Laboratory Service Guide

gnosis Laboratories

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OVERVIEW

Gnosis Laboratories (M) Sdn Bhd, a medical laboratory company which began operation in year 2002 was jointly created by Lezen Reference Laboratories and local medical laboratory professionals. Gnosis Laboratories work with physicians, hospitals and other healthcare providers to help deliver better outcomes in patient care. We offer the following services:

- **A broad range of routine laboratory tests**
- **Access to highly specialized clinical tests**
- **Occupational Health Services**
- **Functional Health Test**
- **Laboratory testing and management for hospitals**
- **Professional health services for employers, insurers and government agencies**

Lezen Reference Laboratories (http://www.lezen.com.tw) is a well-known and respected company of Taiwanese nationality. Lezen Reference Laboratories was established in 1978 and has since grown to be a major medical reference laboratory for clinic, medical laboratories, hospital and university research units. They received and performed about 5,000 patient cases a day with vast requests of routine and special testing. As a reference and research-led medical laboratory, Lezen Reference Laboratories always seek collaboration with medical and academy institutions to actively involved in research projects.
For Lezen Reference Laboratories, joint venture partnerships open up new market opportunities and access to Malaysia local market knowledge. For Gnosis Laboratories (M) Sdn Bhd, the benefits include gaining access to world-leading technologies and proven experience in delivering large-scale projects.

Service Quality
Gnosis Laboratories core concern is always about providing accurate and time efficient laboratory results to our medical partners. We demonstrate our commitment for continuous quality improvement through a series of inter-related quality control and quality assurance program which evaluate our pre-analytical, analytical and post-analytical services. Among the programs are:

- Taiwan Accreditation Foundation (TAF) according to ISO 15189 standards
- College of American Pathologists (CAP) Proficiency Surveys
- Biorad, External Quality Assessment Scheme (EQAS) from California, USA
- The Royal College of Pathologists of Australasia Quality Assurance Programs (RCPAQAP)

LOCATION OF THE LABORATORY AND CONTACT DETAILS

The addresses and contact numbers of Headquarters Laboratory and Branch Laboratories are as below. All the laboratories as listed formed the entire organization.

Website: gnosis-healthcare.com

Subang Jaya (Central Lab):
Address: 64-1, Jalan SS15/4, 47500 Subang Jaya, Selangor, Malaysia.
Tel: 603-5621 9177/ 9277/ 9377 Fax: 603-5621 9077
Contact Person: Yap Choon Pee, Edwin Singhe, Lam Mun Churn
E-mail: hqlab@gnosis-healthcare.com

Ipoh Branch
Address: Hospital Seri Botani, Level 1, Pathology Lab, No. 3, Dataran Botani 2, Bandar Seri Botani, 31350 Ipoh, Perak Darul Ridzuan.
Tel. No.: +605-226 2768 / +6012 500 1822
Contact Person: Shirley Yeoh Yee Siew
E-mail: ipoh.manager@gnosis-healthcare.com

Penang Branch
Address: 70-2-56A, D'Piazza Mall, Jalan Mahsuri, 11900 Bayan Baru, Penang
Tel. No.: +604-642 8771
Contact Person: Chuah Ban Chung, Foong Yao Ping
E-mail: penang.manager@gnosis-healthcare.com, penanglab@gnosis-healthcare.com

Johor Bahru Branch
Address: 10-A, Jalan Indah 1, Taman Bukit Indah, 81200 Skudai, Johor Bharu, Johor.
Tel. No.: +607-2445177
.Fax. No.: +607-2445077
Contact Person: Malar Valyy A/P Thulasidasan
E-mail: jblab@gnosis-healthcare.com

Kulim Branch
Address: 9, Jalan Lunas, Taman Badlishah, Kelang Lama, 09000 Kulim, Kedah.
Tel. No.: +604-4902315
.Fax. No.: -
Contact Person: Chuah Ban Chung
E-mail: penang.manager@gnosis-healthcare.com

Melaka Branch
Address: No. 9-1 (1st Floor), Jalan KL 3/15, Taman Kota Laksamana, Seksyen 3, 75200 Melaka.
Tel. No.: +606-2811288
.Fax. No.: -
Contact Person: Lee Kah Wai
E-mail: melaka.manager@gnosis-healthcare.com

Klang Branch
Address: 38A, First Floor, Jalan Batu Unjur 1, Taman Bayu Perdana, 41200 Klang, Selangor.
Tel: +603-3311 5817
Contact Person: Puan Zawin
Email: klanglab@gnosis-healthcare.com

Seremban Branch
Address: 28-1, Jalan Rasah Prima 2, Pusat Komersial Rasah Prima, 70200 Seremban, Negeri Sembilan Darul Khusus.
Tel: +606-6316 788
Contact Person: Ms Kuga Andy
Email: serembanlab@gnopsis-healthcare.com

Kota Kinabalu Branch
Address: Lot A-1-1, First Floor, Block A, 88 MarketPlace, Jalan Pintas, 88300 Kota KInabalu, Sabah.
Tel. No.: +6088-212 525
Contact Person: Liew Gar Yee
E-mail: sabah.manager@gnosis-healthcare.com

Sibu Branch
Address: 14, Jalan Pedada, 96000 Sibu, Sarawak.
Tel. No.: +084-332600
.Fax. No.: +084-346700
Contact Person: Doreen Tiong
E-mail: doreentiong@gnosis-healthcare.com

Kuching Branch
Address: 33, Sublot 7, Lot 1108, Block 10, KCLD Kueh Hock Kui Comm Ctr, Jalan Tun Ahmad Zaidi Adruce, 93250 Kuching, Sarawak.
Tel. No.: +082-245996
.Fax. No.: +082-245996
Contact Person: Joseph Niler AK Bimbang
E-mail: josephniler@gnosis-healthcare.com

Miri Branch
Address: Lot 292, Beautiful Jade centre, Jalan Bendahara, 98000 Miri, Sarawak.
Tel. No.: +085-439068
.Fax. No.: +085-439069
Contact Person: Doreen Tiong
E-mail: doreentiong@gnosis-healthcare.com

Bintulu Branch
Address: 1st Floor, Lot 3302, No. 16, Parkcity Commercial Centre, 97000 Bintulu, Sarawak.
Tel. No.: +6086-317400
Contact Person: Doreen Tiong
E-mail: doreentiong@gnosis-healthcare.com

OPERATION HOURS OF LABORATORY

Day	Routine Hours	*On-Call Hours*
Monday to Friday	9:00 am to 5:30 pm	5:30 pm to 7.00 pm
Saturday	9:00 am to 1:00 pm	1:00pm to 3:00 pm
Sunday	-	9:00am to 3:00 pm
Public Holiday	Close	Subject to notification

Above service hours are applicable to HQ only. Please check with particular branch for the exact opening hours.

Operation hour for Sarawak lab:
Mon-Fri : 8:00am to 5:00pm Sat, Sun & Selected PH: 8:00am to 12:00pm

TYPES OF CLINICAL SERVICES

Routine Tests
Gnosis Laboratories always seek for and employ the state-of-the-art technology in providing the highest quality and reliable test results for our customers. The routine tests that we are providing are:

1. Clinical Chemistry
2. Haematology
3. Urinalysis
4. Immunoassay
5. Microbiology
6. Histology
7. Cytology

Our routine tests package is design based on cost-effectiveness and it's usefulness in helping the physicians to assess and diagnose patients.

Refer to our Service Catalogue for details.

Specialized Tests
Together with our partners, we provide access to specialized clinical tests that range from early detection of cancer to diagnosing allergies, from measuring Growth Hormone, HBV DNA Viral Load to providing Functional Medicine Testing. Among the specialized clinical laboratory tests are as follow:

