## ABOUT US

Innoquest Pathology Malaysia commenced operations in late 1996 and has over the years established itself as one of the most trusted medical diagnostics brands in the Malaysian healthcare industry. Innoquest Pathology performs over 4 million patient test episodes per year and provides medical testing in all disciplines to over 6,000 Medical Practitioners, Hospitals and Corporate Clients.

Innoquest Pathology, formerly known as Gribbles Pathology, is part of a consortium of laboratories in Malaysia that represents the largest and most trusted private diagnostic laboratory service providers in the country. The consortium is part of a regional network, Pathology Asia Holdings, the largest in South-East Asia, with operations across Australia, Malaysia, Singapore, Indonesia and Vietnam. The laboratories conduct over 200,000 tests per day for over 20,000 patients daily. The group's laboratories ensure the highest standards of quality with strict adherence to ISO 15189 and the College of American Pathologists (CAP) (USA).

## VISION & MISSION

Innoquest Pathology aspires to be the most reputable, trusted and accessible medical laboratory service providers in Malaysia. Being a medically-managed laboratory, we work closely with stakeholders in our community to deliver innovative and uncompromising patient centric services to advance health outcomes for all in our community.

Our mission is to educate and promote the use of diagnostic tests of clinical value to the medical and patient community. We will deliver information that is accurate, relevant, timely and useful for guiding patient care.

## LOCATION

Innoquest Pathology headquarters is located at Petaling Jaya. Our branches comprise of COVID-19 Laboratories, Hospital Laboratories, Stat Laboratories and Collection Centres.

**CORE LABORATORY**

Address: 2nd Floor, Wisma Tecna, 18A, Jalan 51A/223, 46100 Petaling Jaya, Selangor.

Customer Careline: 1300-88-0234

Operaltion Hours: 24 hours a day , Mondays-Sundays

## RANGE OF SERVICES

We are currently offering a comprehensive and growing menu of laboratory services in the following disciplines:

i. Biochemistry
ii. Immunochemistry
iii. Haematology
iv. Microbiology
v. Cytology
vi. Histopathology
vii. Immunohistochemistry
viii. Allergy testing
ix. Molecular diagnostics/ Genetics

There are some tests offered which are referred to other accredited laboratories for processing. It is our practice to ensure that all results generated are of high quality reporting. We also strive to measure ourselves with our peers. All analytical processes are monitored by rigorous quality control which is assured by participation in external Quality Assurance Programs.

## SERVICE INFORMATION

**Advisory Service**
We provide clinical consultation service for our clients. The consultation covers multiple disciplines such as Molecular, Special Chemistry, Haematology, Histology and Cytology. They also work with us hand in hand to provide support and are available for consultation via our Customer Service Hotline.

**Phlebotomy**
In addition to analytical services we can also provide phlebotomy service to clients where required. Should this service be required, please discuss with the Key Account Manager assigned to your practice.

**Pick Up Service (Courier)**
Courier service is categorized into 2 services, round arrangement (daily/scheduled visit) or on call arrangement (by calls). The Key Account Manager assigned to your practice will discuss your needs and can be adjusted should these change.

**Consumables**
We provide the consumables to all doctors who use our service. Please contact our call center 1300-88-0234. Wherever possible we ask that requests for consumables be made 3 working days in advance from the expected delivery date.

**IT Services**
Our IT Department is able to provide you the following services to enhance your user experience with our laboratory, including:

- eOrder
- eResults
- System integration with Hospital Information System (HIS), Clinical Management System (CMS) and Third party mobile applications
- Training
- Support services (Hardware, software & connectivity)

**Queries**
Should you have any queries, feel free to contact our Key Account Manager assigned to your practice or contact our Customer Service Hotline.

**Lodging a Complaint/Comment Service**
We welcome comments or complaints as we are committed to continuously improve our services in order to deliver the highest levels of service to your practice. Should you have any comments or complaints, feel free to contact our Key Account Manager assigned to your practice to lodge a complaint or provide feedback

**Type of Request - Urgent or Routine**
Analytical services are categorized to URGENT (URG, result TAT 4 hours with fee from call time on selected area) and Routine (TAT 24 hours from samples arrival to laboratory). We have dedicated requisition forms for these services. Therefore, kindly use the dedicated forms provided for the choice of service required.

**Turnaround Time (TAT)**
Kindly contact our Key Account Manager assigned to your practice, should you need information pertaining to the TAT of a test or report.

## PRICING & PAYMENT POLICY

All prices are in Malaysian Ringgit and quoted as Nett Price. Prices are subject to taxes imposed or levied by the Malaysian government. The applicable tax rate will be added to the quoted prices

Kindly refer any price inquiries on our invoices and/or statement of accounts with our Finance staff at 1300 13 3522 during office hours (Mon – Fri: 9 am – 5 pm).

We seek your cooperation on the following matters to prevent any dispute:

I) Please check your invoices promptly.

II) Kindly notify us of any discrepancy on the invoice or statement of account within 30 days from the date indicated.

III) Insist on a credit note if you have been incorrectly billed.

IV) We encourage electronic funds transfer (EFT) to our bank account. Please ask our Key Account Executive/Manager for details. Payment must be made to Innoquest Pathology (M) Sdn. Bhd.

V) Do not hand over cash to our couriers.

VI) Always insist on official receipt if cash is handed over to our office staff and notify our Finance Department immediately.

VII) For payments issued under local cheque/ banker cheque:

a) Innoquest Pathology (M) Sdn. Bhd.
b) Please write on the back of the cheque, the following:-
1. Name of Clinic
2. Billing Account Number
3. The invoice number(s) for this payment

VIII) Our Marketing and Courier staff are also authorized to collect cheques on behalf of the Company. Alternatively you may wish to mail the cheques to our Headquarters in 2nd Floor, Wisma Tecna, No, 18A, Jalan 51a/223, Seksyen 51a, 46100 Petaling Jaya, Selangor.

