central Region
3	Dr Ahmad Toha Bin Samsudin	• Histopathology • Cytopathology	Gleneagles Kota Kinabalu branch.
4	Dr Poh Bee Hoon	• Histopathology • Cytopathology	Ipoh Branch Northern Region
5	Dr Noraidah binti Masir	• Histopathology • Cytopathology • Cytogenetic & Molecular Pathology	Reference Specialised Lab, Bangsar Central Region
6	Dr Sabariah binti Abdul Rahman	• Histopathology • Cytopathology	Reference Specialised Lab, Bangsar Central Region
7	Dr Reena Rahayu binti Md Zin	• Histopathology • Cytopathology	Reference Specialised Lab, Bangsar Central Region
8	Dr Leslie Charles Lai Chin Loy	• Chemical Pathology	Gleneagles Kuala Lumpur Branch
9	Dr Zubaidah binti Zakaria	• Cytogenetic & Molecular Pathology	Reference Specialised Lab, Bangsar Central Region
10	Dr Ariza binti Adnan	• Microbiology Pathology	Reference Specialised Lab, Bangsar Central Region
			Gleneagles Medini Branch Southern Region
11	Dr Rohani binti Md Yasin	• Microbiology Pathology	Gleneagles Kuala Lumpur Branch Central Region
		• Molecular Pathology	Reference Specialised Lab, Bangsar Central Region
12	Dr Amir Hamzah bin Dato' Abdul Latiff	• Clinical Immunology & Allergy	Bangsar Branch, Central Region

13	Dato' Dr Vijaya Sangkar Jaganathan Naidu	• Haematology & Immuno-Haematology Pathology	Bangsar Branch, Central Region
14	Dr Rudy Yeoh Seok Ching	• Haematology Pathology	Gleneagles Kuala Lumpur Branch, Central Region
15	Dr Eow Geok Im	• Haematology Pathology	Ipoh Branch, Northern Region
16	Dr Guan Yong Khee	• Haematology	Ayer Keroh Branch, Southern Region
17	Dr Wan Aswani binti Wan Yusof	• Haematology Pathology	Ayer Keroh Branch, Southern Region
18	Dr Indhira Subbiah	• Haematology Pathology	Gleneagles Medini branch, Southern Region
19	Dr Yabitha a/p Vasan	• Histopathology • Cytopathology	Gleneagles Medini branch, Southern Region

For pathologist advisory services kindly contact the respective laboratories.

OPERATION HOURS, LOCATION AND CONTACT NUMBERS

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

Customer Service Hotline
(T) +603 4280 9115 (F) +603 4297 4911
info@premierpathology.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 LABORATORIES	TEL NO.	FAX NO.	OFFICE HOURS
CORE LABORATORY (PANDAN INDAH) 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
BANGSAR, KUALA LUMPUR Level 2, Block A, Pantai Hospital Kuala Lumpur, No 8, Jalan Bukit Pantai, 59100 Bangsar, Kuala Lumpur	+603 2282 875	+603 2287 2622	Mon - Fri : 9am - 5.30pm Sat : 9am - 1pm
REFERENCE SPECIALISED LAB, BANGSAR, KUALA LUMPUR Level 8, Block A, Pantai Hospital Kuala Lumpur, No 8, Jalan Bukit Pantai, 59100 Bangsar, Kuala Lumpur.	+603 2282 8795 Ext. 171 (CMDL), 176 (Cyto), 134 (Histo)	+603 2287 2622	Mon - Fri : 9am - 5.30pm Sat : 9am - 1pm
CHERAS, KUALA LUMPUR Basement, Pantai Hospital Cheras, No. 1, Jalan 1/96A, Taman Cheras Makmur, 56100 Cheras, Kuala Lumpur.	+603 9131 7147	+603 9131 7141	Mon - Fri : 8.30am – 5.00pm Sat : 8.30am - 1pm

KLANG, SELANGOR Ground Floor, Pantai Hospital Klang, Lot 5921, Persiaran Raja Muda Musa, 41200 Klang, Selangor.	+603 3373 6252	+603 3373 6271	Mon - Fri : 9am - 5pm Sat : 9am - 1pm
KLANG OFF SITE, SELANGOR No.125, Ground Floor, Lebuh Turi Off Persiaran Raja Muda Musa, 41200 Klang, Selangor.	+603 3370 1315	+603 3370 1329	Mon - Fri : 9am - 5pm Sat : 9am - 1pm
GLENEAGLES, KUALA LUMPUR 2nd Floor, Gleneagles K.L. (Hosp. Block), No 286, Jalan Ampang, 50450 Kuala Lumpur.	+603 4141 3064	+603 4141 3065	Mon - Fri : 8.30am - 5pm Sat : 8.30am - 1pm
SUNGAI PETANI, KEDAH Ground Floor, Pantai Hospital Sungai Petani, No. 1, Persiaran Cempaka, Bandar Amanjaya, 08000 Sungai Petani, Kedah.	+604 441 2994	+604 441 3012	Sun - Thu : 8.30am - 5pm Fri : 8.30am - 1pm
PENANG 3rd Floor, Pantai Hospital Penang, No. 82 , Jalan Tengah, 11900 Bayan Baru, Penang.	+604 646 5505	+604 646 6606	Mon - Fri : 8.30am - 5pm Sat : 8.30am - 1pm
GLENEAGLES, PENANG (Histo & Cyto) 6th Floor, Gleneagles Penang, No. 1, Jalan Pangkor, 10050 Georgetown, Penang	+604 220 0838 +604 210 8202	+604 210 6006	Mon - Fri : 9am - 5.30pm Sat : 9am - 1pm
IPOH, PERAK 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
PERAK COMMUNITY SPECIALIST HOSPITAL (SATALLITE LABORATORY – IPOH BRANCH) 277, Jalan Raja Permaisuri Bainun, 30250 Ipoh, Perak.	+605 241 9000	-	Mon-Fri : 8am-6pm Sat : 8am-1pm
SERI MANJUNG, PERAK 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
SEREMBAN, NEGERI SEMBILAN Ground Floor, Oakland Commerce Square, No.55 Jalan Haruan 5/2, 70300 Seremban, Negeri Sembilan.	+606 601 6466	+606 601 6467	Mon - Fri : 9am - 5.30pm Sat : 9am - 1pm
AYER KEROH, MELAKA Ground Floor, Pantai Hospital Ayer Keroh, No. 2418-1, Km 8, Lebuh Ayer Keroh, 75450 Ayer Keroh, Melaka.	+606 231 7977	+603 4141 3065	Mon - Fri : 8.30am - 5pm Sat : 8.30am - 1pm