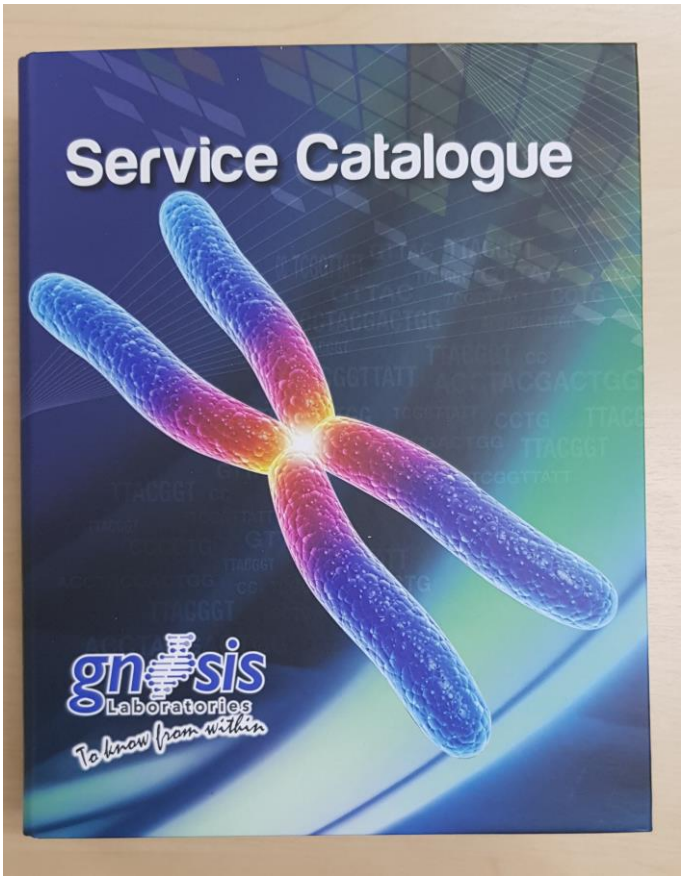
1. Anti-CCP
2. Allergy Testing: Allergy AD40 (40 types of allergens)
3. Tumor marker for lung: Cyfra 21-1,NSE,SCC Ag
4. Tumor marker for stomach: CA 72-4
5. Infertility testing: Anti-Mullerian Hormone (AMH)
6. DNA Paternity Testing
7. Prenatal Screening Test: Double Tests (Down's syndrome screen), First Trimester Down's Syndrome Screen, Second Trimester Quadruple test for Down's syndrome screen
8. Herpes simplex virus (HSV 1 & 2) typing
9. Human Papillomavirus (HPV) genotyping and Cervical Cancer screening
10. HBV DNA Viral Load and Genotyping
11. HCV RNA viral Load and Genotyping
12. HIV RNA Viral Load
13. Chlamydia DNA Test
14. Gonorrhoea DNA Test
15. Mycobacterium Tuberculosis DNA Testing
16. Aging Hormone: IGF-1, DHEA-S, Insulin, C-peptide, Testosterone, Dihydrotestosterone, etc
17. Protein electrophoresis, immunoglobulin electrophoresis, Hb electrophoresis etc
18. Heavy Metal toxicity: Mercury, Arsenic, Lead, etc
19. Oncology Testing

Functional Health Tests
Gnosis laboratories dedication to innovation has lead us to investigate a variety of new areas to expand our testing base, thereby providing healthcare providers a comprehensive diagnostic menu to serve their patients. Gnosis Laboratories are looking at Functional medicine as a new approach to help physicians to manage and prevent chronic disease that embodies the art and science of medicine. Functional Medicine integrates what we know about how the human body works with patient-centered, science-based care. Functional medicine addresses the causes of chronic disease, which are rooted in lifestyle choices, environmental exposures, and genetic influences.
Please refer to Nutritional Medicine Assessment Service Catalogue for details.

EXAMINATION OFFERED BY LABORATORY

Please refer to **Gnosis Service Catalogue** for the full range of examinations offered by the laboratory including, as appropriate, information concerning samples required, primary sample volumes, special precautions, turnaround time, and price.

Please contact lab servicing at your area for detail of biological reference intervals and clinical decision values.



DESCRIPTION OF VACUTAINER BLOOD COLLECTION TUBES

The table below gives a summary of the tubes available:

Cap Colour	Code & Additives	Vol.	Note
Yellow	**Plain** SST (with Serum Separation Gel & Clot Activator)	5 ml	No need mixing, avoid shaking. Mainly for most routine biochemistry assays, hormones, tumour markers, serology assays, virology assays etc. Preferably using this tube rather than total plain tube, for speedy processing, unless specifically indicated.
Red	**Plain** (without Gel)	7 ml	No need mixing, avoid shaking.
Lavender	**EDTA** (K2 EDTA)	3 ml	**Gently Mix well, 8 to 10 times**. For most of haematology assays and blood lead assay. If ESR requested, need min 1.5 ml.
Grey	**Fluoride** (KF+Na2EDTA)	2 ml	**Mix well, 8 to 10 times**. For glucose test, min 1 ml, too little of blood may cause blood haemolysis. Too much of blood may reduce glycolytic inhibition.
Green	**Heparin** (Na/Li Heparin)	2 ml	**Mix well, 8 to 10 times.**
Light Blue	**Citrate** (Buffered Citrate 3.2%)	2 ml	**Fill to the marked line/specified volume and mix well 3 to 4 times.** Ensure citrate to blood ratio is 1:9. Not to draw first blood for coagulation tests, either use the first draw for other tube or discard the 1st tube.
Royal Blue w Red Label	**Trace Element (TET) Plain**	7 ml	No need mixing. For trace element or heavy metal assays on serum or urine.
Royal Blue w Lavender Label	**Trace Element (TET) EDTA**	7 ml	**Mix well, 3 to 4 times**. For trace element or heavy metal assays on whole blood or red blood cells.
Royal Blue w Royal Blue Label	**Trace Element (TET) Heparin**	7 ml	**Mix Well, 3 to 4 times.** For trace element specially blood Aluminium assay.

PATIENT PREPARATION AND INFORMATION

Patient Preparation

Pre-instruction shall be provided to the patient, such as fasting, special dietary consumption, or other requirements before sample collection. In the event of test requires self-collection of sample, kindly provide specific instruction to the patient.

Patient Identification

Each patient must be identified using active communication techniques. At least **two patient identifiers** (patient's name / Identification number (I.C. No / Passport number / MRN etc) are needed before collect the sample from the patient.

The patient's identity is verified by asking the patients to identify themselves prior to collect the samples.

The sample tubes/containers shall be labelled with the identifiers in the presence of the patient at the time of collection.

Patient's Informed Consent

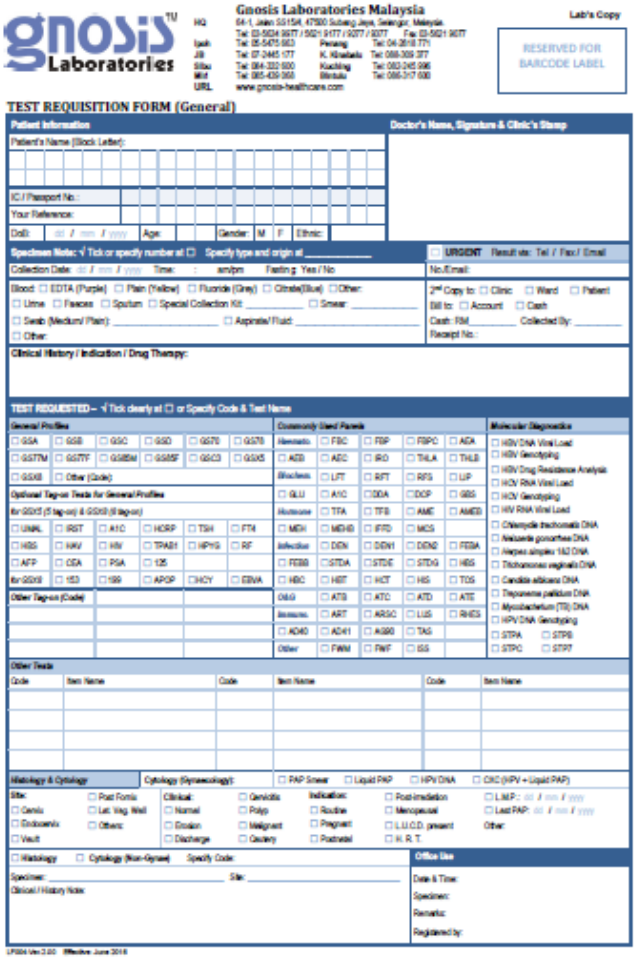
For test such as HIV, documented consent shall be obtained from the patient.

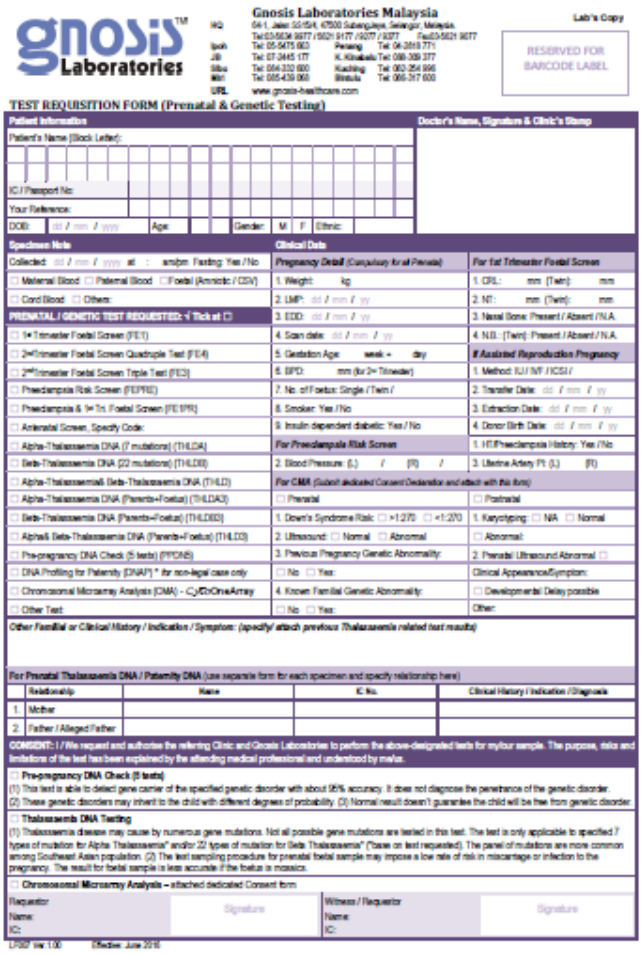
INSTRUCTIONS FOR COMPLETION OF TEST REQUISITION FORM

Test order shall be attached with Gnosis Test Requisition Form and submitted to the laboratory. This requisition form must contain essential information in order to proceed for laboratory testing. The essential elements of the requisition form are

a. Patient's Full Name & second identifier (NRIC or Passport)
b. Patient's age, date of birth & gender
c. Date & time of specimen collection
d. Diagnosis or Clinical History (Where Applicable)
e. Name and signature of requesting doctor, clinic stamp and telephone number
f. Special attention if required (Urgent//Phone/Fax No.)
g. Nature / source of specimen
h. Specimen Status (Fasting or non-fasting)
i. Examination required

Under emergency situation, consent might not be possible; under these circumstances it is acceptable to carry out necessary procedures, provided they are in patient's best interest. Remark it under Specimen Note in Test Requisition Form.