Our credit term is strictly thirty (30) days from the date of the invoice. We reserve the right to impose a late penalty charge for outstanding invoices.

## QUALITY MANAGEMENT SYSTEM

Innoquest Pathology is committed to providing fast turnaround times, high quality reporting and evolving into the "medical laboratory of the future". Apart from listening to our clients, brainstorming with new ideas and new ways to deliver the best service, we are also committed to stringent internal quality control procedures and practices.

**Validity & Reliability of Test Results**

The validity and reliability of test results are dependent on a number of variables:

a) Pre-analytical variables which include the following:

1. Specimen Collection:
   - Improper Patient Identification
   - Incorrect Order of Draw
   - Incorrect Tube Selection
   - Traumatic draws leading to hemolysis
   - Inadequate mixing or insufficient sample
2. Specimen Handling/Processing:
   - Serum tubes not thoroughly clotted before centrifugation
   - Delay in Centrifugation
   - Storing specimens in incorrect temperatures
3. Specimen Transportation
   - Frozen specimens thawing during transport
   - Unspun specimens transported >2 hours from collection

b) Analytical variables include the precision and accuracy of the test method and factors which may interfere with a particular assay e.g. lipaemia, in vitro haemolysis and medication.

c) Post analytical variables include data entry and calculations by laboratory staff, result validation, interpretation of the results, data transfer and the method used to report the results (electronic, paper or telephone).

**How does the Laboratory Control Variables**

The laboratory controls the impact of these variables, as far as possible, by two processes:

**a) Quality Control**

On each occasion that the patient samples are tested, the laboratory also tests 'controls' with known concentrations of analyte or cells, of known reactivity in the test system.

The control levels are such that they control the entire analytical range and are "matrix matched" i.e. Urine based control material is used to control urine assays, serum based controls are used to control serum assays and whole blood controls are used to control whole blood assays.

**b) Quality Assurance**

All of our laboratories participate in external quality assurance programs in which the results from each laboratory are compared to the results obtained by a group of laboratories as well as known values.

**Variables Outside the Laboratory Control**

Quality control and quality assurance help maintain both the accuracy and the consistency of laboratory results but absolute accuracy is not technically possible. Variables cannot be entirely avoided and the interpretation of any results must take these factors into consideration.

**a) Selection of Test(s)**

Discretionary testing is the selection of a single test, or a small number of tests on the basis of the clinical findings.

Profile testing is the ordering of tests as 'screening tests' and may involve a 'battery' of tests.

In a normal individual, the greater the number of tests performed, the greater is the chance of finding at least one abnormal result. Isolated slightly abnormal results are often of no clinical significance, however if clinically indicated after explanation to the patient, it may be prudent to check these after a few days or weeks depending on the analyte.

**b) The Specimen**

The laboratory results are dependent on the quality of the specimen which it receives for example an inadequate biopsy or a poor cervical smear results in an incomplete and possibly inaccurate opinion. In other circumstances, an inaccurate volume of blood in a sodium citrate or EDTA tube, or improper collection of urine may cause inaccurate reporting. E.g. For urine FEME and culture, it is crucial that a Mid Stream Specimen of urine is collected (MSSU) for accurate results.

**c) The Request Form**

Provision of appropriate clinical information is essential if the pathology laboratory is to assess the results and their likely significance. Any difficulty in obtaining the specimen should also be noted on the request form as they may affect the test result. It is also essential that all requested information is filled in adequately on the request form.

**Quantitative Test Results and the Reference Interval**

Generally reference intervals represent the test results which would be obtained in the normal population and are based on the results obtained on a series of normal 'healthy' individuals. Other reference ranges may be specific e.g. lipids and glucose which are evidence based with respect to disease prevention.

The reference intervals quoted generally lie between the 2.5 and 97.5 percentiles for the group which they were derived from.

Age, gender, race and test methodology are important variables so the reference intervals quoted in the literature may not be generally applicable.

Wherever possible laboratories establish their own reference intervals but this is not always feasible.

As the reference interval represents the 2.5 to 97.5 centiles, inevitably 5% of entirely normal people will have test results outside the reference interval. Minor variations should thus be interpreted with caution.

**The Sensitivity and Specificity of a Qualitative Test**

The ability of a test to discriminate between normal and abnormal individuals is described by its sensitivity and specificity.

Test sensitivity is defined as the percentage of people with a specific disease who have an abnormal test result.

The specificity is defined as the percentage of people without the disease who have a normal result.

Generally, the balance of sensitivity and specificity is a major consideration in the choice of a test methodology. This balance must consider the ability of the test not to have false negatives and the ability not to produce false positives. Most screening tests employed will be biased towards reducing false negatives which may lead to a very few unaffected individuals having false positive results – this is particularly evidenced in assays such as HIV, Hepatitis B & C and cancer markers. Should the results not "fit" the clinical picture, please do not hesitate to discuss with our senior scientific staff.

## CRITICAL/PANIC VALUES AND OUR RESPONSES

The laboratory will call you/your clinic immediately should a critical results is obtained. Should you require the most updates list of Critical/Panic values, kindly contact your assigned Key Account Manager.

## SPECIMEN COLLECTION, FORMS & REPORTS

The laboratory will call you/your clinic immediately should a critical results is obtained. Should you require the most updates list of Critical/Panic values, kindly contact your assigned Key Account Manager.

Guidelines To Filling Request Forms

**A. Type of Request Forms**

I. General Request Form
II. Prenatal Diagnosis Request Form
III. Histology & Cytology Request Form
IV. Request for Antenatal Screening Form
V. Third Party Form (eg FOMEMA, PEKA B40, PERKESO HS, Insurance etc)
VI. For guidelines on E-Order (Biomark) please refer to the Biomark - Doctor's Platform on http://www.innoquest.com.my

**I. General Request Form**

**Patient Details**

- Please fill in the patient's name in the space provided in BLOCK letters
- Please fill in the patients IC No (Malaysian ) / Passport No (Non-Malaysian), Date of Birth and Gender
- If there is a reference no. that you would like to be on the report, please fill in the space under "Your Ref"
- Please include date and time of collection on the request form /E-Order

**Referring Doctor's Name, Address & Clinic Stamp**

There are 2 types of general request forms: Pre- printed and standard request forms.