AYER KEROH OFF SITE, MELAKA B7, B7-1, B8, B8-1 & B9-1, Jalan PKCAK 1, Pusat Komersial Cendana Ayer Keroh Hang Tuah Jaya, 75450 Melaka	+606-2313232	+606-2312277	Mon - Fri : 8.30am - 5pm Sat : 8.30am - 1pm
MUAR (SATELLITE LABORATORY – AYER KEROH BRANCH) No. 6, Tingkat 1,Jalan 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
BATU PAHAT, JOHOR 3rd Floor, Pantai Hospital Batu Pahat, No. 9S, Jalan Bintang Satu, Taman Koperasi Bahagia, 83000 Batu Pahat, Johor.	+607 432 8855	+607 432 5885	Sun - Thu : 8.30am - 5pm Fri : 8.30am - 1pm
KUANTAN, PAHANG Ground Floor, No. A29, Lorong Tun Ismail 10, Sri Dagangan, 25000 Kuantan, Pahang.	+609 513 0886	+609 513 0885	Mon - Fri : 9am - 5.30pm Sat : 9am - 1pm
KOTA BHARU, KELANTAN Kota Bharu Medical Centre Sdn Bhd PT179-184, Jalan Sultan Yahya Petra Lundang, 15200 Kota Bharu, Kelantan.	+609 743 3535	+609 743 3530	Sat - Thu : 8.30am - 5.30pm
KERTIH, TERENGGANU 1st Floor, Lot 50058, Jalan Kemaman-Dungun, 24300 Kertih, Terengganu.	+609 826 2187	+609 826 1730	Sat - Thu : 8.30am - 5.30pm
GLENEAGLES, KOTA KINABALU 2nd Floor, Riverson@Sembulan, Block A-1, Lorong Riverson, Sembulan, 88100 Kota Kinabalu, Sabah.	+6088 518908	-	Mon - Fri : 7.30am - 5pm Sat : 7.30am - 1pm
GLENEAGLES MEDINI, JOHOR BAHRU Level 1, No.2, Jalan Medini Utara 4, Medini Iskandar, 79250 Iskandar Puteri, Johor.	+607-5601042	+607-5601050	Mon - Fri : 9 am – 5.30pm Sat : 9 am - 1pm
PENGERANG (SATELLITE LABORATORY – GLENEAGLES MEDINI, JOHOR BAHRU) Central Medical Facility (CMF) Plot 113, Petronas RAPID Project Pengerang, 81900 Kota Tinggi, Johor.	+607-8244881	+607-8244882	Mon - Fri : 9 am – 5.30pm Sat : 9 am - 1pm
BANDAR PENAWAR (SATELLITE LABORATORY – GLENEAGLES MEDINI, JOHOR BAHRU) 49A, Jalan Jelutong 1 Taman Desaru Utama 81930 Bandar Penawar, Johor.	+607 – 8861880	-	Mon - Fri : 9 am – 5.30pm Sat : 9 am - 1pm

CHERAS, KUALA LUMPUR (UKMSC) 7th Floor, Clinical Block, UKM Medical Centre, Jalan Yaacob Latif, Bandar Tun Razak, 56000 Cheras, Kuala Lumpur.	+603-9171 1748/ 1749	+603-9171 1629	Mon - Fri : 8.30 am – 9 pm Sat : 9 am – 5 pm
ALOR SETAR, KEDAH Ground Floor, INS Medical Centre, 639-D, Jalan Pintu Sepuluh, 05100 Alor Setar, Kedah.	+604-730 8110	+604-730 8110	Sun - Thu : 8.30am - 5pm Fri : 8.30am - 1pm

24 HOURS EMERGENCY SERVICES

The hospital based laboratory provides 24 hours emergency services to the Pantai Hospital inpatients and outpatients for the essential tests while others test are only done during office hours. All specimens sent to for testing outside the normal office hours are subject to additional charges.

OUTPATIENT PHLEBOTOMY SERVICES

Phlebotomy services are available during the outpatient operating hours at our laboratories. Referring clinics shall issue a Laboratory Request Form for patients to bring along to our outpatient department to ensure correct and adequate specimens are collected. Please refer to page 7, 8 & 9 for the operating hours. We are close on public holidays.

SPECIMENS PICK UP SERVICES

Kindly call up our service call line provided for specimen pick up services.
Specimen pick up service is available during the below operating hours (except for Kota Bharu, Kertih, Sungai Petani & Batu Pahat):

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

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

SUPPLIES

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

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

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

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

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 “Pantai Premier Pathology Sdn Bhd” only.

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

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

LABORATORY REQUISITION

TEST REQUISITION
All specimens shall be accompanied by a request form filled with the following particulars:
- Patient's Full Name & second identifier (Government ID or Passport No/Medical Record Number)
- Patient's age, date of birth & gender
- Date & time of specimen collection
- Diagnosis or Clinical History (Where Applicable)
- Name and signature of requesting doctor, clinic stamp and telephone number
- Billing mode (Cash, Clinic, Hospital and Employer/GL)
- Special attention if required (Urgent/Overtime/Phone/Fax No.)
- Nature / source of specimen
- Specimen Status (Fasting or non-fasting)
- Examination required

TYPE OF REQUEST FORMS
- Blood Bank/Transfusion Request Form
- Clinical Request Form
- Histopathology & Cytopathology Request Form
- Allergy Diagnostic Request Form
- PMCare Request Form
- Prudential Request Form
- Specialized Testing Request Form
- Microbiology Request Form

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

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

URGENT TEST
Tick on the **URGENT** box.
- Send specimen in **URGENT Specimen Carrier Bag.**
- Tick on phone/ fax and provide phone/fax number on the request form if verbal/faxing of report is required.

ADD TEST

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

SPECIMENS COLLECTION AND HANDLING

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

TYPES OF CONTAINERS AND ANTICOAGULANT

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

Refer to Appendix 1: BD Tube Guide

ORDER OF DRAW FOR BLOOD SPECIMENS

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

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

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

COLLECTION OF SPECIMENS

- Correct patient identification before specimen collection is extremely important. Identify the patient prior to specimen collection, using at least two patient identifiers and label at the specimen container.
- Avoid drawing blood below or from the infusion side to prevent dilution of blood specimen.
- Select specimen containers according to the tests requested (Refer to Price and Service Catalogue)
- Label specimen with water proof ink at the point of specimen collection.
- Indicate the source of specimens on containers for anatomical pathology and microbiology specimens.
- Do not pre-label the empty specimen containers before attend to the patient.