TEST REQUEST & COLLECTION / TRANSPORTATION OF SPECIMEN

1. Our courier will make the routine specimen collection ***twice a day*** (morning or afternoon) for normal working day. Please kindly inform us if you need different arrangement for routine specimen collection.

2. ***Urgent Requests***- We will respond immediately to urgent requests during our routine hours. Urgent specimens should be packaged in our red coloured marked as Urgent packaging specimen bags. It is ESSENTIAL to tick the urgent box on the request form and that contact details are provided for results to be telephoned, fax or email when required. For urgent specimen collection, please phone our service line as stated above.

3. During ***On-Call Hours***, our laboratory will only respond to urgent tests. An extra ***RM 4.00 Surcharge*** for urgent tests will be charged per case send within On-Call Hours. If Sunday collection for non-urgent or routine tests, pre-arrangement is needed, please contact your service branch or service representative for such arrangement.

4. Submission of requests for laboratory testing shall be accompanied by a GNOSIS request form. The ***Request From*** must be filled-in clearly (type or hand printed). **Name, Sex, Age, IC number, Doctor/Clinic's stamp & Signature and date and time of Specimen Collection** are essential, **Time** of collection will be important for time sensitive parameters. **Clinically relevant information** and **drugs treated** would be most helpful in the interpretation of results, and for the lab to access the necessity for follow-up testing or alternative tests which are more indicative for a particular condition. Include the anatomic site o origin of specimen, where relevant.

5. Gnosis **Tests Codes** should be clearly written on the Request Form to indicate the tests ordered. All phoned in verbal requests for additional test requests to be added to a written order should be followed by written confirmation as soon as possible.

6. All specimen containers must be ***labelled*** with ***patient's name*** and a unique numerical identifier and accompanied with the Request Form. The specimen container must be tightly capped and put into the Biological Specimen Bag and zipped it. The Request Form shall be place into the "kangaroo" pocket.

7. Use the ***appropriate containers*** for different types of tests and provide enough amount of sample. Specimen send in with incorrect container or improper/no labelling will be rejected. Refer to Gnosis Service Guide Guideline for further detail.

8. If immediate delivery of specimen to laboratory is unavailable, please keep the specimens in the ***suitable temperature***, refer to page 30 to 33.

9. If a test is ordered that can be performed by several ***methodologies*** and the method is not specified on the Test Request Form, the test will be performed by method which generally has the greatest clinical utility or availability.

10. An ***additional*** or ***follow-up test*** can be ordered on a previously submitted specimen, provided there is sufficient specimen volume and the specimen still useable. In some cases, the laboratory personals may consult the referral physician and suggest a further investigational/differential/confirmatory test. In any case, written verification must be provided by fill-in the Test Request Form again with appropriate note and fax or courier to the laboratory.

    Add-on Test by Verbal order
    - Adding test to old specimen is subject to specimen availability, adequacy and suitability
    - Please check with laboratory staff before adding additional tests on same specimen
    - Verbal order of adding "tag-on tests" to an old specimen is **acceptable**.
    - Verbal order is generally not accepted for any other add-on. The ordering clinician can call laboratory to check sample availability, suitability and place a verbal order but must signed a supplementary Test Requisition Form and submit to laboratory

11. The laboratory will accept requests for ***test cancellation*** received prior to test set-up at no charge. Cancellation requests received after test set-up cannot be honoured; the test will be performed, a report will be issued, and the client will be charged appropriately.

SAMPLE COLLECTION

A. BLOOD SAMPLE COLLECTION

Blood Sample

Laboratory tests are performed on anti-coagulated whole blood, plasma or serum.

The following order-of-draw is recommended when drawing multiple samples for laboratory testing during a single venipuncture. It is to avoid cross contamination from tube additives.

1. Blood culture tube
2. Coagulation tube (e.g. blue closure)
3. Serum tube with or without clot activator, with or without gel (e.g. red closure)
4. Heparin tube with or without gel plasma separator (e.g. green closure)
5. EDTA (e.g. lavender closure)
6. Glycolytic inhibitor (e.g. gray closure)

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 as below:

Order of Draw

Tube Closure Color	Collection Tube	Mix by Inverting	Min. Clot Time
	Blood Cultures – SPS	8 to 10 times	N/A
	Citrate Tube (Light Blue)	3 to 4 times	N/A
	Serum Separator Tubes (Gold and Tiger)	5 times	30 minutes
	Serum Tube (Red)	5 times (plastic) None (glass)	60 minutes
	Rapid Serum Tube (Orange)	5 to 6 times	5 minutes
	Plasma Separator Tube	8 to 10 times	N/A
	Heparin Tube (Green)	8 to 10 times	N/A
	EDTA Tube (Lavender)	8 to 10 times	N/A
	PPT Separator Tube (Pearl)	8 to 10 times	N/A
	Fluoride Tube (Gray)	8 to 10 times	N/A

NOTE: Tubes with additives must be thoroughly mixed. Erroneous test results may be obtained when the blood is not thoroughly mixed with the additive.

Collection of Blood Specimen

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. Several essential steps are required for every successful collection procedure:

1. Patient comfort. Is the seating comfortable and has the patient been seated for at least 5 minutes to avoid being rushed or confused.

2. Carry out hand hygiene before and after each patient procedure, before putting on and after removing gloves.

3. Identify the patient using two different identifiers, asking open ended questions such as, "What is your name?" and "What is your date of birth?"

4. Check the requisition form for requested tests, patient information, and any special requirements and select specimen containers according to the tests requested.

5. Label the collection tubes at the bedside or drawing area. Do not pre-label the empty specimen containers before attend to the patient. The label should include at least 2 identifications e.g. the patient's full name, MRN, NRIC or DOB. (Refer to labeling the sample)

6. Select a suitable site for venipuncture. Avoid drawing blood below or from the infusion side to prevent dilution of blood specimen.

7. Prepare the equipment, the patient and the puncture site.

8. Perform the venipuncture, collecting the sample(s) in the appropriate container(s). The date and time of collection must be indicated on Test Requisition Form.

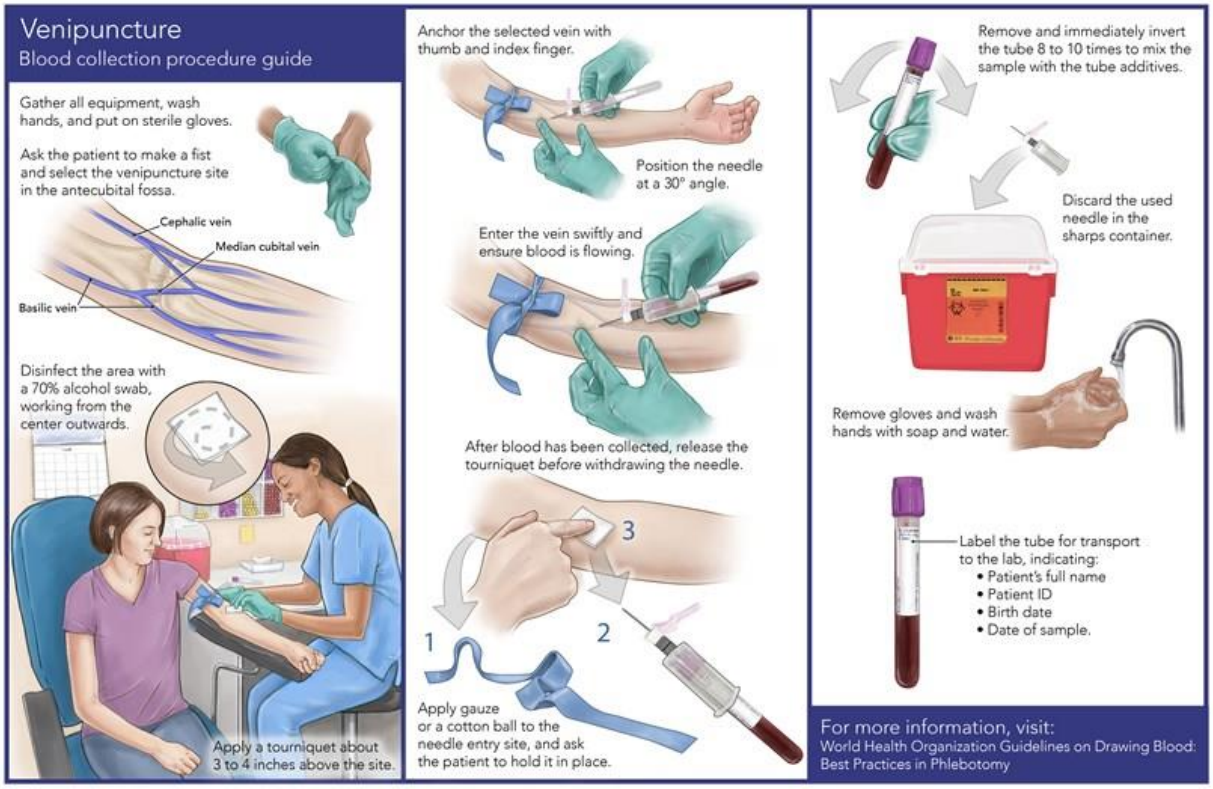
9. Place specimens in the inner pocket of the specimen carrier bag and seal the zip.