Pre-printed request forms can be requested through our Key Account Manager or as per consumables requisition process. Please ensure that the information is correct before using it for test requisition.

If you are using standard request forms, please ensure that you stamp the clinic chop under this section along with the Doctor's name. Reports cannot be issued if the name of the doctor and clinic chop and requestors MMC number is not on the request form.

**Urgent**

Please indicate if the results for this test(s) are needed urgently by ticking the URGENT box. The phone/facsimile number should be written clearly for our laboratory staff to report the results immediately once the test(s) has been completed.

**Copy To**

Reports are delivered automatically to the Referring Doctor's clinic address. If the reports needs to be delivered to an alternate/ additional address from the Referring Doctor's, please indicate it in this space.

**Bill To**
This is for use where the billing shall go to. The column is auto-filled for clients using pre-printed request forms.

**Specimen Type**
Please indicate the sample type by ticking the relevant box on the form or if it is other than the choices available, please write exactly what it is under “Others”.

**Specimen Taken From Patient**
Please write the date and time specimen was taken from the patients for proper results evaluation. Please indicate whether the patient has been fasting/not fasting before the test.

**Drug Therapy**
If the patient is under medication that could influence his/her test results, please indicate the drug name and the date & time of the last dosage. Please indicate the name of the antibiotic(s) taken if culture specimens are obtained after antimicrobial therapy has been started.

**Clinical History**
Details such as below should be written in this section to assist with test results evaluation:
- Clinical diagnosis
- Suspected disease / organism
- Brief clinical history
- Name, date & duration of antibiotic(s) administered
- Any previous culture or serological test results
- Immune status of patient e.g.: underlying diseases, cancer chemotherapy, and immunosuppressive treatment.

For Bone Marrow and Trephine Biopsy, please provide:
- Clinical history, provisional diagnosis, significant physical findings
- Site of bone marrow specimen
- Recent FBC results or EDTA blood sample
- Peripheral blood film or EDTA blood sample

**Test Required**
Please tick the relevant test.

**Additional Tests**
For tests that are not listed on the request form, kindly write it under the blank column provided at the end of the form.

## II. Prenatal Diagnosis Request Form

For Prenatal Diagnosis the additional information required for you fill, apart from what was explained under General Request Form is explained below:

a) Race and weight (kg)
b) Pregnancy details, please indicate if this is a single / twin pregnancy
c) Gestational Details & Timing Requirements for Sampling

For both 1st Trimester and 2nd Trimester screens, please fill in the following gestational details in weeks and days according to either:
- Dates (indicate date of LMP, EDD and if certain of date or not)
- Ultrasound (indicate date of ultrasound) – REQUIRED for 1st Trimester screen.

For 1st Trimester screen only, please fill in CRL and NT measurements along with the date of measurement.

## III. Guidelines for the Requests of Histophathology & Non- Gynaecological Cytology Examinations

A definitive histopathology/cytopathology diagnosis is never made in isolation. It is always made in consideration with the clinical history and where relevant with other investigations (imaging, serology, etc). Relevant clinical history and sample type and site are vital for the pathologist to provide a comprehensive and clinically relevant report and appropriate advice/suggestions.

To ensure an accurate, clinically relevant and timely report is provided , kindly adhere to the following guidelines [mandated by ISO 15189 (International standard for medical testing labs) and College of Ammerican Pathology (CAP).

### Request Form

All specimens must be accompanied by a Histopathology/Cytopathology request form*. The request form must include the following:

1. Patient's name, age, sex and identification number (NRIC/Passport).
2. The hospital and ward number, or name of clinic and telephone number, as this facilitates dispatch of reports .
3. Relevant clinical history including operative findings (where relevant) and provisional diagnosis (where possible).
4. Type of sample and anatomical site must be stated and must match with specimen label.
5. Date and time of issue removal/ excised (cold ischemic time) and the date and time immersion of the tissues in 10% neutral buffered formalin fixative must be recorded (stated) on the request form.
6. Name and contact details of physician/surgeon in charge of case.

*When more than one specimen is sent from the same patient (same operation), use only one form.

### Specimens

1. Specimens for routine surgical biopsies should be sent in clean containers with 10% buffered neutral formalin, unless otherwise stated.
2. Whenever possible, there should be one specimen per container. If multiple specimens are placed in one container, they should be clearly identified by size or suture marking. This information should be included in the Histopathology/Laboratory Request Form .
3. Label each container with the patient's name, identity card or admission number, the source (site) of the specimen and nature of specimen.

**Failure to adhere to the above will delay turnaround time as a report will not be issued until all the required (as stated above) information is obtained and discrepancies are rectified.**

## IV. Guidelines For The Requests Of Gynaecological (Pap Smear) Cytology Examinations

A reliable cytological interpretation and advice relating to further management depends both on the cytological findings and the patients' clinical information provided.

To ensure an accurate, clinically relevant and timely report is provided, kindly adhere to the following guidelines [mandated by ISO 15189 and the College of Ammerican Pathology (CAP).

### Specimens (slides or containers)

Must be labelled with the patient's full name and NRIC or passport number.

### Request form

All specimens must be accompanied by a Histopathology/Cytopathology request form. The request form must include the following:

1. Patient's name, age/date of birth and identification number NRIC/Passport). This must match with that stated on the specimen label.
2. The hospital/name of clinic and telephone number to facilitate contact and dispatch of reports.
3. The name, signature and contact details of doctor/smear taker .
4. Date of smear taken.
5. Relevant clinical information . The minimum clinical information required is as follows:
    i. Menstrual status (LMP/pregnant/postpartum , post-menopausal) .
    ii. Origin (site) of sample (cervix, vault, etc).
    iii. History of hormone therapy (OCP/hormones/HRT) and IUCD.

iv. Status of cervix: Normal, erosion, discharge, suspicious, etc.
v. History of gynecological surgery or radiation therapy - Yes/No.