- Blood bank specimen must be labelled clearly and accurately at patient's bedside immediately after blood taking. **DO NOT** share blood bank specimen with other tests. Use only hand written label and never use pre-printed label or labelling specimen. The label should include at least 2 identifications e.g. the patient's full name, MRN, NRIC or DOB. The date and time of collection and the initial/signature of the person taking the blood.
- Label Glucose Tolerant Test specimens according to collection time.
- Fill up the citrate and EDTA specimens to the volume mark available on the tube to ensure the correct anticoagulant to specimen ratio.
- Do not send specimen in syringes, regardless of whether the needles are attached or not.
- Place specimens in the inner pocket of the specimen carrier bag and seal the zip.
- Place the request form at the outer pocket of the specimen carrier bag.
- For collection of urine specimen for drug abuse testing, collection site must be secure in order to eliminate the possibility of specimen tampering or adulteration.

GENERAL PRINCIPLES IN HANDLING LABORATORY SPECIMENS

Known factors significantly affect the performance of the examination or interpretation of the results as below:

- Secure all specimen containers' caps to prevent leakage and cross contamination.
- Mix plasma specimen gently by inverting the specimen tubes. **Avoid vigorous shaking to prevent blood specimen haemolysis.**
- Unless indicated, specimens should be stored at room temperature (air condition) and avoid exposing specimens to extreme heat or cold.
- Place specimens in the inner pocket of the specimen carrier bag and seal the zip.
- Place the request form at the outer pocket of the specimen carrier bag.
- Send specimen(s) together with request form to the laboratory for testing as soon as possible.
- Do not keep specimens overnight as these specimens may give erroneous and misleading results. To ensure the integrity of specimens.
- Do not use expired collection container for specimen collection. **Expired supplies shall be returned to us or being disposed at your end. Please give us a call for the arrangemen**t.
- Fill up the citrate and EDTA specimens to the volume mark available on the tube to ensure the correct anticoagulant to specimen ratio.
- Ensure correct type specimens in used.
- Avoid drawing blood below or from the infusion side to prevent dilution of blood specimen.

PREVENTION OF HAEMOLYSIS

Allow alcohol on venepuncture site to dry before inserting needle into the vein.
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.

During venepuncture for collection of blood using non-vacutainer tubes, the plunger of the syringe should be drawn back slowly and the blood should flow freely.

After venepuncture for collection of blood using non-vacutainer tubes, remove the needle before allocating blood into the blood tubes and expel blood gently into the correct collection container.

After collecting blood into the blood tube containing anticoagulant, immediately invert the capped blood tube gently for several times to allow blood mixing with anticoagulant thoroughly to prevent clotting. Do not shake the blood tube vigorously as this may cause haemolysis.

PACKING & STORAGE OF SPECIMENS

- Avoid exposing specimens to extreme heat or cold.
- Place specimen in the inner pocket of the specimen carrier bag and seal the zip.
- Request form shall be placed at the outer pocket of the specimen carrier bag.
- Send specimens with Request Form attached.

GENERAL SPECIMEN STORAGE

- All specimen collected or obtained, except for a few that require other specific instructions as indicated in the specimen types, are to be left at room temperature in the clinics while awaiting for pick-up by the despatchers.
- Do not keep the specimens overnight in the clinics as these specimens may give erroneous and misleading analytical results to some tests reported. Examples are falsely elevated potassium level, falsely low glucose result, etc.

TRANSPORT OF SPECIMENS

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

SPECIMEN REJECTION

SPECIMENS REJECTION CRITERIA

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

- Broken / Leaking / Spilt Containers
- Clotted EDTA/Citrate specimen
- Discrepancies between specimen and request form
- Haemolysed specimen
- Incorrect / Insufficient / Overfilled Specimen
- Insufficient clinical information
- No request form attached
- No requesting doctor's name
- Overnight / Delayed specimen
- Test required not fully specified
- Unlabelled specimen
- Wrong usage or expired container
- Test not available
- Microbiology specimens without proper transport medium
- Microbiology specimens collected in non-sterile container
- Collection swab has dried out for microbiology specimens.
- Histopathology and microbiology not labelled with specimen source.
- Tissue block specimen contain less than 10% of tumour for Molecular Oncology testing.

REJECTED SPECIMENS

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

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

- Is not an approved Outsource Referral Laboratory by Pantai Premier Pathology Sdn. Bhd.

PREPARATION OF SPECIMENS

Preparation of specimens consists of the following:
1. Collecting A Clean Catch Urine
2. Collecting 24 hour Urine
3. Oral Glucose Tolerance Test
4. Urea Breath Test
5. Blood Gases pH
6. Semen Analysis
7. Cytopathology Guidelines
8. Histopathology Guidelines
9. Microbiology Guidelines

COLLECTING A CLEAN CATCH URINE

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

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

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

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

COLLECTING 24 HOUR URINE

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

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

Patient Preparation for urine VMA

Many Laboratory restrict food. Such as coffee, tea, bananas and others foods. Some ask for no drugs use (except for digitals) for 2 weeks before the test. Aspirin, Peroxidane, Levodopa, Amoxicilin, Cardidopa, Reserpine and Disulfiram commonly interfere.
Monoamine oxidase inhibitor decrease VMA excretion.
For an infant, thoroughly wash the area around the urethra. Open a urine collection bag (a plastic bag with an adhesive paper on one end), and place it on the infant. For males, place the entire penis in the

bag and attach the adhesive to the skin. For females, place the bag over the labia. Diaper as usual over the secured bag.
This procedure may take a couple of attempts -- lively infants can move the bag, causing the urine to be absorbed by the diaper. The infant should be checked frequently and the bag changed after the infant has urinated into the bag. Drain the urine from the bag into the container provided by your health care provider.
Deliver it to the laboratory or your health care provider as soon as possible upon completion.