10. Place the Test Requisition Form at the outer pocket of the specimen carrier bag.

11. Promptly send the specimens with the Test Requisition Form to the laboratory.

Wash Hand Before Venipuncture

Venipuncture – Blood Collection Procedure Guide



B. 24-HOUR URINE COLLECTION

Procedure of collection:

- The 24-hour urine container which contains preservative for the required test is available upon request. It is important for the requesting doctor to advise the patient NOT to discard the preservative.
- On the day of collection, discard the first voided urine. Time of first urine voided is the start of the timing for the 24-hour urine collection.
- Collect the second and subsequent voided urine for 24-hour into the 24-hour urine containers.
- Collect the last voided urine at the end of 24 hours.
- Label the container according to the standard protocol and send to laboratory soonest possible.
- Example of the test: 24-hours urine catecholamine

24- Hour Urine Catecholamines

- Refer to the procedure for 24-hour urine collection as above.
- Instructions on patient preparation and specimen collection:
  - Abstain from bananas, coffee, pineapple and walnuts one day prior to and during the 24-hour urine collection.
  - Certain drugs alter the metabolism of catecholamines. It is advisable to stop such medications at least days prior to urine sampling. The medications include: Alpha2 agonists, Calcium channel blockers, ACE inhibitors, Bromocriptine, Methyldopa, Monoamine oxidase inhibitors, Alpha blockers and Beta blockers, Phenothiazines and Tricylic antidepressants.
  - Please advise patient to avoid stress, exercise, and smoking prior to and during urine collection.

C. SPECIMEN COLLECTION FOR MICROBIOLOGY TEST

General Guidelines for Proper Specimen Collection and Transport

- Specimen shall be collected before administering antimicrobial agents, where possible.
- Use sterile containers and aseptic technique to collect specimens.
- Collect adequate amount of specimen. Inadequate amounts of specimen may affect the accuracy of test results.
- Swabs shall be transported in suitable media.
- Specimens collected by using needle aspiration should be transferred to a sterile container and transported to the laboratory soonest possible. If there is only a small volume of material in the syringe, add some sterile saline, mix well before transfer to a sterile container.
- All specimens from high risk patients (HIV, Hep B, TB, and others) must be clearly marked as high risk.
- The specimen container must be properly labeled, placed in a biohazard plastic bag and accompanied by a completed laboratory Test Requisition Form.
- Specimens should be transported to the laboratory soonest possible and preferably within the same day.

Special Instructions

(1) Urine Culture

A clean mid-stream Urine for culture should be collected in a sterile 90ml urine container and refrigerated while waiting for specimen pick up from laboratory. The patient's full name, I.C. Number, source of specimen and date and time of collection should be specified on the Test Requisition Form and urine container. Relevant information, such as pregnancy, antibiotic medication, drug allergies, etc. shall be indicated in the requisition form.

Collection of a Mid-stream Urine Samples

(a) Urine collected at other times of the day are acceptable, preferably early morning urine specimen.

(b) Use a sterile urine container for collection.

(c) Provide information as required in the label of the urine container, such as full name, IC Number, source of specimen and date and time of collection.

(d) Provide the following Instruction to the patient:

- Wash and dry your hands thoroughly.
- Remove the container lid. Do not touch inner surfaces of container.
- Wash your urogenital area ("lower parts") with the towelette
- For women, wipe from front to back between the folds of skin
- For men, retract the foreskin (if un-circumcised), and clean the glans (head of the penis)
- Pass a small amount of urine into the toilet (a women needs to hold the skin folds apart) and then midway through urination, urinate into the container. The container should only be 1/2 to 2/3 full. A specimen contains stool, vaginal discharge, or menstrual blood cannot be used.
- Replace the lid and tighten firmly.
- Wash and dry your hands thoroughly.

(e) Immediately refrigerate the specimen and send to laboratory within 24 hours. Urine specimen shall be maintained at 2-8^{o}C during transportation. Call laboratory for further advice if specimen is expected to be collected more than 24 hours.

(2) Blood Culture

Aseptic technique shall be in practice, which is critical for proper blood culture collection.
Source of blood collection: Venous blood

Acute Sepsis: Collect **two or three** sets of culture from **separately prepared sites** prior to initiating antimicrobial therapy. Each set consists of two bottles, one aerobic and one anaerobic or two aerobic.

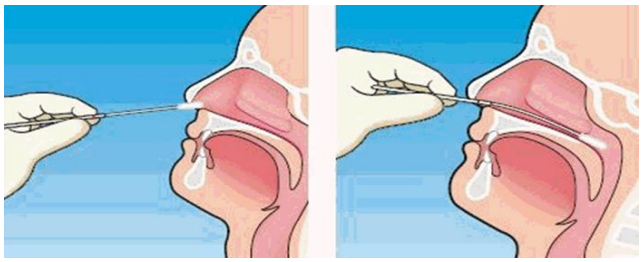
Acute Endocarditis:
Obtain **three** blood cultures from **separate venipuncture sites** over 1 – 2 hours, prior to initiating therapy. These cultures are often obtained **30 minutes apart** in order to document persistent bacteremia.

Subacute Endocarditis:
Obtain **three** blood cultures on **day 1** (15 minutes or more apart). If cultures are negative after 24 hours, obtain 3 more.

Adults: **10 ml** of blood per culture bottle. In the event that **less** than 10 ml of blood is obtained from an adult, put it all into **one aerobic** blood culture bottle.

Children and infants: **1 – 3 ml** of blood per culture bottle. The minimum volume is dependent upon the weight of the child/infant, please contact the microbiology department prior to obtaining the blood if assistance is needed in determining the correct amount of blood needed for the child/infant.

(3) Nasal Swab



Nasopharyngeal Swab Procedure

- Wear a surgical mask and disposable gloves.
- Wash hands thoroughly with soap and water or alcohol-based hand gel (before and after the procedure)
- Remove patient's surgical mask to perform the procedure and replace with a new one when done.
- Use a flexible fine-shafted aluminum swab with a polyester tip.
- The distance from the patient's nose to the ear gives an estimate of the distance the swab should be inserted.
- Insert swab into one nostril down and backward into the nasopharynx and leave in place for a few seconds.
- Slowly withdraw swab with a rotating motion.
- Place tip of the swab into a vial containing 2–3 ml of Viral Transport Medium and cut the shaft.
- dispose of all PPE and other contaminated materials in the trash.

Storage Condition

- Specimen can be kept refrigerated at **4°C for up to 72 hours**
- Specimens that cannot be processed within 48-72 hours should be kept in the refrigerator at **4°C.**

(4) Genital Infections Sexually Transmitted Diseases

Specimen Required

Female: Cervical or High vaginal swabs, Urethral swabs
Male: Urethral swab, penile swab

Genital tract swabs

Use speculum to take Cervical and high vaginal swabs. Avoid vulvar contamination of the swab.

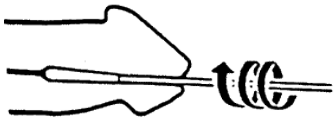
High Vaginal Swabs

Roll firmly the swab over the surface of the vaginal vault. Then placed the swab in transport medium.

Cervical Swabs

Rotate the swab inside the endocervix. The swab should then be placed in transport medium.

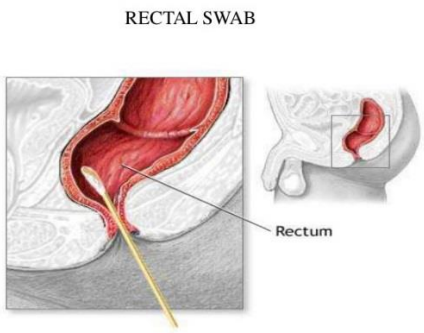
Urethral Swabs



Practice aseptic technique to avoid contamination with micro-organisms from the vulva or the foreskin.
Thin swabs are available for collection of specimens.
The patient should not have passed urine for at least 1 hour.
The swab is gently passed through the urethral meatus and rotated. Place the swab in transport medium.

Intrauterine Contraceptive Devices (IUCDs)
The entire device should be sent in a sterile universal container.

