

# **Guide to Laboratory**

# Services

MediLabz Sdn Bhd.

June 2023

#### **OVERVIEW**

MediLabz Sdn Bhd is a start-up diagnostic private laboratory which began operation in June, 2021, with four (4) branches:

#### 1.1 Kelantan Branch:

Pt2507, Ground Floor, Taman Kenangan, Jalan Hospital, 15200 Kota Bharu, Kelantan. Operating Hour: Sunday-Friday (8.00 am -6.00 pm)

Contact Details: 09-747 0683

#### **1.2 Johor Branch:**

118, Jalan Serampang, Taman Tebrau Jaya, 80400 Johor Bahru, Johor. Operating Hour: Monday-Sunday (8.00 am -6.00 pm) Contact Details: 07-336 0683

#### 1.3 Penang Branch:

1, Lorong Setia Sentral 1, Pusat Perniagaan Setia Sentral, 14000 Bukit Mertajam, Pulau Pinang. Operating Hour: Monday-Friday (8.30 am -6.30 pm) Contact Details: 04-505 9045

#### 1.4 Selangor Branch:

22-1, Jalan PJU 5/21, Pusat Perdagangan Kota Damansara, 47810 Petaling Jaya, Selangor. Operating Hour: Monday-Friday (8.00 am -6.00 pm) Contact Details: 03-6145 0682

#### VISION

#### EMPOWERING INSIGHTS, IMPACTING HEALTH

To empower quick and accurate health insights to impact healthcare.

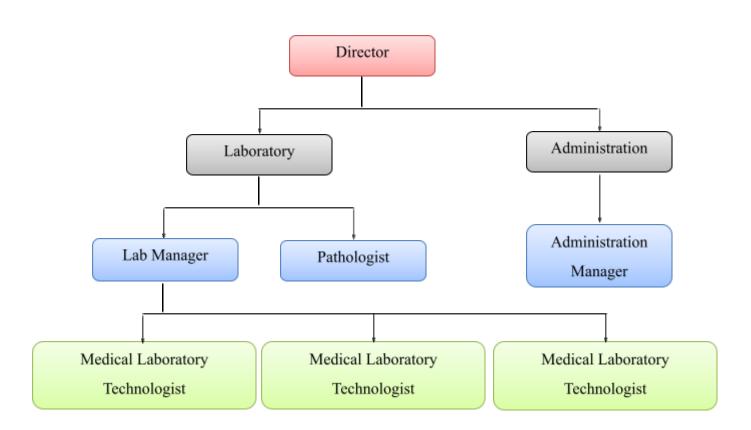
#### MISSION

- 1. We strive to provide innovative, timely and accurate insights of your wellbeing through reliable clinical laboratory testing.
- 2. We are passionate to serve the community by providing the highest quality of technical and clinical competence, aided by innovative and advanced tools.

#### **QUALITY POLICY**

MediLabz is committed to providing high quality medical laboratory service and products that consistently meet the needs and expectations of our clients. To achieve this, we have implemented a Quality Management System in compliance with ISO 15189 Medical Laboratories which serves as the basic foundation of our work standards.

#### **ORGANIZATIONAL CHART**



#### **QUALITY SERVICES**

Our laboratories provide a comprehensive range of tests for diagnostics and clinical services that include specimen collection and identification, sample processing and carrying out result and compliance for specimens with a good turn around time.

# **TYPES OF TESTS OFFERED**

We provide quality laboratory services in the following disciplines:

MOLECULAR TEST	
Pertussis (Whooping Cough)	Influenza A
Dengue Test	Influenza B
Chikungunya fever	H1N1
HIV-1 antibodies	Influenza A subtype H3N2
Tropical fever test	MERS-COV
Malaria	SARS-COV-2
Leptospirosis	Mycobacterium tuberculosis complex (MTBC)
Hepatitis B	Non-Tuberculosis mycobacterium
Hepatitis C	Hepatitis D
Zika virus	

RAPID TEST	
Chikungunya IgG/IgM Antibodies	Covid-19 Antigen
Covid-19 IgG/IgM Antibodies	Dengue
Influenza	Adenovirus and Rotavirus

# LIST OF MOLECULAR TESTS OFFERED

Influenza A (subtype H1N1 and H3N2)	
Description	Influenza A is a contagious viral respiratory disease that spreads through respiratory droplets and is characterized by fever, cough, sore throat and headache.