ORAL GLUCOSE TOLERANCE TEST

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

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

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

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

UREA BREATH TEST

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

Step 1

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

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

Step 2

The Patient swallows a PYtest® capsule (containing a small amount of 14C-labelled urea) with 30mls of water using paper cup provided. Wait 3 minutes then swallow the second cup of water and wait for another 7 minutes before proceeding to Step-3. When the 14C-urea comes into contact with H.pylori in the stomach, it is hydrolyzed 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 minutes after ingesting the capsule, a breath specimen is collected in a special metalised mylar balloon. The balloon containing the breath specimen may be analysed on-site or sent to a pathology laboratory for analysis.

BLOOD GASES AND pH

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

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

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

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

SEMEN ANALYSIS

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

CYTOPATHOLOGY GUIDELINES

Table 2: Specimen Collection and Handling for Cytopathology Specimens

SPECIMEN TYPE	COLLECTION & HANDLING GUIDELINES
BRONCHIAL BRUSHINGS	• Roll brush over clean, dry slide. • Fix immediately the labelled slides with spray fixative or 95% ethyl alcohol. • The brush used to prepare bronchial brushing slides may be swished in a container of Cytolyte solution to dislodge remaining specimen. • Label containers/ slides with at least 2 identifiers (e.g. patient's name, IC, passport number or MRN) • Submit to the laboratory using one request form.
FINE NEEDLE ASPIRATION (FNA)	• Advanced booking is required for FNA by Consultant Cytopathologist as well as when assistance is required by MLT. • Fix 2 to 3 slides immediately (within a few seconds) using Cytopathology spray fixative or immerse in 95% ethyl alcohol for 15-30 minutes. • Provide another 2 to 3 air dry slide without fixative. • Fluid obtained with a needle pass shall be expressed into a sterile container. • Label containers with at least 2 identifiers (e.g. patient's name, IC, passport number or MRN) and indicate nature of the specimen. • Label slides to indicate air dried or alcohol fixed smears. • Submit to the Laboratory using one request form.

<table>
<tr><td>FLUIDS</td><td>• Including CSF, bronchial washing, colonic washing, pelvic washing, effusion, etc.
• Collect in a sterile container, label with at least 2 identifiers (e.g. patient's name, IC, passport number or MRN) and indicate nature of the specimen, and send immediately to the laboratory.</td></tr>
<tr><td>GYNAECOLOGY SMEAR</td><td>• 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.

Liquid Based (ThinPrep)
• To obtain an adequate sample from the cervix, insert the central bristles of the broom into the endocervical canal deep enough to allow the shorter bristles to fully contact the ectocervix. Push gently and rotate the broom in a clockwise direction 5 times.
• Rinse the broom in the PreserveCyt® solution vial by pushing the broom into the bottom of the vial 10times, forcing the bristles apart. Swirl the broom vigorously to further release the material. Discard the broom.
• Tighten the cap so that the torque line on the cap passes the torque line on the vial.
• Label the test vial with at least 2 identifiers (e.g. patient's name, IC, passport number or MRN).
• Submit to the laboratory using one request form.
• Refer to Appendix 3: ThinPrep® 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>
<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.</td></tr>
</table>

HISTOPATHOLOGY GUIDELINES

HANDLING OF SPECIMEN

- Routine specimens should be fixed in 10% buffered formalin unless otherwise stated.
- Unfixed biopsy specimens for special immunofluorescence stains shall be sent to laboratory immediately.
- Unfixed and fresh specimen for frozen sections shall be delivered to laboratory immediately.
- All specimens shall be labelled with patient's 2 unique identifiers and nature of specimens.
- All histopathology specimens shall be sent in containers with proper labelling.
- Large specimen shall be sent in double-bagged plastic bag to prevent leakage.
- Multiple small specimens, such as gastrointestinal biopsies, shall be mounted on a piece of filter paper and properly labelled.
- 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, size and nature of specimens, complexity and not depending on the size of containers.

FROZEN SECTION

- At least one day advance booking is required.
- Contact Histopathology section for enquiry.
- Specimen for frozen sections will be done 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) STAINS

- At least one day advance booking is required.
- Fresh unfixed specimen for Renal and Skin biopsy shall place on filter paper soaked with saline and another specimen in 10% buffered formalin.

SPECIAL STAINS & IMMUNOHISTOCHEMISTRY (IHC) STAINS

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

RADIOACTIVE BIOLOGICAL SPECIMEN

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

Table 3: Histopathology Specimen and Code

CODE	SPECIMEN
BX (Biopsy specimen)	1. Antral biopsy 2. Gastric biopsy 3. Stomach biopsy 4. Tru-cut biopsy (breast, prostate-1 site) 5. Liver biopsy 6. Cervical biopsy (TRO CIN) 7. PNS/NPC 8. Endometrial curettings 9. Endometrial sampling/pipelle 10. Skin bx, skin lesion 11. Brain tumour <10mm 12. POC (<30mm) 13. Endocervical polyps
MUS (Medium uncomplicated specimen)	1. Fallopian tubes – Rt & Lt. (even in 2 containers) 2. Appendix 3. Ovary (1 side- <30mm) 4. Lipoma (small) <30mm 5. Sebaceous cyst (<30mm) 6. Tonsil (1 side)

LS (Large specimen)	1. Thyroid lobe (1 side) 2. Appendix(>50mm) 3. Breast lump (big container) <30mm 4. Lipoma (big container)>30mm 5. Omentum 6. Axillary tail 7. LLETZ 8. Prostatic chips <30mm 9. Gallbladder 10. Lymph node 11. Axillary Lymph Node 12. Mole with skin 13. Tonsil (Rt & Lt in 1 container) 14. Ovary (40-50mm) 15. Fibroid (<50mm) 16. Molar/Ectopic pregnancy >30mm 17. Skin with tumor 18. Doughnut (rectum)
LCS (Large complicated specimen)	1. Segment of colon 2. Ovary (>50mm) 3. Fibroid (>50mm) 4. Breast WLE <50mm 5. Prostatic chips >30mm 6. Cervix (Cone)
CC (Complex complicated)	1. Uterus with appendages (TAHBSO) 2. Mastectomy specimen/ WLE >50mm 3. Hemicolectomy specimen 4. Gastrectomy 5. Laryngectomy 6. Total prostate 7. Bladder 8. Kidney 9. Radical neck 10. Total thyroidectomy 11. Femur
Immunofluorescence(IF)+(Routine HPE)	Skin in-house Renal- send away to referral lab
Photo	Charge to histopathology specimen with photo
2nd opinion (H218)	In-house pathologist
IHC (Immunohistochemistry)	*Package IHC stain for 2-3 IHC stain
SIHC (Single Immunohistochemistry)	*Breast marker IHC stain and other single stain
SS1 (Special stain)	*Histochemical stain, e.g.: PAS,DPAS, Giemsa

Note: Please contact histopathology lab for assistance.