Rectal Swabs



Rectal swabs should be taken via a proctoscope.
Advantages of rectal swabs:

- Convenient
- Adapted to small children, debilitated patients and other situations where voided stool sample not feasible

Drawbacks of rectal swabs:

- No macroscopic assessment possible
- Less material available
- Not recommended for viruses

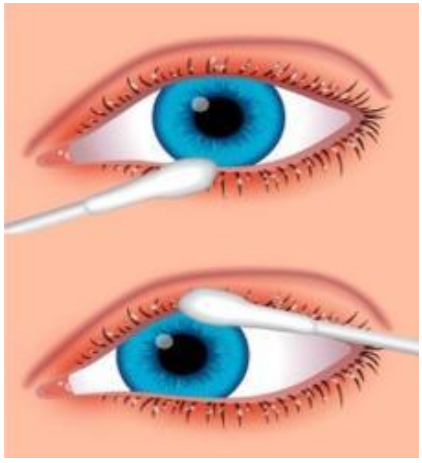
Pus Samples/ Wound Swabs
Wound swabs should only be taken when signs of clinically infection is relevant.
Please indicate clearly on the requisition form and the swab, the site of the wound to facilitate interpretation of culture results.

Specimens Required
1. **Pus** sample (preferable to a wound or pus swab) in sterile container.
2. **Wound swab** in transport medium.

Wound or Pus samples are screened for all likely bacterial pathogens and, if present, these organisms and their antibiotic sensitivity results will be reported. The inclusion of relevant clinical information on the Test Requisition Form will assist in determining the bacterial isolates.

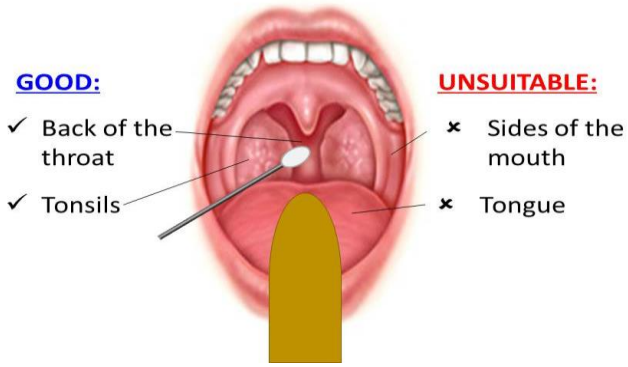
Abscess
1. Decontaminate the surface with 70-95% alcohol and 1-2% tincture of iodine.
2. Collect the purulent material aseptically from an un-drained abscess, using a **sterile needle and syringe**. Open miliary abscesses with a sterile scalpel and collect the expressed material with a sterile needle and syringe.
3. Transfer 5-10 ml of the aspirated material to an **anaerobic** transport vial. Transport immediately. *Anaerobic transport media is **not recommended** for AFB culture. If requesting AFB culture, transfer at least 1 ml of the aspirated material into a sterile container.*
4. **Swabs are not recommended** because they dry easily and because of the limited amount of material obtained. Swabs are not optimal for fungal, anaerobe cultures, or decubitis ulcers. Swabs are **not** accepted for mycobacterial cultures, perirectal abscesses, oral abscesses. Gram stains cannot be provided from a single swab. If a Gram stain is needed, collect two swabs.

(5) Eye Swab



- Explain the procedure and the purpose of the investigation to the patient to obtain informed consent, gain co-operation, and allay any fears and anxieties.
- Sit or lay the patient with head well-supported and with the chair at an appropriate height to ensure safety for the patient and the nurse.
- Perform hand washing to reduce the risk of cross infection
- Ask the patient to look up and gently pull down the lower lid exposing the conjunctiva.
- Gently sweep the swab stick along the lower fornix, from inner to outer canthus. Do not touch the eyelids.
- Swab is placed immediately into bacterial medium container.
- Ask patient to close the eye for a few seconds. This will ensure safe technique of swab taking and avoid damage to the cornea.
- Repeat the procedure to the other eye with separate swab, if needed.
- Wash hands in between to minimize the risk of contamination to the other eye.

(6) Throat Swab



- Hold tongue away with tongue depressor.
- Locate areas of inflammation and exudate in posterior pharynx, tonsillar region of throat behind Uvula.
- Avoid swabbing soft palate.
- Do not touch tongue.
- Rub the affected area back and forth with swab

D. SPECIAL PROCEDURES FOR HISTOPATHOLOGY AND CYTOLOGY TEST

Histopathology

Do not share Histopathology and Cytology requests from the same patient into one Test Requisition Form. Use separate test requisition form.

Specimen Container guidelines

1) Preferably transparent so that laboratory and other staff can see and verify the specimen without having to open the cap.
2) Size is adequate so that it has enough capacity to hold the specimen, with at least thrice its volume of fixative.
3) Containers should be appropriately labeled and tally with the Test Requisition Form.

Fixative

10% buffered neutral formalin solution is recommended for routine fixation. For large specimens, please cut open the tissue to facilitate penetration of fixative. Formalin usually does not penetrate tissues for more than a depth of about 1.0cm.

Tissues not placed in fixatives will undergo **autolysis**. Lysed blood could be seen in the solution. The tissue will not change dull chocolate brown. Please transfer the specimen to formalin fixative if this is occurring.

Small Biopsies

Punch biopsies (endoscopic, bronchoscopic and trucut biopsies, aspiration biopsies, etc) are preferably mounted on pieces of paper prior to placing in the fixative. This helps to reduce tissue loss and damage.

If incisional biopsies are done, try to obtain wedges of tissue instead of irregular fragments. Irregular fragments are difficult to orientate and interpret. In general, the larger the lesion, the bigger should be the incisional biopsy specimen.

Biopsies from multiple sites should be placed in different containers.

Gynaecological Pap Smears (Pap Test)

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

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

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

Patient Preparation

1) Do not use a vaginal douche or topical vaginal medications for 48 hours prior to examination.
2) Do not have sexual intercourse for 24 hours prior to examination.
3) Schedule examination 14 days after onset of the last menstrual period.

The Pap smear is primarily for detection of cervical premalignant and malignant changes and should not be relied upon to detect endometrial malignancy

Collect sample with a spatula followed by the cytobrush. Use the spatula for scraping of the ectocervix.
The brush specimen should be in addition to, never instead of, the ectocervical scraping.
Smears should be made with **one or two swipes** of the spatula on the slide, not with a mixing motion. The cytobrush should be **rolled** on the slide.
The smears should be fixed immediately to avoid air-drying. If an aerosol spray is used, the spray nozzle should be about **twelve inches** from the slide. If held too close, the spray "freezes" the cells and also lifts them from the slide, causing them to clump.
It is important that clinical information is also included, as it helps in the interpretation of the specimen.

Reporting of PAP Smear

The following table is an estimated equivalent terms in the various systems of PAP smear classification and reporting.

PAP	**DYSPLASIA**	**CIN**	**BETHESDA (1988)**	**BETHESDA (2001)**
0	Unsatisfactory	Unsatisfactory	Unsatisfactory	Unsatisfactory
I	Negative	Negative	WNL (Within Normal Limits)	NILM
II	Negative	Negative	BCC	NILM
III	No term	No term	ASCUS/AGUS	ASCUS/ASC-H
III	Mild	I	LGSIL	LGSIL
No term	Moderate	II	HGSIL	HGSIL
IV	Severe	III	HGSIL	HGSIL
IV	CIS	III	HGSIL	HGSIL
V	Carcinoma	Carcinoma	Carcinoma	Carcinoma

Notes:

1) CIS – Carcinoma in situ.
2) WNL – Within Normal Limits.
3) BCC – Benign cellular changes. These include those due to infection, atrophy, radiation or repair on Bethesda system).
4) NILM – Negative for intraepithelial lesion or malignancy. These include those that are within normal limits, benign cellular changes and other non-neoplastic findings.
5) ASCUS – Atypical squamous cells of undetermined significance. A high percentage of these cases will be found to have more severe lesion (LGSIL or HGSIL) subsequently.
6) AGUS – Atypical glandular cells of undetermined significance.
7) LGSIL/LSIL – Low grade squamous intraepithelial lesion. This includes CIN I changes. Cellular changes due to HPV are usually classified at least as LGSIL.
8) HGSIL/HSIL – High grade squamous intraepithelial lesion. This includes CIN II and III changes on histology.
9) ASC-H – Atypical squamous cells, cannot exclude high-grade squamous intraepithelial lesion.

Adequacy of Smears

Smears may be unsatisfactory for reporting due to the following:

1) The presence of an endocervical component (endocervical or metaplastic cells) is generally considered necessary to classify a smear as a satisfactory specimen. However, we have found positive smears even in the absence of an endocervical component and the data available is not conclusive as to whether absence of endocervical component will increase the risk of a false negative smear. In addition, some smears are also taken without sampling of the endocervical canal and are not expected to contain an endocervical component. Hence, we may report PAP smears without an endocervical component as satisfactory, but the absence of this component will be recorded in the report.

2) Inadequate cells in smear

3) Too thick a smear

4) Too much blood, secretions or contaminating lubricants in the smear

5) Too much inflammatory cells

6) Too much crush artifacts

7) Poorly fixed smears or severe air drying artifact

Non-Gynaecological Cytology

Refer to gynaecological cytology for fixation and labeling of smears.