***Failure to adhere to the above requirements will delay turnaround time as a report will not be issued until the required (as stated above) information is obtained and discrepancies are rectified.***

**False Negative Notification :**

**Pap test is a screening test for cervical cancer with inherent false negative results . Factors that can cause false negative results include an inadequate collection of cells , a small number of abnormal cells , blood or inflammatory cells obscuring the abnormal cells and other possible reasons.**

## CONSENT

Listed below are the tests that require the patient and/or the physician to sign a consent form. This consent form will be given to you upon request. You may also contact our Customer Care Centre if you do not have any.

1. Alpha and Beta Thalassemia
2. Panorama NIPT
3. HFE Gene
4. Reproductive Genetic Testing
5. Onco-Genes Tests

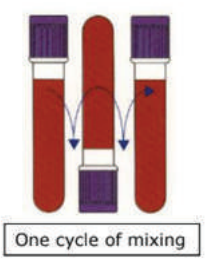
## GUIDELINES FOR SPECIMEN COLLECTION

The integrity of the sample must be preserved to ensure accuracy of results. The requirements for sample collection and handling must be followed. It is critical that adequate volumes are collected on each patient and the patient preparation is adhered to follow test requirements such as fasting.

Following proper phlebotomy techniques will assist in preventing inaccurate test results:

1. Tourniquet left on <1 minute to prevent haemolysis. A prolonged tourniquet time may lead to blood pooling at the venipuncture site, a condition called hemoconcentration. Hemoconcentration can cause falsely elevated results, mainly the potassium.
2. All tubes collected must be collected in the correct Order of Draw and inverted gently to ensure proper mixing of additive or anticoagulant. Blood collected using syringe and needle by a direct venipuncture, must be transferred into the tubes with the correct Order of Draw as well. This is very important as puncturing a EDTA/Heparin/Fluoride anticoagulant tube prior to transferring blood into a Plain tube, definitely will cause anticoagulant contamination into the needle.

| Closure Color | Collection tube | Mix by Inverting |
|---|---|---|
| | Sterile samples (e.g. BD BACTEC bottles) | 8 – 10 times |
| | BD Vacutainer® Citrate Tube | 3 – 4 times |
| | BD Vacutainer® SSTII™ Gel Separator Tube | 5 times |
| | BD Vacutainer® Heparin Tube | 8 – 10 times |
| | BD Vacutainer® K2EDTA Tube | 8 – 10 times |
| | BD Vacutainer® Fluoride (Glucose) Tube | 8 – 10 times |

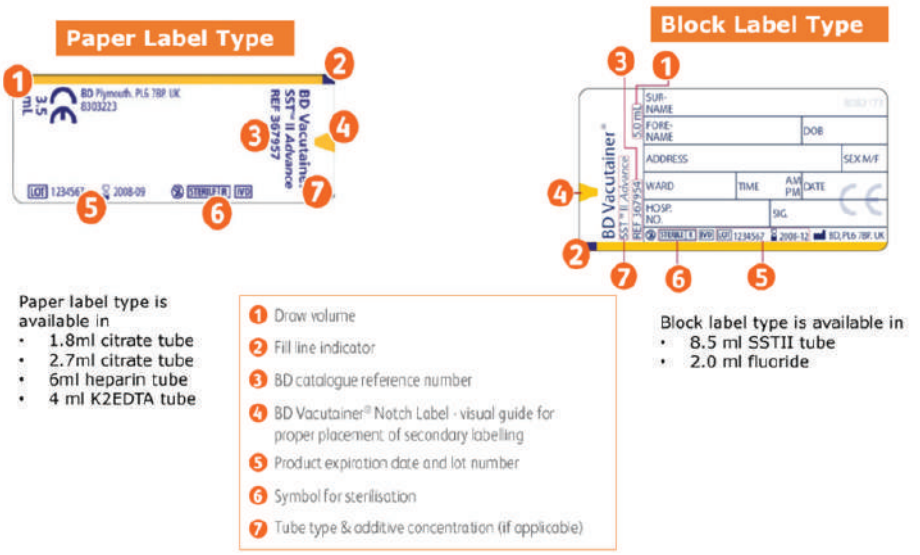

One cycle of mixing

**Order of Draw**

1) Blood culture tubes (applying full aseptic technique)
2) Blue cap (sodium citrate)
3) Red cap (Plain tube)
4) Yellow cap (Serum Separator Tube)
5) Green Cap (Heparinized tube)
6) Purple cap (EDTA tube)
7) Royal Blue cap
8) Grey cap (fluoride tube)

3. Incorrect Order of Draw will introduce contamination with anticoagulants and often produce inaccurate results. An example would be increased Potassium if the EDTA tube is drawn prior to collection of plain/ gel tubes.
4. Blood collected using syringe and needle by a direct venipuncture, must be transferred into the tubes with the correct Order of Draw as well. This is very important as puncturing a EDTA/Heparin/Fluoride anticoagulant tube prior to transferring blood into a Plain tube, definitely will cause anticoagulant contamination into the needle.
5. All collection tubes must be filled with the required volume. Fill lines are indicated by the black and white notches on the side of the label.


6. Do not use expired tubes. Expiration dates can be found on each paper label on the tube.




7. Specimen Labeling: All specimens must contain two specimen identifiers:
    1. Patient's full name
    2. Patient's IC number / Passport number
    3. Any other unique Identifying number ONLY if IC / Passport number is not available.

## SPECIMEN TRANSPORT AND STORAGE

**Normal Weekday Storage**
Recommended storage conditions for samples prior to normal courier transport collection are that samples should be stored at room temperatures that do not exceed 25˚C. Do not keep samples near a source of heat or in direct sunlight.