MICROBIOLOGY GUIDELINES

GENERAL PRINCIPLES

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

SPECIAL PRECAUTIONS

- Specify specimen collection site in the test order to ensure optimal recovery of micro-organisms.
- Specimen for urine culture shall be sent to the laboratory immediately after collection. Otherwise it shall be refrigerated.
- CSF specimens shall be transported to the laboratory immediately after collection. Refrigeration is strictly prohibited as fastidious bacteria do not withstand refrigeration.

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

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

	(a teaspoonful) or 5g solid (peanut sized)			
Nail	Clean, dry leak-proof screw cap containers	Ambient temperature	Wipe nail with sterile saline. Clip away the affected areas and collect material under the nail	NA
Pernasal/ nasopharyngeal Swab	Swab in transport medium Calcium alginate swab in transport medium (for pertussis) Swab must be fully immerse in the transport medium	Ambient temperature	NA	Swabs not in transport medium
Sputum **Bronchial Lavage (BAL)** **Tracheal aspirate** **Nasopharyngeal aspirate**	Plain sterile container Sufficient amount depending the number of test requested	Transport in sealed container as soon as possible Bacteria – Ambient temperature. If > 24 hours, refrigerate at 4 to 8°C	Instruct patient to gargle or rinse mouth with water. Instruct patient to cough deeply to produce a specimen from the lower respiratory tract and not saliva.	>25 ephithelial cells/ Low power field.
Sterile Body Fluids	Plain sterile container Blood culture bottles Sufficient amount depending the number of test requested	Ambient temperature. If > 24 hours, refrigerate at 4 to 8°C	Clinician obtain specimen via percutaneous needles aspiration or surgery. **Fluid specimens are preferable than swab culture.**	Insufficient specimen
Wound swab / pus	Swab with transport medium Swab must be fully immerse in the transport medium	Ambient temperature. If > 24 hours, refrigerate at 4 to 8°C	Disinfect surface of the wound with sterile saline. If swab is used, obtain specimen at the time of incision or drainage of wound. Avoid sampling of the surface area as it may contaminate the specimen with flora not involved in the infection.	Swab without transport medium
Throat Swab	Swab with transport medium Swab must be fully immerse in the transport medium	Ambient temperature. If > 24 hours, refrigerate at 4 to 8°C	Depress tongue with a sterile tongue depressor. Specimen inflamed area, exudates and/or lesions with the suitable swab for the test.	Swab without transport medium

Vaginal And Urethral Swab	Swab in transport medium Swab must be fully immerse in the transport medium	Ambient temperature. If > 24 hours, refrigerate at 4 to 8°C	Avoid collection from the areas of normal flora. Please notify if *Neisseria gonorrhoe*a is suspected.	Swab without transport medium
CSF	Plain sterile bottle Minimum 0.5ml each in 3 different bottles	Transport in sealed containers as soon as possible. Bacteria – Ambient temperature. If > 24 hours, keep at 37ºC (incubator)	**Do not refrigerate specimen**	Insufficient specimen
Urine	Clean, screw-top specimen transport container Minimum 1ml	Transport to laboratory within 2-3 hours or store at 4 to 8°C not more than 24 hours	Avoid overnight specimens.	Insufficient specimen
Urine from indwelling catheter	Clean, screw-top specimen transport container	Transport to laboratory within 2-3 hours or store at 4 to 8°C not more than 24 hours	Disinfect the catheter collection port with 70% alcohol. Use a needle and syringe to aseptically collect 5-10ml of urine. Transfer the urine to a sterile container	Foley catheter tips

Our routine Culture & Sensitivity of Bacterial Pathogen procedure identify and report the susceptibility pattern of the following bacterial species:

- Enterobacteriaceae
- Haemophilus and Pasteurella
- Neisseria and Moraxella
- Pseudomonas and other aerobic Gram Negative Bacilli
- Staphylococcus
- Streptococcus and Enterococcus

Our routine Stool Culture procedure identifies and reports the susceptibility pattern of Salmonella, Shigella and Vibrio species.

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

MOLECULAR ONCOLOGY GUIDELINES

SAMPLE REQUIREMENTS FOR REAL TIME PCR OR SEQUENCING

- Tissue should be fixed in formalin and not exposed to decalcification solution.
- The paraffin block should contain no less than 3 mm or at least 10% area of tumor.
- The laboratory accepts tissue sections. At least ten (10) 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 labeled with a block ID that matches the surgical pathology specimen number on the surgical pathology report.
- Block or slide/ tube should be sent at room temperature in proper storage containers (e.g plastic slide boxes) to protect them during transport/shipment.
- A surgical pathology report and completed request form must accompany all specimens.

SAMPLE REQUIREMENTS FOR TISSUE FISH

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

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

WHOLE BLOOD FOR LIQUID BIOPSY (*Refer Appendix 6*)

- Whole blood in two (2) 10 mL Cell-Free DNA (cfDNA) BCT Tubes provided or please contact Pantai Premier Pathology at +603 2280 0187 ext 171/173 for further information. (TUBES MUST BE IDENTIFIED WITH THE SAME NUMBER AS THAT REGISTERED IN THE ATTACHED REQUEST FORM AND MUST BE SENT TO THE LAB AS SOON AS POSSIBLE AT AMBIENT TEMPERATURE)After collection, immediately and gently invert the tubes 10 times. Inadequate or delayed in mixing may result in inaccurate test result.
- After 10 times inverted, store at room temperature (2°C to 30°C).
- Specimen must be reached at RSL, Pantai Premier Pathology Sdn Bhd. Within 3 days.
- Please contact Pantai Premier Pathology Sdn Bhd. for collection of specimens.

MOLECULAR INFECTIOUS DISEASE GUIDELINES

GENERAL PRINCIPLES

- Avoid contaminating the specimen.
- Sufficient specimen must be collected to ensure an accurate examination.
- Transport specimens quickly to the laboratory with ice packs.

SPECIAL PRECAUTIONS

- Specify specimen collection site in the request form.
- Urine specimen 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.