For Urine, body cavity fluids, cerebrospinal fluids and secretions, if delivery to laboratory is not immediate, specimen should be refrigerated or transported in cold chain. Smears from FNAC procedures should be **fixed immediately**. Please provide at least two air-dried and alcohol-fixed smears.

Sputum Collection

Instruction to the patient:

- gargle or rinse mouth with water.
- Instruct patient to cough deeply to produce a specimen from the lower respiratory tract and not saliva.
- Collect in plain sterile container, with sufficient amount depending the number of test requested

If > 24 hours, refrigerate at 4 to 8°C

LABELING THE SAMPLE

A properly labeled sample is essential so that the results of the test match the patient. The key elements in labeling are:

a. Patient's surname, first and middle.
b. Patient's ID number.
c. **NOTE:** Both of the above MUST match the same on the requisition form.

PACKAGING THE SAMPLES

Clinical/biological samples should be placed in a sealed container or a specimen container. Refer to the relevant sections in the specific sample collection.

SAMPLE STORAGE

All samples collected are kept within the recommended temperature while waiting for laboratory pick-up services.
Blood specimen for electrolytes assay, especially potassium, blood for cytogenetics, leukocytes antigen, lymphocytic markers, cryoglobins and blood culture should NOT keep refrigerated. It should be delivered to lab as soon as possible.
Most hormones and enzymes will decrease in activity through time or in warm temperature. It should be keep refrigerated if immediate delivery to lab is unavailable.
Refer to Page 30-33 Specimen storage information.

SAMPLE TRANSPORTATION TO LABORATORY

- All samples collected are sent to laboratory as soon as possible.
- All samples will be picked up from the clinics via the morning and evening routes, or according to pre-determined schedules.
- Sample pick-ups for urgent test request can be arranged with Gnosis respective branch laboratories.
- Please do not send samples that are not urgent after normal office hours.

LABORATORY'S CRITERIA FOR REJECTING SAMPLE

The following criteria will be used to consider a sample is unacceptable and will be rejected.

a. Incompletely filled or no sample identify on the Test Requisition Form
b. Sample without accompanying Test Requisition Form
c. Sample without any label
d. Discrepancy in patient's identity between the Test Requisition Form and sample label
e. Inappropriate test sample, e.g. wrong use of container/preservative or anticoagulant
f. Leaking specimen container
g. Grossly haemolysed sample

CRITICAL LABORATORY VALUES

Critical laboratory result is test result or value that falls into critical limits or the presence of any unexpected abnormal findings, cells or organisms which may cause imminent danger to the patient, and/or require immediate medical attention.

Notification shall be given to the clinician who had ordered the test or to the authorized personnel if the responsible clinician is not around.

Critical Values for Hematology Test

Test Code	Tests Name	Units	Lower Critical Values	Upper Critical Values
HB	Haemoglobin (Adult) Haemoglobin (Neonate)	g/dL	7.0 g/dl	20.0g/dL
RBC	Red Blood Cell	x 10^6/L	2.0	8.0
HCT	Hematocrit (Adult) Hematocrit (Neonate)	%	20% 25%	60% 70%
WBC	Total White Blood Cells	x 10^9/L	2.0	50.0
PLT	Platelet	x 10^9/L	50	1000
PBF	Blast cells in PBF	%		5 (new cases)
DEN	Dengue IgM and IgG	-	-	Reactive
NS1	Dengue NSI	-	-	Reactive
MALA	Malaria Parasite	-	-	SEEN (any species)

Critical Values for Biochemistry Tests

Code	Name	Units	Low critical value	High Critical value
NA	Sodium	mmol/L	120	160
CL	Chloride (neonates)	mmol/L	70	120
K	Potasium (above 18 years old)	mmol/L	2.5	6.0 *
BIL	Bilirubin (neonatal)	umol/L	-	260
GLU	Fasting Glucose (Adult)	mmol/L	2.6	25.0
MGS	Magnesium	mmol/L	0.4	1.90
UREA	Urea	mmol/L	1.1	28.6
CREA	Creatinine	umol/L	18.0	442
CK	Creatinine Kinase	U/L	-	1000
TROPI	Troponin I	-	-	Positive
CA	Calcium	mmol/L	1.5	3.5
AMY	Amylase	U/L	-	1000
PHOS	Phosphorus	mg/dL	≤ 1.0	-

Critical Values for Special Chemical Pathology Test

Code	Name	Units	Low critical value	High Critical value
FT4	FT4 (Free Thyroxine), <50 yrs	pmol/L	-	≥ 100.4
FT4	FT4 (Free Thyroxine), ≥50 yrs	pmol/L	-	≥ 77.2

* Adopted from Mayo Clinic Laboratories, DLMP critical Values/Critical Result List

***Note: Based on the clinical note given and remark appropriately in report if it is a general screening.**

Critical Findings for Microbiology

Test	Results
Cerebrospinal fluid C&S	Microscopic result (N or abN)
Cerebrospinal fluid Ag	Positive rapid Antigen detection
Blood Culture	Positive result gram stain/culture
Sterile body fluids	Positive result gram stain/culture
Acid Fast Bacilli	Positive smear result /culture
Malaria Parasite	Presence of parasite on blood film
Stool Culture	Salmonella typhi, vibro cholerae, shigella, E.coli O157
Any Type Culture	ESBLs, MRSA, MRO, VRE, VRSA.
Antigen detection	Legionella sp
Pernasal swab	Bordetella Pertussis, Corynebacterium diptheria

Critical Findings for Anatomical Pathology

Test	Results
Unexpected /discrepant findings	Unexpected malignancy, wrong organ removed
Reports of infections	Bacteria in heart valve or bone marrow Organisms in an immune-compromised patients such as AFB, fungi, viral, protozoa Organisms in CSF Unusual organisms or organism in unusual sites
Reports on critically ill patients requiring immediate therapy	Crescents in greater than 50% of glomeruli in renal biopsy specimen Transplants rejections
Cases that have immediate clinical consequences	Fat in an endometrial curettage Mesothelial cells in heart biopsy Fat in snare colon biopsy specimens

LIST OF FACTORS THAT AFFECTS THE TESTS PERFORMANCE

Blood Collection or Handling Technique	Potential Error	Correct Procedure
Not allowing alcohol to air dry after cleansing the venipuncture site	The introduction of alcohol into the specimen may cause hemolysis.	Allow alcohol to completely air dry on skin before drawing the sample.
Not following the order of draw	Contamination from other additives could interfere with test results. Plastic or glass serum tubes containing a clot activator may cause interference in coagulation testing.	Always follow correct order of draw.
Improper mixing, including inadequate mixing or vigorously shaking tube after collection	Vigorous shaking of tubes can cause hemolysis. Inadequate mixing can cause clotting or presence of clots	Gently invert tubes the specified number of times immediately after draw: Blue top (Sodium citrate) 3 to 4 times. All other tubes (including light green/mint (PST) and lavender (EDTA) 8 to 10 times.
Under-filling or over-filling tubes	The ratio of blood to additive is altered which can cause incorrect test results. Examples: Under-filling blue top sodium citrate tubes for coagulation testing can drastically alter results. Over or under-filling blood culture bottles can result in false negative results.	Allow tube to completely fill so vacuum is exhausted. Exception is blood cultures: allow the required amount of blood to enter bottle, using guide lines marked on bottle to determine fill. For correctly filled blue top sodium citrate tubes which contain a liquid anticoagulant, the ratio of blood to anticoagulant is 9:1, which is important for accurate test results.
Combining two partially filled tubes, or filling one type of tube from another type of tube	If two different types of tube are used (e.g. lavender top into SST tube), incorrect additives can interfere with test results. If the same type of tube is used, the ratio of blood to additive is altered which can cause incorrect test results. Opening tubes can change the pH of the specimen which may affect the stability of the specimen and test result. In addition, opening tubes of blood without the use of protective equipment is a safety risk due to the possible production of aerosols or spillage.	Never combine two tubes. If blood stops flowing into the first tube before adequate volume is collected, collect a new tube. Leave tube lids on to maintain stability for some tests.

Blood Collection or Handling Technique	**Potential Error**	**Correct Procedure**
Using a partially filled tube when attempting another venipuncture.	Loss of vacuum can cause insufficient draw. Delay in mixing sample may cause clotting of specimen.	Always use a new tube when performing a second venipuncture.
Leaving tourniquet on longer than one minute	Prolonged tourniquet application may result in hemoconcentration and erroneously increased levels of protein based analytes, packed cell volume, or other cellular elements.	Do not leave tourniquet on for longer than one minute; remove as soon as possible after the blood begins to flow.
Using a winged collection device (butterfly) and not removing air in tubing when blue top sodium citrate tube for coagulation is the first tube collected	Air in the tubing will reduce the amount of blood drawn and alter the blood to anticoagulant ratio, and can cause incorrect test results.	Use a discard tube (either another blue top sodium citrate tube or a BD discard tube) to remove the air from the tubing, before collecting specimen into the blue top tube.
Delay in separation of serum or plasma due to overnight storage or delay in transit	Potentially caused of hemolysis	Arrange courier pick up as soon as possible according to test requirement.
Photolabile analytes (Specimen not protected with aluminum foil wrap/equivalent)	Low Folate, Vitamin B12, Porphyrins Neonatal Bilirubin, Vitamin A	Wrap with aluminum foil during transit and before test run.
Clots in anticoagulated blood due to difficult venipuncture or specimens not mixed well	• Shortened PT • Spurious results in FBC, ABG, Cyclosporin, hormones and other assays requiring whole blood specimens	Avoid prolong venipuncture period and mix specimen well.
Specimens not chilled or sent to the laboratory immediately	• Spurious results in Ammonia (NH_3), Lactate, Pyruvate, ABG, Gastrin, Parathyroid Hormone (iPTH), Adrenocorticotropic Hormone (ACTH), Renin and complement. • May not identify Chlamydia, amoeba and some microorganisms because of poor viability	Keep the specimens at required temperature before picking up by lab.
Avoid using syringe to manually inject blood into vacuum tubes without taking off the needle.	• Increase the risk of blood hemolysis.	Using the vacuum needles for blood withdrawal directly into vacuum tube. If using syringe, do not manual inject blood into vacuum tube.