**Note:**
**Please do not delay on specimen transportation - always dispatch samples with the next available courier collection.**

**Overnight storage**
If delays are unavoidable the following guidelines should be observed as sample integrity can vary. In all cases storage should be no longer than overnight and samples/request forms should show the date the sample was taken. Store all samples at room temperature (<25˚C). If samples are refrigerated overnight (2-8C), blood samples will be unsuitable for most biochemistry analysis.

**Note:**
**Please do not store unspun serum/plasma tubes in refrigerator. Tubes must be centrifuged before storage to ensure specimen integrity.**

## CYTOLOGY

**General Instructions on Specimen Fixation**

**Smears**
Rapid fixation of smears is necessary to preserve cytological detail. If smears are allowed to dry on the slides prior to fixation, marked distortion of cells occurs.

Smear preparation such as cervical specimens should be fixed immediately in a solution of 95% ethyl alcohol or a coating fixative such as Cytofix; other commercial spray fixatives may be used. A minimum of fifteen to twenty minutes fixation is required in the case of ethyl alcohol fixation (although prolonged fixation will not materially alter the cytology). In the case of spray fixatives, the smear should be allowed to dry for 10 minutes prior to placing into slide holders for dispatch to the laboratory.

**Cell Block**
It is found that cell block preparation offers a better architectural pattern for interpretation compared to smear preparations, which will therefore help improve our accuracy in reporting malignancy. Furthermore, the samples can also be tested via immunohistochemistry and even molecular testing if necessary. As such all pleural, pericardial and peritoneal fluid samples will be automatically subject to cell block preparation before analysis.

**Fine Needle Aspiration Cytology**
To prepare one air dry and one alcohol fixed smear and the balance sample to be collected using SurePath vial. Cellblock preparation is needed for ancillary test which may be required, therefore it is advisable not to prepare more than two slides .

Please label each slide whether it is an air dry or alcohol fixed.

## HISTOLOGY

**Special Instructions**

i. Routine specimens should be sent in containers with 10% buffered formalin unless otherwise stated.

ii. Appropriate containers are available from the laboratory on request. To prevent leakage it is advised to double wrap the specimen container.The recommended ratio for most tissue samples fixed in 10% formalin is 1:10 (tissue: fixative).

iii. Multiple small specimens, such as gastrointestinal biopsies, should be mounted on a piece of filter paper and properly labeled.

iv. Large specimens such as colon must be completely immersed in formalin. Containers must be tightly secured. Do not crush specimens with forceps, hemostats or other instruments. Avoid using cautery.

v. Do not force a large specimen into a small container. Large specimens must be completely surrounded by formalin for proper fixation.

vi. “URGENT REPORT” requests have to be clearly indicated on the request form; otherwise they will be processed as per according to the queue.

vii. For specimens where orientation is important, mark or tag the specimen e.g. Axillary tail of mastectomy specimens, orientation of surgical margin..

## MICROBIOLOGY

Kindly refer to Schedule 1.

## CRITERIA FOR UNACCEPTABLE SPECIMENS

a) **Unlabeled or Inadequately Labeled Samples**

All samples must be clearly labeled with the patient's full name and another identifier. Samples which are not labelled will be rejected. For samples that are inadequately labelled , our Customer Service Agent will call and confirm the patient's sample, however this is only applicable if the sample was packed in an individual transport bag along with the request form.

In these cases, our laboratory records will carry a statement of spoken to, date time details of the patient were confirmed. Only then will the sample be processed.

b) **Incorrect Specimen Type for Test Requested**

The clinic will be informed and we will act on instruction e.g. either wait for a repeat sample to be collected or delete the test which cannot be done. Action taken will be recorded in our laboratory information system.

c) **Grossly Haemolysed Sample**

The clinic will be informed and we will act on instruction e.g. wait for a repeat sample or delete test that cannot be done.

For mild degrees of hemolysis, the sample will be brought to the attention of the Senior Scientist or Head of Department who will then advise whether the degree of hemolysis will significantly interfere with the particular test requested.

d) **Unsuitable Specimens**

The most common reasons the sample are unsuitable are:

i. *Insufficient specimen
ii. Clotted EDTA specimen
iii. Citrate Tube – not correctly filled
iv. Specimen received in unsuitable containers e.g. blood still in syringe
v. Leaking specimens

*** If you want to send a second sample for insufficient samples, kindly fill the request form and indicate on the form that it’s a second sample from which date of test order.**

e) **Specimen without Request Form**

If the clinic can be identified, then our staff will phone to clarify the requested test and a fax copy of a completely filled request form must be faxed over. If the clinic cannot be identified then the most common test will be performed for each sample type. Results will be held until a request is received.

## REQUESTING OF PRELIMINARY CULTURE REPORTS

Preliminary reports are provided for critical tests such as blood culture and body fluids. The preliminary reports are provided after 24 hours of receiving the sample at the Microbiology Department in HQ or by the Microbiology department on site should the service be provided.

## INTERFERENCES WHICH CAUSE INACCURATE RESULTS

**Additive caused interference**

Lithium heparin, ammonium heparin or sodium heparin are the anticoagulants which are not appropriate to use for lithium, ammonium and sodium determinations, consequently. Heparin is unsuitable for the CK assay.

The thrombin evacuated blood collection tubes contain thrombin as a clot activator. However, shortening the coagulation time causes some interferences detected for chloride (Cl), calcium, LDH and potassium (K[+]). The higher values for Cl are attributed to the rapid separation from the cells, which prevents uptake of Cl by the erythrocytes. The increase in LDH and K[+] may be due to invisible haemolysis, and high calcium values may be due to the rapidity of the clotting process.

EDTA is unsuitable for iron and calcium analysis as it chelates both iron and calcium and has an effect to inhibit alkaline phosphatase (ALP), creatine kinase (CK), Sodium (Na) and leucine aminopeptidase activities, probably by chelation of metallic cofactors. Moreover, EDTA falsely elevates Potassium (K) due to the K2 or K3 EDTA anticoagulant content.