Specimen Type	Container	Storage and Transport	Precaution	Rejection Criteria
Nasal/Nasopharyngeal /Throat Swab	Cotton/Dry/Rayon-Dacron Swab, in Viral Transport Medium (VTM)	2°C-8°C	NA	NA
Sputum, Bronchial Alveolar Lavage, Bronchial Lavage, Bronchial Aspirate, Bronchial Washing, Nasopharyngeal Aspirate, ETT Secretion	Sterile Leak-Proof Container	2°C-8°C	Instruct patient to cough deeply to produce a specimen from the lower respiratory tract and not saliva.	Salivary sample
Stool	Sterile Leak-Proof Container	2°C-8°C	Do not scoop specimen from the toilet bowl Do not freeze specimen prior to testing	NA
Plain Serum/Edta Plasma	2x Plain Tube/EDTA Tube	Refrigerate serum/plasma at 2°C-8°C for 3 days. Freeze serum/plasma in -20°C or cooler if more than 3 days	NA	Lysed specimen
Urine	Sterile Leak-Proof Container	2°C-8°C	Ensure to collect 1st void urine	NA
Urethral/Vaginal/Anal Swab	Dry/Cotton/Gel Swab	2°C-8°C	Avoid collection from the areas of normal flora.	NA
Liquid Base Cytology	Thinprep, Surepath Or Pathtezt	2°C-8°C	NA	NA
FFPE Block/Cell Block/FNAC/EUSFNA	Container	Ambient temperature Avoid high temperature during transportation	NA	NA
Body Fluid; Pleural, Peritoneal, Pus, Abscess, Ascitic, Gastric Lavage, Pericardial Fluid	Sterile Leak-Proof Container	2°C-8°C	NA	NA
CSF	Sterile Leak-Proof Container	Ambient temperature	Do not refrigerate	NA

CYTOGENETICS GUIDELINES

PERIPHERAL BLOOD (KARYOTYPE)

- Proper specimen collection and sterile handling are absolutely critical for cytogenetic studies.
- Draw 5-10 mL (paediatric: 2-5 mL) peripheral blood in a green-top (sodium heparin) collection tube.
- Collection containers must be closed tightly to prevent leakage of sample during transportation to the laboratory.
- Label specimen tube with patient's name and a second identifier (ex: DOB, MRN).
- All requests should be accompanied with the request form signed by the respective medical officers / consultants.
- The REFERRAL REASON(S) for the test (compulsory requirement). A history 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.
- The culture procedures were made everyday afternoon (except Sunday & Public Holiday) at about 5 pm (usually). Any changes of culture time need to adjust timing for thymidine and harvest process.
- Specimens should be received by the laboratory as soon as possible (ideally within 24 hours). It is generally recommended that specimens be maintained at ambient temperature during transit. Extreme temperatures should be avoided. Never freeze, add fixative or preservative.
- If it is not possible to process samples as soon as they arrive, they should be stored at 4°C. However, since delays affect quality, cultures should be initiated as soon as possible.
- Only the specimen collect with sodium heparin media will 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;
    - In blood which is partially clotted, particularly haemolysed, or in which the log time before receipt by laboratory of sample is more than 24 hours, studies may be attempted, although are considered suboptimal specimens and are less likely to be successful.
    - Metaphase spreads may obtain from the sample collected in lithium heparin, however, sodium heparin is preferred since lithium heparin may cause toxicity to cells.
- Do not use expired collection containers or transport media for specimen collection.

BONE MARROW (KARYOTYPING)

- Proper specimen collection and sterile handling are absolutely critical for cytogenetic studies.
- Aspirate 1-5 mLs of a first draw of bone marrow aspirate into a sodium heparin tube and mix well to prevent clotting.
- Collection containers must be closed tightly to prevent leakage of sample during transportation to the laboratory.
- Label specimen tube with patient's name and a second identifier (ex: DOB, MRN).
- All requests should be accompanied with the request form signed by the respective medical officers / consultants.
- The REFERRAL REASON(S) for the test (compulsory requirement). A history 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.
- The culture procedures were made everyday afternoon (except Sunday & Public Holiday) at about 5 pm (usually). Any changes of culture time need to adjust timing for blocking, releasing and harvest process.
- Specimens should be received by the laboratory as soon as possible (ideally within 24 hours). It is generally recommended that specimens be maintained at ambient temperature during transit. Extreme temperatures should be avoided. Never freeze, add fixative or preservative.
- If it is not possible to process samples as soon as they arrive, they should be stored at 4°C. However, since delays affect quality, cultures should be initiated as soon as possible.
- Only the specimen collect with sodium heparin media will 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;
    - In bone marrow which is partially clotted, particularly haemolysed, or in which the log time before receipt by laboratory of sample is more than 24 hours, studies may be attempted, although are considered suboptimal specimens and are less likely to be successful.
    - Metaphase spreads may obtain from the sample collected in lithium heparin, however, sodium heparin is preferred since lithium heparin may cause toxicity to cells.
- Do not use expired collection containers or transport media for specimen collection.

FLUORESCENCE IN SITU HYBRIDIZATION (FISH)

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

RESULTS REPORTING

REPORTING OF LABORATORY RESULTS

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

REPORTS FROM THE EXTERNAL REFERRAL LABORATORIES

The laboratory is responsible to channel the entire original report from the outsource referral laboratory to the requesting clinician without alteration.
If transcription is required the transcribed results shall be legible without mistake and verified by key personnel.