Serum Indices – A Tool to Measure Interfering Substances in Blood Samples

Serum Indices are intended for use as part of laboratory practice to monitor the instrument response to detect hemolyzed, icteric, or lipemic samples. Hemolysis, icterus, and lipemia (HIL) are the most commonly tested interferences that may affect the integrity of patient samples.

The flags indicated in report characterize the kind of chromatic substance (LIP: Lipaema/turbidity, ICT: Bilirubin and HEM: Haemoglobin) and approximate concentration of the interferent as in the following table:

Flag	LIP (mg/dL Intralipid)	ICT (mg/dL Bilirubin)	HEM (mg/dL Hemoglobin)
N	< 40	< 2.5	< 50
+	40 – 99	2.5 – 4.9	50 – 99
++	100 – 199	5.0 – 9.9	100 – 199
+++	200 – 299	10 – 19.9	200 – 299
++++	300 - 500	20 – 40	300 – 500
+++++	> 500	>40	>500

Kindly refer to the below table for Hemolysis, icterus, and lipemia (HIL) toleration level for each test.

Assay	Lipid interference		Icterus interference		Hemolysis interference		Remark
	mg/dL	Flag	mg/dL	Flag	mg/dL	Flag	
Cortisol	1800	+ + + + +	10	+ + +	500	+ + + +	
Ferritin	900	+ + + + +	5	++	300	+ + + +	
Folate	1800	+ + + + +	10	+ + +	Avoid	Not Applicable	Do not use hemolyzed samples. The folate level in red cells is much greater than that of the serum or plasma (heparin), leading to spuriously high results
Vitamin B12	1800	+ + + + +	10	+ + +	Avoid	Not Applicable	
iPTH	3000	+ + + + +	20	+ + + +	500	+ + + +	
Vitamin D	3280	+ + + + +	40	+ + + +	50	+ +	Avoid hemolysed samples
hs-Troponin I	3000	+ + + + +	40	+ + + +	400	+ + + +	
Insulin	1800	+ + + + +	10	+ + +	Avoid	Not Applicable	Hemolysis releases enzymes which degrade insulin
AMH	666	+ + + + +	43	+ + + + +	300	+ + + +	
DHEAS	1750	+ + + + +	30	+ + + +	1000	+ + + + +	
FSH	1800	+ + + + +	10	+ + +	1000	+ + + + +	
LH	1800	+ + + + +	10	+ + +	300	+ + + +	
PAPP-A	3000	+ + + + +	40	+ + + +	500	+ + + +	
Progesterone	450	+ + + +	5	++	500	+ + + +	
Prolactin	1800	+ + + + +	10	+ + +	500	+ + + +	
SNSE2	666	+ + + + +	40	+ + + +	300	+ + + +	
SHBG	5000	+ + + + +	30	+ + + +	400	+ + + +	
β-HCG	3000	+ + + + +	40	+ + + +	500	+ + + +	
Testosterone	1800	+ + + + +	10	+ + +	1000	+ + + + +	
Estradiol	1800	+ + + + +	20	+ + + +	500	+ + + +	
AFP	520	+ + + + +	25	+ + + +	1200	+ + + + +	
CA153	3000	+ + + + +	40	+ + + +	500	+ + + +	
CEA	1800	+ + + + +	30	+ + + +	500	+ + + +	
Free PSA	1500	+ + + + +	20	+ + + +	500	+ + + +	
CA199	1000	+ + + + +	60	+ + + + +	50	+ +	
CA125	1800	+ + + + +	20	+ + + +	1000	+ + + + +	

PSA	1500	+ + + + +	20	+ + + +	500	+ + + +	

*Adopted from respective reagent insert.

Assay	Lipaemic interference		Icterus interference		Hemolysis interference		Remark
	mg/dL	Flag	mg/dL	Flag	mg/dL	Flag	
Albumin BCG	800	+++++	40	+++++	450	+++++	
ALP	100	+++++	28	++++	450	+++++	
ALT	300	+++++	40	+++++	500	+++++	
Amylase	1000	+++++	40	+++++	500	+++++	
AST	300	+++++	40	+++++		+	
Calcium Arsenazo	1000	+++++	40	+++++	500	+++++	
Creatinine Enzymatic	600	+++++	40	+++++	500	+++++	
Cholesterol	1000	+++++	8	++	500	++++	
Creatinine	600	+++++	40	+++++	500	+++++	
DDimer	700	+++++	40	+++++	500	+++++	
Direct Bilirubin	300	+++++		+++++		+	
GGT	1000	+++++	40	+++++	250	+++++	
Glucose	700	++++	40	++++	500	+++++	
HBA1C (B00389)	500	+++++	30	+++++		+++++	
HDL-C	900	+++++	40	+++++	500	+++++	
Iron	100	+	40	+++++	100	+	
LDL-R	1000	++++	40	+++++	500	+++++	
Magnesium	200	++	28	++++	150	++	
Phosphorus	800	+++++	40	+++++	Avoid	+	Hemolysis must be avoided as Phosphate may be split off from labile esters in the erythrocytes.
Total Bilirubin	1000	+++++		+++++	45	+	
Total Protein	1000	+++++	24	+++	300	+++	
Transferrin	1000	+++++	40	+++++	500	+++++	
Urea	500	+++++	20	+++	250	+++++	
Uric Acid	1000	+++++	40	+++++	500	+++++	
Triglyceride	1000	+++++	40	+++++	500	+++++	Grossly lipemic samples under rare circumstances may evade the Data Check Parameters (Flag: F, Z, @, &) and should routinely be diluted 1 part sample to 4 parts saline prior to analysis, and the results multiplied by 5.
HsCRP	1000	+++++	40	+++++	500	+++++	
Apo A1	900	+++++	40	+++++	500	+++++	
Apo B	200	+++	40	+++++	500	+++++	
RF	750	+++++	40	+++++	500	+++++	
CHE	1000	+++++	40	+++++	500	+++++	
CK	1000	+++++	40	+++++	500	+++++	
LDH	1000	+++++	40	+++++		+	
Na	500	+++++	40	+++++	500	+++++	
K	500	+++++	40	+++++	50	+	
CL	500	+++++	40	+++++	500	+++++	

*Adopted from respective reagent insert.

COMMON GENERAL SCREENING TEST REFERENCE INTERVAL & SPECIMEN STORAGE INFORMATION

TEST NAME	REFERENCE INTERVAL	UNIT	SPECIMEN STORAGE
HAEMATOLOGY			
Haemoglobin (Hb)	Male:13.0–18.0 Female:11.5-16.0	g/dL	2 – 8 °C
Red Blood Count (RBC)	Male:4.5-6.5 Female:3.8-5.8	mil/cumm	2 – 8 °C
Haematocrit (Hct / PCV)	Male: 40-54 Female: 35-47	%	2 – 8 °C
Mean Corpuscular Volume (MCV)	78 – 100	fl	2 – 8 °C
Mean Corpuscular Hb (MCH)	27 – 33	fl	2 – 8 °C
Mean Corpuscular Hb Conc. (MCHC)	30 – 37	g/dL	2 – 8 °C
Red Cell Distribution Width (RDW)	11.5 – 16.0	%	2 – 8 °C
Platelet Count (PLT)	150 – 400	thu/cumm	2 – 8 °C
White Blood Cell Count (WBC)	4.0 – 11.0	thu/cumm	2 – 8 °C
Neutrophils	40 – 75	%	2 – 8 °C
Lymphocyte	20 – 45	%	2 – 8 °C
Monocyte	2 – 10	%	2 – 8 °C
Eosinophils	1 – 6	%	2 – 8 °C
Basophils	0 - 1	%	2 – 8 °C
BIOCHEMISTRY			
AST	Male: <50 Female: <35	U/L	2 – 8 °C
ALT	Male: <50 Female: <35	U/L	2 – 8 °C
Albumin	35 - 52	U/L	2 – 8 °C
Alkaline Phosphatase	Male: 43 -115 Female: 33 - 98	U/L	2 – 8 °C
Bilirubin Total	5-21	µmol/L	2 – 8 °C
Bilirubin Conjugated	<3.4	µmol/L	2 – 8 °C
Calcium	2.2-2.65	mmol/L	2 – 8 °C
Chloride	101-109	mmol/L	2 – 8 °C
Cholesterol Total	Desirable: < 5.2 Borderline High: 5.2 – 6.1 High: ≥ 6.2	mmol/L	2 – 8 °C