**Factors affecting results**

**Potassium**

Pseudohyperkalemia is defined as a marked elevation of potassium. There are many causes for falsely increased potassium involving pre analytical. During phlebotomy if the patient is in a state of fear it may increase the potassium readings especially when the patient is also feeling stressed and anxious. If there was difficulty in getting the patients vein and the blood flow was too slow, this could also lead to falsely elevated potassium especially if the blood has undergone haemolysis. It is essential that proper phlebotomy technique is used when drawing blood that involves electrolyte testing. For patients on drips, the blood drawn for analytical testing should be taken from a non IV drip arm if possible. Transportation of the samples to the lab for testing is crucial and exposure to heat or light is prohibited. Any amount of lysis to the blood sample can cause some alterations to the potassium results.

Pseudohyperkalemia or falsely elevated hyperkalemia is commonly observed and are due to the following pre-analytical factors:

1. **Mechanical:** Prolonged tourniquet application (> 1 min) causes haemoconcentration, altered water balance and hemolysis. Fist clenching causes local release of potassium from cells of the forearm muscles.
2. **Venipuncture:** Probing, inappropriate needle diameter, excessive force with syringe draws either during aspiration or transfer, increased turbulence due to diameter mismatch of catheter, tube adapter device and needle.
3. **Chemical:** Ethanol containing antiseptics that are not allowed to dry completely before venipuncture can enter the bloodstream and disrupt cell membranes.
4. **Temperature:** Cold temperature inhibits the sodium-potassium pump resulting in leakage of potassium. Specimens stored at temperatures between 2°C and 8°C or above room temperature for more than 24 hours leads to leakage of cellular potassium.
5. **Time:** Delays in arrival of samples to the lab for processing (>4 hrs), results in exhaustion of available glucose to generate ATP, reducing sodium-potassium pump resulting in leakage of potassium from the cells.
6. **Contaminant:** Wrong order of draw subjects the samples to contamination from preservatives in the respective collection tubes, sampling from an IV drip site containing potassium,
7. **Patient:** Thrombocytosis or leucocytosis due to release of potassium during the clotting process or leakage of potassium due to cell fragility respectively.

**Bilirubin**

Haemolysis interferes in the bilirubin procedure with pseudo-peroxidase activity of free haemoglobin by inhibiting the diazonium colour formation. Due to the haemolysis, total bilirubin concentrations were found to decrease even at mildly haemolysed specimens (0.5–1 g/L).

Because bilirubin is photosensitive, samples have to be protected from the light exposure up to analysis.

**AST (aspartate aminotransferase) and ALT (alanine aminotransferase)**
In haemolysed specimens, AST and ALT rich cell content enters into the plasma, increasing the AST and ALT levels falsely.

**LDH (lactate dehydrogenase)**
LDH activity is present in all cells, in the cytoplasm, thus the lysis of cells causes falsely elevated LDH levels. The 0.27 g/L of free Hb in plasma resulted in an increase in levels of more than 20% which is at a degree of an invisible haemolysis.

**Sodium**
Pseudohyponatremia may result from the sample collection from IV site, thus the sample is diluted by the hypotonic fluid (5% dextrose), and the sodium levels will result as hyponatremia which can easily be identified by the high serum glucose level. Increased viscosity due to the monoclonal gammopathy and subsequent decreased watery portion of plasma can thus cause false low sodium concentrations.

**Incorrect Order of Draw**
Incorrect order of draw can be a source of spurious hyperkalaemia and hypocalcaemia in patients' samples due to EDTA carry over or contamination. EDTA contamination occurs when the blood is drawn into EDTA tubes first before other tubes. Common analytes influenced by EDTA contamination are Potassium, Calcium and ALP (Alkaline Phosphatase)

**Incorrect Phlebotomy Practice**
Many inpatients have intravenous (IV) catheters. While IV lines provide a means of direct vascular access for infusing fluids, collection of specimens through these lines can result in contamination of the specimen with the contents of the line. Specimens should be collected from the arm opposite the line to avoid contamination. Specimens should never be collected distal to a catheter because fluids tend to pool in the periphery of the limb. Collection of samples proximal to a catheter will be diluted by the infusion fluid.

A perfect example is the collection of a specimen for plasma glucose measurement from a line being used to infuse 5% dextrose. Although 5% dextrose does not sound like a lot, it denotes a glucose concentration of 277.5 mmol/L. Contamination of the blood specimen with just one part in twenty of this highly concentrated solution can falsely elevate the glucose concentration by as much as 5.55 mmol/L. Additionally, electrolytes and other biochemistry parameters measured on this contaminated specimen will be falsely decreased due to dilution.

Similarly in a patient being infused with saline, Sodium and Chloride measured would be falsely elevated. Potassium and other biochemistry parameters measured on this contaminated specimen will be falsely decreased due to dilution. In these infused patients, FBC (Full Blood Count) results should also be reviewed to determine if the hemoglobin or hematocrit is consistent with previous. An unexplained decrease may be due to IV contamination. Another parameter worth examining is MCV which should not fluctuate more than 1-2 fL within an individual. A sudden shift of 4-5 fL, in the absence of a recent transfusion, is another reliable indicator of IV fluid contamination.

## LABORATORY REPORTS

- All test results will be computer printed on a Laboratory Report.
- The report notes all patient details and doctors details that are on the request form.
- All quantitative results will be reported together with reference ranges which are appropriate for the patients, age and sex.
- Summary comment and clinical interpretation by Pathologist will be included for clinical significant results.
- Urgent results will be reported via phone or fax as indicated on the request form. (Phone/fax number must be noted on the request form). A printed report will follow.
- Every possible attempt will be made to phone clinically critical results to the requesting clinician.
- Laboratory reports are printed on completion of ALL the test associated with the request and are dispatched in the next scheduled courier round to your area.
- E-reporting is available. Kindly provide an email address to your Sales & Marketing Agent and indicate that you wish to use this service.
- If you require the test results before the printed report reaches you, then all completed test results may be obtained at any time by contacting our Client Services Department.
- Should there be any deviation in tests methodology or promised TAT, customers will be informed via respective marketing agents .