URGENT RESULTS

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

TURNAROUND TIME

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

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

CRITICAL / PANIC VALUES

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

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

Table 6: Critical Values

HAEMATOLOGY	CRITICAL VALUE	EXCEPTION
APTT	≥ 80 sec	Nil
Blood Parasite	Seen	Previously reported
Fibrinogen	≤ 1 g/L (Adult)	Nil
	≤0.7g/L(Paediatric)	
Haemoglobin	< 8.0 g/dL or ≥19.0 g/dL (Adult)	Nil
	< 8.0 g/dL or ≥ 20.0 g/dL (Paediatric)	
	< 8.0 g/dL or ≥ 22.0 g/dL (Neonatal)	
Total White Cell (WBC) (Paediatric)	≤2.0 x 10^9 /L or ≥50.0 x 10^9 /L	Nil
Platelets Count	≤80 x 10^9 /L or ≥1000 x 10^9 /L	Previously reported
Prothrombin Time (PT)	≥ 40 sec	Nil
BIOCHEMISTRY	**CRITICAL VALUE**	**EXCEPTION**
Bilirubin	≥ 256 µmol/L (Neonatal)	Nil
Calcium	≤1.5 mmol/L or ≥3.00 mmol/L (Adult)	Dialysis Patient
	≤1.7mmol/L or ≥3.10mmol/L (Paediatric)	
Creatine Kinase (CK)	≥ 600 IU/L	Nil
Creatinine	≥330µ mol/L (Paediatric)	Dialysis Patient
Glucose	**≤**2.8 mmol/L or **≥**20.0 mmol/L (Adult)	Nil
	≤1.6 mmol/L (Paediatric, CSF)	
Magnesium	≤0.4 mmol/L or ≥2.00mmol/L (Adult)	Nil
	≤0.5 mmol/L or ≥1.8 mmol/L (Paediatric)	
Phosphate	≤0.32 mmol/L or ≥2.87 mmol/L (Adult)	Nil
	≤0.40mmol/L or ≥2.80mmol (Paediatric)	
Potassium (> 18 years old)	≤2.8 mmol/L or > 6.0 mmol/L	Nil

Sodium	≤ 125 or > 155 mmol/L	Nil
Troponin	>50ng/L(Trop T)	Nil
	>0.07 mg/ml (Trop I)	
Immunology/Serology	**CRITICAL VALUE**	**EXCEPTION**
HIV	All reactive	Nil

Cytopathology
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.

Bacteriology	
Blood Culture	Positive Gram Stain/ Culture
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 Bacteria	**Extended-spectrum Beta Lactamase Producer (ESBL)** **Methicillin-Resistant Staphylococcus aureus (MRSA)** **Multi-drug Resistant Organisms (MDRO)** **Vancomycin -Resistant Enterococcus (VRE)** **Vancomycin- Resistant Staphylococcus aureus (VRSA)** ***Salmonella typhi*** ***Vibrio cholerae*** ***Corynebacterium diphtheriae*** ***Leptospira*** ***Histoplasma*** ***Neisseria gonorrhoeae*** ***Neisseria meningitidis*** ***Burkholderia pseudomallei***
Blood Bank	
Direct Coombs	Positive
Indirect Coombs	Positive
Crossmatch	Incompatible (Especially after the release of un-crossmatched blood or emergency crossmatched blood.)

Appendix 1

BD Helping all people live healthy lives

BD Vacutainer® Venous Blood Collection

Tube Guide

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

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

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

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

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

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

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Appendix 2

BD

Helping all people live healthy lives

BD Vacutainer® Order of Draw for Multiple Tube Collections

Designed for Your Safety

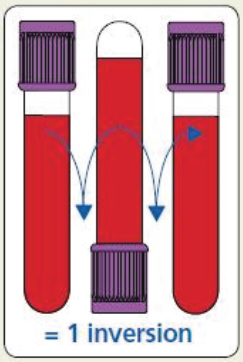
Reflects change in CLSI recommended Order of Draw (H3-A5, Vol 23, No 32, 8.10.2)

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

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

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

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



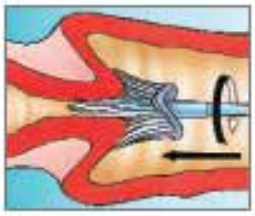
BD Technical Services
1.800.631.0174
BD Customer Service
1.888.237.2762
www.bd.com/vacutainer

1 Becton Drive
Franklin Lakes, NJ 07417
www.bd.com/vacutainer

Franklin Lakes, NJ, 07417 1/10 VS5729-6

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.

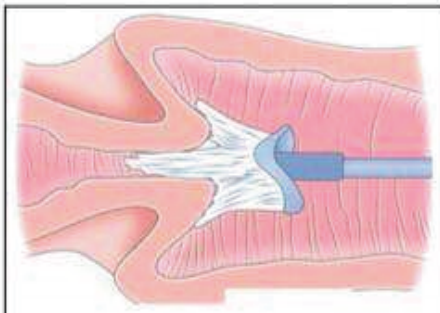
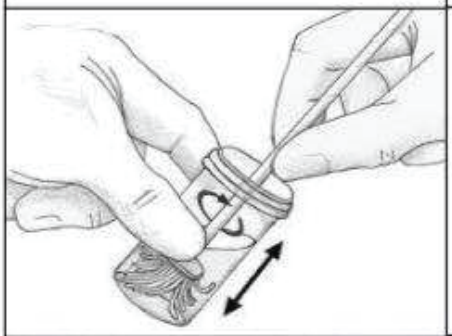
THE ThinPrep® PAP TEST

The Test You Trust

www.thinprep.com

Appendix 4

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.

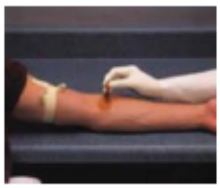
BacT/ALERT® BLOOD CULTURE COLLECTION

Diagnosis of septicemia is one of the most important functions of the microbiology laboratory. Left undetected and untreated, septicemia can be fatal. Samples collected with good technique lead to accurate laboratory results and excellent patient care. The procedures below are provided to help your institution maintain good blood culture collection technique.

BacT/ALERT® 3D instruments are automated systems that incubate, shake and monitor culture bottles for signs of microbial growth. Samples from patients suspected for septicemia are inoculated into BacT/ALERT culture bottles for monitoring. The bottles are color coded for easy identification of media type and are made of plastic for added safety.

1. Skin Preparation

- Palpate to identify the vein and cleanse using Appropriate disinfectant such as 2% chlorhexidine in 70% isopropyl alcohol, 70% isopropyl alcohol , or iodine in swab or applicator form.



2. Bottle Preparation

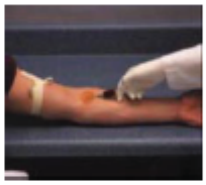
- Inspect the bottle. Do not use the bottle if the broth is cloudy, the sensor is damaged or yellow.
- Remove the protective flip top overcap. Cleanse the septum with 70% alcohol or tincture iodine solution.
- Allow to dry 1 minute before inoculation.

3. Venipuncture and Bottle Inoculation

One of two methods may be used to obtain the sample and inoculate the bottles.

➢ **Needle and Syringe:**

- Draw appropriate amount.
- Directly inoculate the bottles, using the syringe markings as a guide for correct volume.
- Inoculate the **ANAEROBIC** bottle first to avoid entry of air.



OR

➢ **Direct Draw with Blood Collection Set:** Use the BacT/ALERT Blood Collection Adapter Cap and Insert.