TEST NAME	REFERENCE INTERVAL	UNIT	SPECIMEN STORAGE
Cholesterol HDL	Low: < 1.03 High: ≥ 1.55	mmol/L	2 – 8 °C
Cholesterol LDL	Optimal: < 2.6 Desirable: 2.6 – 3.3 Borderline High: 3.4 – 4.0 High: 4.1 – 4.8 Very High: ≥ 4.9	mmol/L	2 – 8 °C
Creatinine	Male (adult): 56-104 Female (adult): 45-84	µmol/L	2 – 8 °C
HbA1c	Normal: <5.6, Impaired: 5.6-6.2, Diabetes: >6.3, Control Target: <6.5	%	2 – 8 °C
GGT	Male <55 Female <38	U/L	2 – 8 °C
Glucose	Normal: <6.1 Impaired: 6.1-6.9 Diabetes: >7.0	mmol/L	2 – 8 °C
GTT, 2 HOURS	Normal: <7.8 Impaired: 7.8-11.0 Diabetes: >11.1		
Hs-CRP	0-10 < 1.0 Low risk 1.0 – 3.0 Average risk > 3.0 High risk	mg/L	2 – 8 °C
Ferritin	Male: 23.9 - 336.2 Female: 11.0 - 306.8	ng/ml	2 – 8 °C
Iron	Male 12.5-32.2 Female 10.7-32.2	µmol/L	2 – 8 °C
Magnesium	Male: 0.73-1.06 Female: 0.77-1.03	mmol/L	2 – 8 °C
Phosphate	Adult: 0.81-1.45	mmol/L	2 – 8 °C
Potassium	3.5-5.1	mmol/L	2 – 8 °C
Protein-Total	66-83	g/L	2 – 8 °C
Sodium	136-146	mmol/L	2 – 8 °C
Transferrin	2.0 – 3.6	µmol/L	2 – 8 °C
Triglyceride	Optimal: < 1.7 Desirable: 1.7 – 2.25 High: 2.26 – 5.64 Very High: > 5.65	mmol/L	2 – 8 °C
Urea	2.8-7.2	mmol/L	2 – 8 °C
Uric Acid	Adult Male: 208.3-428.4 Adult Female: 154.7-357	µmol/L	2 – 8 °C

TEST NAME	REFERENCE INTERVAL	UNIT	SPECIMEN STORAGE
Morphine	Negative (Cut-off: 300 ng/mL)	ng/ml	2 – 8 °C
Cannabinoid	Negative (Cut-off: 50 ng/mL)	ng/ml	2 – 8 °C
Amphetamine	Negative (Cut-off:1000 ng/mL)	ng/ml	2 – 8 °C
Urine Pregnancy Test (UPT)	Negative	-	2 – 8 °C
IMMUNOASSAY			
Alpha Feto Protein (AFP)	0-.0	ng/ml	2 – 8 °C
CA125	0-35.0	U/ml	2 – 8 °C
CA 15-3	0–23.5	U/ml	2 – 8 °C
CA19-9	0-35.0	U/ml	2 – 8 °C
Carcinoembryonic antigen (CEA)	0-5.0	ng/ml	2 – 8 °C
Prostate Specific Antigen (PSA)	Males: 0.0-4.0 (no range for females)	ng/ml	2 – 8 °C
Anti-Mullerian Hormone (AMH)	Below for general guides only, physician discretion is crucial. Ovarian Reserve: Very low <1.5 Low 1.5 - 6.5 Normal 6.5 - 19.8 Good >19.8 Ovarian Stimulation Response: Poor Response <14.3 High/Excessive Response >22.8 PCOS SUSPECTED >52	pmol/L	2 – 8 °C

TEST NAME	REFERENCE INTERVAL	UNIT	SPECIMEN STORAGE
Estradiol (E2)	Males: < 55.1 - 115.6 Early Follicular: 82.23 - 422.2 Mid-follicular phase: 91.8 - 422.2 Ovulatory Peak: 117.8 - 1897.9 Mid-luteal phase: 134 - 903.1 Post-menopausal (Not on Hormone Therapy): < 55.1 - 92.1	pmol/L	2 – 8 °C
Follicle Stimulating Hormone (FSH)	Males: 1.27-19.26 Mid-Follicular Phase: 3.85-8.78 Mid-Cycle Peak: 4.54-22.51 Mid-Luteal Phase: 1.79-5.12 Post-Menopausal: 16.74-113.59	mIU/mL	2 – 8 °C
Cortisol	184.85-623.50(8am), <275.9(4pm)	mmol/L	2 – 8 °C
Beta-HCG	Males: 0.1 - 1.0 Non-pregnant Females (= 18 and < 40 years): 0-0.6 Post-menopausal: 0.1 – 11.6	IU/L	2 – 8 °C

Luteinizing Hormone	Males: 1.24-8.62 Mid-Follicular Phase: 2.12-10.89 Mid-Cycle Peak: 19.18-103.03 Mid-Luteal Phase: 1.20-12.86 Post-Menopausal: 10.87-58.64	mIU/mL	2 – 8 °C
Progesterone	Males: 0.45 - 6.55 Mid-Follicular Phase: 0.99 - 4.83 Mid-Luteal Phase: 16.41 - 59.02 Post-Menopausal: < 0.25 - 2.48 1st Trimester: 15.04 - 161.35 2nd Trimester: 61.7 - 144.1	nmol/L	2 – 8 °C
Prolactin	Males: 2.64-13.13 Premenopausal: 3.34-26.72 Postmenopausal: 2.74-19.64	mIU/L	2 – 8 °C
Testoterone	Male: 5.57 - 24.84 Female: < 0.32 - 2.39	nmol/L	2 – 8 °C
Thyroid Stimulating Hormone	0.4-4.0	mIU/L	2 – 8 °C
T3, Free	2.3-6.3	pmol/L	2 – 8 °C
T4, Free	10.3-24.5	pmol/L	2 – 8 °C
Hepatitis Bs Antigen	Non-Reactive	-	2 – 8 °C
Hepatitis Bs Antibody	Non-Reactive:<10, Strong immunity:>100	-	2 – 8 °C
Hepatitis Be Antigen	Non-Reactive	-	2 – 8 °C
Hepatitis Be Antibody	Non-Reactive	-	2 – 8 °C
HIV (1&2(Ab+Ag) p24	Non-Reactive	-	2 – 8 °C
HCV Ab	Non-Reactive	-	2 – 8 °C

Anti-HAV	Reactive: Immunity	-	2 – 8 °C
Syphilis, VDRL	Non-Reactive	-	2 – 8 °C
Syphilis, TP	Non-Reactive (<1:80)	-	2 – 8 °C
Malaria Parasite	Not seen	-	2 – 8 °C

Please contact our laboratory or your assigned clinician service personnel if other item(s) information required.

LABORATORY'S POLICY ON CONFIDENTIALITY OF PATIENT INFORMATION

1. Gnosis is committed to ensuring the confidentiality of all patient data and sensitive information. The following summarize how we handle patients' results: -

    a. Patient results are only telephoned to the ordering clinician or authorized/designated employees within the originating clinic or healthcare facility.

    b. Patient results must only be faxed to designated fax numbers as provided by clinician

    c. Electronic results sent via email are transmitted in an encrypted format to designated addresses

    d. Access to patients' results on the Laboratory Information Management System is restricted to certain staff and is password protected

    e. Hard copy reports are placed in closed folders or envelopes before being send to originating clinic or ordering physician.

    f. Sensitive results (where known esp HIV reactive, Western Blot etc) are handled with extra precaution. with results sent to the ordering physician in a sealed envelope if the ordering physician is still routinely receiving paper copies of results.

    g. Once the report is successfully sent and acknowledged receipt by the requestor, it is considered the property to the requestor. Kindly manage it by following standard guideline/Act. e.g. PDPA 2010. **Do not attempt to recycle the unused Laboratory report for any purposes.**

    h. As a general rule if there is any uncertainty regarding the confidentiality of any patient's results the query should be referred to Quality Manager and Technical Managers.

LABORATORY's COMPLAINT PROCEDURE

1. GNOSIS Laboratories Sdn. Bhd, has a systematic, accessible and impartial process for dealing efficiently and effectively with concerns or complaints to ensure that any issues raised are dealt with promptly and fairly, We are committed to using feedback from complaints and concerns in a positive way by listening to our users and learning lessons from their experiences, as this is a welcome and valuable source of feedback which can be used to improve the quality of the laboratory services offered. Kindly refer to our laboratories contact numbers and location as above.

2. We will always work hard to resolve your concerns as quickly as possible and to your satisfaction, but if we fail to do so, the complainant may wish to make a formal complaint. Any concerns or complaints should initially be referred to our Area Managers or to the Quality Manager who will listen to the details of the complaint, initiate an appropriate investigation, collate the evidence needed to respond appropriately, and formulate remedial, corrective and/or preventative action to address any underlying sources of service deficiency or failure.

3. We seek to resolve all complaints as quickly and efficiently as possible. Any formal complainant will receive an initial response within three working days and we will aim to resolve the complaint within 30 working days of receipt.