## ADD ON TEST

For all ambient or refrigerated samples, an add on test can be done provided it meets the laboratory's retention criteria for the test. Please contact our customer service hotline and provide the patient details such as I.C or passport number to request for an add on test. The customer care agent shall assist to verify the patient details, specimen retention period and specimen suitability before proceeding to add the test requested. The customer care agent shall update you if we are able to proceed with the add on test request. It is advised to recollect a fresh specimen should the add on test request fail to meet the criterias stipulated above.

## Schedule 1 : Bacteriology Specimen Collection and Transport by Specimen Type

**General Guidelines**

Specimen collection and handling are critical considerations, because results generated by the laboratory are limited by the quality and condition of the specimen upon arrival in the laboratory. Specimens should be obtained to minimize the possibility of introducing contaminating microorganisms that are not involved in the infectious process.

**General Requirements**

1. Method for proper collection of culture specimens from different sources
2. Perform hand hygiene and put on gloves if necessary
3. Aseptic technique shall be observed for sample collection
4. Collect samples before antibiotic therapy if possible.
5. Proper labeling of culture specimens
6. Use of appropriate transport media when necessary
7. Safe handling of specimens (tightly sealed containers, no external spillage)
8. Need for prompt delivery of specimens to ensure minimum delay and processing (eg, CSF, wound cultures, anaerobes)
9. Method for preservation of specimens if processing is delayed (eg, refrigeration of urines)

**Preliminary culture reports**

Preliminary reports are provided for critical tests such as blood culture, body fluids, Gram stain and AFB stains.

**Specimen storage and transportation**

Kindly follow detailed sample collection requirements in Schedule 1.

| SPECIMEN TYPE | COLLECTION GUIDELINES | CONTAINER & STORAGE / TRANSPORTATION | COMMENTS |
|---|---|---|---|
| **Abscess/Wound**<br>Open<br>Closed | Remove surface exudate by wiping with sterile saline<br>Aspirate if possible. Place fluid or tissue in sterile container<br>Syringes are acceptable if delivered promptly:<br>1) Aspirate abscess wall with needle and syringe<br>2) Syringes are acceptable if delivered promptly<br>Disinfect surface of the wound (if not broken) with 70% alcohol or wipe with sterile saline (if broken). Aspirate if possible. If swab used, obtain at the time of incision, drainage or debridement of wound. | Sterile container/ transport swab/sterile syringe<br>Room Temperature | Tissue or fluid samples are preferable to swabs.<br>Sampling of the surface area may contaminate the sample with flora not involved in the infection. |

| SPECIMEN TYPE | COLLECTION GUIDELINES | CONTAINER & STORAGE / TRANSPORTATION | COMMENTS |
|---|---|---|---|
| **Biopsy/Bone/Tissue** | Submit in sterile container without formalin<br>Specimen may be kept moist with 0.85% sterile saline | Sterile container<br>Room Temperature<br>**DO NOT** Refrigerate or place it near the ice pack. | Sampling of the surface area may contaminate with normal flora not involved in the infection.<br>Brain abscess/CNS biopsy- must be sent fresh and immediately to the laboratory. **DO NOT** add formalin. |
| **Sterile Body Fluids**<br>Abdominal Ascites, Bile, Synovial, Pericardial, Peritoneal, Pleural | 1. Disinfect overlying skin with iodine tincture<br>2. Generally, specimens are obtained via percutaneous needles aspiration or surgery<br>3. Transfer fluid to sterile container or blood culture bottles with syringes. | Sterile container/ blood culture bottle.<br>Room Temperature.<br>**DO NOT** Refrigerate or place near ice pack. | Fluid samples are preferable to swabs dipped in fluid |
| **Cerebrospinal fluid (CSF)** | The physicians generally obtains these samples. | Sterile container/ blood culture bottle.<br>Room Temperature.<br>**DO NOT** Refrigerate or place near ice pack. | If sharing with another test, send to bacteriology first.<br>Use the most turbid tube for microbiology testing. |
| **Blood Culture** | **Aseptic technique is critical to proper blood culture collection**<br>1. Clean venipuncture site using 70% alcohol and followed by 2% Chlorhexidine.<br>2. Collect 8-10 ml blood into each bottle for adults, 1-3ml blood for children | Blood culture bottle<br>Room Temperature<br>**DO NOT** Refrigerate or place near ice pack | A blood culture set consists of an aerobic and anaerobic bottle for adults and older children.<br>For children, a single pediatric bottle. |
| **Ear** | 1. Use a moistened swab to remove any debris or crust from the ear canal. Discard swab.<br>2. Obtain samples by firmly rotating the routine culture swab in the outer canal. | Transport swab<br>Room Temperature | If otitis externa is suspected, vigorous swabbing is needed as simple surface swabbing may miss a streptococcal infection. |
| **Eye (Conjunctiva)** | 1. Pre Moistened swab with sterile saline unless sufficient exudate is present. Roll swab over the conjunctiva<br>2. The clinician may opt to inoculate culture plates directly at time of collection<br>3. May submit samples on routine culture swabs. | Transport swab<br>Room Temperature | Nil |
| **Eye, Cornea (scrapings)** | 1. The physicians usually obtain these samples<br>2. May opt to inoculate directly onto culture plates<br>3. A swab may also be submitted for routine culture | Transport swab<br>Room Temperature | Nil |