1. Connect the Adapter Cap to the luer connector of the blood collection set.

2. Perform venipuncture When the needle is in the vein, secure it with tape or hold it in place.

3. Place the Adapter Cap on the **AEROBIC bottle first**, follows by anaerobic bottle to avoid entry of air into anaerobic bottles.. Using the fill indicator lines on the label, obtain the recommended volume of blood. **Gently invert bottle(s) to mix blood and the broth .**

4. If additional blood is required for other tests, place the Adapter Insert into the Adapter Cap and snap into place. This makes the cap compatible with vacuum collection tubes.

5. After blood collection is complete, remove the Adapter Cap from the culture bottle and then remove the needle from the patient's vein.

BIOMÉRIEUX medigene

Blood Culture Safety
FIRST and ALWAYS

A Key Investigation for Diagnosis of Bloodstream Infections

Tips ' n' Hints

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

Type of Bottles:

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

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

Recommended Incubation Time

Microorganisms	Days
Routine pathogens	5 Days
Fungal	14 Days

Bottle Storage Instruction

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

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

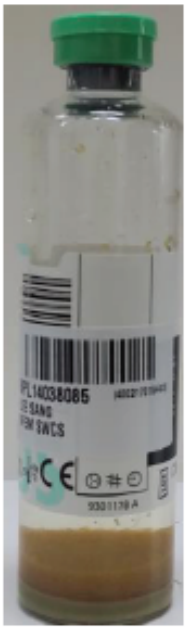
LABELLING BLOOD CULTURE BOTTLE

CORRECT LABELLING

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

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

LAB INTENDED USED For Bottle Tracking



Horizontal position

Covers the bottom

WRONG LABELLING

Cell-Free DNA BCT®

Streck

INSTRUCTIONS FOR USE

Cell-Free DNA BCT® is a direct draw whole blood collection tube intended for collection, transport and storage of blood samples. **This product has not been cleared by the U.S. Food and Drug Administration for In Vitro Diagnostic use. The product is For Research Use Only. Not for use in diagnostic procedures.**

SUMMARY AND PRINCIPLES

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

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

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

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

REAGENTS

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

PRECAUTIONS

1. **For Research Use Only. Not for use in diagnostic procedures.**
2. Do not freeze specimens collected in glass Cell-Free DNA BCT. (Streck part numbers: 218961, 218962, 218992, 230242, 230243)
3. Do not use tubes after expiration date.
4. Do not use tubes for collection of materials to be injected into patients.
5. Product is intended for use as supplied. Do not dilute or add other components to Cell-Free DNA BCT.
6. Overfilling or underfilling of tubes will result in an incorrect blood-to-additive ratio and may lead to incorrect analytic results or poor product performance.
   CAUTION
   a. Glass has the potential for breakage; precautionary measures should be taken during handling of glass tubes (Streck part numbers: 218961, 218962, 218992, 230242, 230243).
   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.
   e. A pediatric tube adapter is strongly recommended to better fit the 10.25mm diameter 2.0ml Cell-Free DNA BCT.
7. SDS can be obtained at www.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 ºC to 37 ºC	6 ºC to 37 ºC	15 ºC to 30 ºC

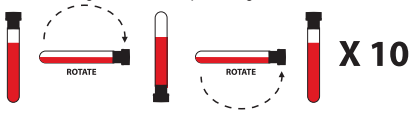
INDICATIONS OF PRODUCT DETERIORATION

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 www.streck.com/mixing.

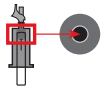
1. Collect specimen by venipuncture according to CLSI GP41-A6[1].
   Prevention of Backflow - Since Cell-Free DNA BCT contains chemical additives, it is important to avoid possible backflow from the tube.
   To guard against backflow, observe the following precautions:
   a. Keep patient's arm in the downward position during the collection procedure.
   b. Hold the tube with the stopper in the uppermost position so that the tube contents do not touch the stopper or the end of the needle during sample collection.
   c. Release tourniquet once blood starts to flow in the tube, or within 2 minutes of application.
2. Follow recommendations for order of draw outlined in CLSI GP41-A6[1]. Cell-Free DNA BCT should be drawn after the EDTA tube and before the fluoride oxalate (glycolytic inhibitor) tube. If a Cell-Free DNA BCT tube immediately follows a heparin tube in the draw order, Streck recommends collecting a non-additive or EDTA tube as a waste tube prior to collection in the Cell-Free DNA BCT.
3. Fill tube completely.
4. Remove tube from adapter and immediately mix by gentle inversion 8 to 10 times. Inadequate or delayed mixing may result in incorrect analytical results or poor product performance. One inversion is a complete turn of the wrist, 180 degrees, and back per the figure below:



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

Note:

1. For best results, a 21G or 22G needle is advised. Slower fill times may be observed when using a smaller gauge needle.
2. When using a winged (butterfly) collection set for venipuncture and the Streck Cell-Free DNA BCT is the first tube drawn, a non-additive or EDTA discard tube should be partially drawn first in order to eliminate air or "dead space" from the tubing.
3. For the 2.0ml Cell-Free DNA BCT, care must be taken to center the tube so the middle of the stopper is punctured per the figure below. To aid with proper insertion of the tube in standard holders and stabilize the tube during the draw, a pediatric tube adapter is strongly recommended to modify the standard holder to fit the 10.25mm diameter 2.0ml Cell-Free DNA BCT (Streck part number: 230242, 230243).



Correctly punctured stopper

4. Cell-Free DNA BCT does not dilute blood samples; therefore, no dilution factor correction is necessary.
5. 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 ºC or -80 ºC.
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.

CONCENTRATED CELLULAR COMPLEMENT

After spinning and the upper plasma layer is collected and transferred to a cryogenic tube, the remaining cellular material in the plastic Cell-Free DNA BCT (Streck part numbers: 230252, 230253, 230254) may be frozen for future use.

1. To Freeze: For long-term storage, freeze the remaining cellular material vertically directly in the plastic Cell-Free DNA BCT at -20 ºC or -80 ºC.
2. To Thaw: Thaw tubes at appropriate temperature as specified in your protocol.
   Note: A plastic Cell-Free DNA BCT, which has been completely filled with whole blood, should not be frozen; breakage may occur.

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-A6, Procedures for the collection of diagnostic blood specimens by venipuncture. Approved Standard - Sixth Edition.

ORDERING INFORMATION

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

GLOSSARY OF SYMBOLS

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

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

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