| SPECIMEN TYPE | COLLECTION GUIDELINES | CONTAINER & STORAGE / TRANSPORTATION | COMMENTS |
|---|---|---|---|
| **Respiratory Tract, Upper** | | | Nil |
| Nasal | 1. Insert swab into nares<br>2. Rotate swab against the nasal mucosa | Transport swab | |
| Oral | 1. Remove oral secretions or debris from the surface of the infected area with a swab and discard.<br>2. Using the swab appropriate for tests ordered, swab the sample site vigorously avoiding areas of normal tissue.<br><br>Bacterial/Fungus : routine culture swab<br>Viral : viral transport media (VTM) | <br><br><br><br><br>Room Temperature<br>Refrigerate | |
| Throat | 1. Depress tongue down with sterile tongue depressor<br>2. Firmly sample inflamed areas, exudate and / or lesions with the swab appropriate for the test ordered.<br><br>Bacterial/Fungus : routine culture swab<br>Viral : viral transport media (VTM) | Transport Swab<br><br><br><br>Room Temperature<br>Refrigerate | |
| **Respiratory Tract, Lower** | | | Nil |
| Sputum, expectorated | 1. Have the patient gargle or rinse his mouth with water.<br>2. Instruct patients to cough deeply to produce a sample from the lower respiratory tract and not saliva.<br>3. Collect sample in sterile container | Sterile container<br><br>Room Temperature | |
| Tracheal aspirate | Please aspirate or washing into sputum trap container | | |
| **Skin Scraping** | 1. Cleanse the area with 70% alcohol<br>2. Scrape area at the active margin of the lesion. Do not draw blood.<br>3. Place scrapings into sterile container. | Sterile container<br><br>Room Temperature | Nil |
| **Nail** | 1. Wipe nail with 70% alcohol.<br>2. Clip away the affected area and collect material or debris from under the nail.<br>3. Place in sterile container. | Sterile container<br><br>Room Temperature | Nil |

| SPECIMEN TYPE | COLLECTION GUIDELINES | CONTAINER & STORAGE / TRANSPORTATION | COMMENTS |
|---|---|---|---|
| **Gastrointestinal Tract**<br>**Fecal specimens** | 1. Pass stool directly into a sterile or clean wide mouth, leak proof container.<br>2. Pass stool into clean, dry bedpan and transfer into container<br>3. Cover toilet seat with plastic wrap and transfer to clean or sterile container<br>Bacterial/Fungus : Clean or Sterile Container<br>Viral : Viral Culture media<br>Rotavirus : Clean or sterile media | Sterile container<br>Room Temperature<br>Refrigerate<br>Room Temperature | All stool specimens must be brought to the laboratory as soon as possible. |
| **Rectal swab** | 1. Pass the tip of the sterile swab approximately one inch beyond the anal sphincter<br>2. Carefully rotate the swab to sample the anal crypts, and withdraw the swab.<br>Bacterial/Fungus : Clean or Sterile Container<br>Viral : Viral Culture media | Room Temperature<br>Refrigerate | |
| **Urine** | Collect 20ml of mid stream urine (MSU) in a sterile specimen container. | Sterile urine container<br>Refrigerate | Send samples to the lab immediately in ice packs.<br>If delay is expected, keep in the refrigerator at 4°C for a maximum of 24 hours.<br>If plated, DO NOT refrigerate, incubate at 35°C until ready for transport. DO NOT keep in an ice pack during transport. |
| **Genital Tract**<br>**Male** | Patient should not have urinated within the past hour.<br>Wipe the urethral, express the exudates from the urethral. If discharge cannot be obtained insert swab approximately 3 to 4 cm into urethral lumen. Rotate 2-3 times.<br>Viral : Viral culture media | Transport swab<br>Room Temperature<br>Refrigerate | Nil |
| **Female**<br>Vagina<br>Cervix<br>Bartholin Gland | Obtain secretions from the mucosal membrane of the vagina vault with the swab appropriate for the test ordered<br>1. Examine cervix with speculum without the use of lubricants.<br>2. Remove mucus and or secretions from the cervix with a swab.Discard this swab.<br>3. Sample the endocervical canal with the swab appropriate for the test ordered<br>Disinfect skin with 2% iodine tincture. Aspirate fluid from ducts | Transport swab<br>Room Temperature | Nil |

| SPECIMEN TYPE | COLLECTION GUIDELINES | CONTAINER & STORAGE / TRANSPORTATION | COMMENTS |
|---|---|---|---|
| **Semen** | 1. Collect after a minimum of 2 days and a maximum of 7 days of sexual abstinence.<br>2. Sample needs to be collected completely into the provided container and should report any loss of any fraction of the sample.<br>3. Sample should be obtained by masturbation or withdrawal method. Do not use a condom or any form of lubricant.<br>4. Return the specimen and request form directly to the closest Innoquest laboratory within 1 hour of collection.<br>5. The specimen container should be kept at ambient temperature, between 20°C and 37°C, to avoid large changes in temperature that may affect the spermatozoa after they are ejaculated into it. | Sterile container | 1. Ensure specimen container is labelled with name, I/C, time and date of collection<br>2. Specimen should be accompanied with the following information:<br>○ Method of collection<br>○ Type of specimen container<br>○ Days of abstinence<br>○ Collection or transport problems (eg, incomplete specimen, exposure to temperature extremes)<br>○ Time of specimen receipt and analysis<br>○ It must be labeled with the patient's name and identification number |

***All samples for PCR must be collected using a dry swab or viral transport media (VTM)**

## Schedule 2 : Referred Tests Specimen Collection and Transportation

**DNA paternity test performed in DNA Diagnostics Center, USA.**

Please contact the laboratory to request the specimen collection kit.

Buccal swab collection procedure (use only the swabs provided):

1. Rub each swab firmly against the inside of the cheek for 10 strokes.
2. Rotate the swabs while rubbing from front to back.
3. Use 2 swabs for each cheek, place used swabs inside the buccal swab envelope and label the envelope with the patient's name and site of the cheek (left or right).
4. Once all the 4 swabs are placed inside the respective envelopes, close the flap and seal with tape (do not lick the flap).
5. Label each envelope with the patient's name and date of birth, the collector's name, the date, and time of sample collection and the site of cheek.

**Non-Invasive Prenatal testing (NIPT)**

Please contact the laboratory to request the specimen collection kit.

Store the collection kit including the 10ml Streck/PAXgene tube at room temperature. Do not freeze or refrigerate.

## PROTECTION OF PERSONAL INFORMATION

It is the organization policy that all results and patient details will be treated as private and confidential as the company's PDPA policy.