Specimen	Bronchoalveolar lavage, tracheal aspirates, sputum, nasopharyngeal or oropharyngeal aspirates or washes, and nasopharyngeal or oropharyngeal swabs Minimum Volume Required:1 mL
Transportation & Storage	Clinical specimens should be placed at 4 °C and transported to the laboratory promptly. Specimens received cold that are to be shipped within 48 hours should be stored refrigerated (2 °-8 °C); otherwise specimens should be frozen at or below -70 °C until shipped. Specimens may be extracted immediately or kept frozen at -20°C to -80°C.
Perform / Test Method	Per request/RT-PCR
LTAT (completion time - sample registration to result reporting)	24 Hours

Influenza B	
Description	Influenza B is a respiratory infection caused by flu viruses that is found exclusively in humans. Although type B flu may cause a less severe reaction than type A flu virus, it may occasionally still be extremely harmful.
Specimen	Bronchoalveolar lavage, tracheal aspirates, sputum, nasopharyngeal or oropharyngeal aspirates or washes, and nasopharyngeal or oropharyngeal swabs Minimum Volume Required: 0.5 mL
Transportation & Storage	Clinical specimens should be placed at 4 °C and transported to the laboratory promptly. Specimens received cold that are to be shipped within 48 hours should be stored refrigerated (2 °-8 °C); otherwise specimens should be frozen at or below -70 °C until shipped.
Perform / Test Method	Per request/RT-PCR
LTAT (completion time - sample registration to result reporting)	24 Hours

MERS-COV	
Description	This virus causes middle east respiratory syndrome (MERS). It is a human coronavirus associated with severe acute respiratory illness, including fever, cough, and shortness of breath in infected patients.
Specimen	Bronchoalveolar lavage, tracheal aspirates, sputum, nasopharyngeal or oropharyngeal aspirates or washes, and nasopharyngeal or oropharyngeal swab Minimum Volume Required:0.25 mL
Transportation & Storage	Transport on ice. Specimens may be extracted immediately or kept frozen at -20°C to -80°C.
Perform / Test Method	Per request/RT-PCR
LTAT (completion time - sample registration to result reporting)	24 Hours

SARS-COV-2 (Covid-19)	
Description	SARS-COV-2 is a virus that causes coronavirus disease 2019 (Covid-19) which led to a pandemic that affect globally. It is associated with three major patterns of clinical course of infection: mild illness with upper respiratory tract presenting symptoms; non-life-threatening pneumonia; and severe pneumonia with acute respiratory distress syndrome (ARDS) that starts with mild symptoms for about a week and then progresses to rapid deterioration and ARDS requiring advanced life support.
Specimen	Bronchoalveolar lavage, tracheal aspirates, sputum, nasopharyngeal or oropharyngeal aspirates or washes, and nasopharyngeal or oropharyngeal swabs collected in VTM tube.
Transportation & Storage	Transport on ice (2-8°C) with three layer packaging. Test Request form must be attached on the outside of ice box. Specimens may be extracted immediately or kept frozen at -20°C to -80°C.

Perform / Test Method	Per request/RT-PCR
LTAT (completion time - sample registration to result reporting)	24 Hours

Mycobacterium tuberculosis complex (MTBC)	
Description	The genus of Mycobacterium partly consists of the members of Mycobacterium tuberculosis complex which can cause tuberculosis (TB) with symptoms such as unexplained weight loss, fatigue, prolonged and persistent cough.
Specimen	Sputum, gastric lavage, and bronchial samples
Transportation & Storage	Transport on ice with three layer packaging. Unprocessed patient samples can be kept at 4°C for long-term storage.
Perform / Test Method	Per request/RT-PCR
LTAT (completion time - sample registration to result reporting)	24 Hours

Non-Tuberculosis mycobacterium (NTB)	
Description	The genus of Mycobacterium partly consists of more than 80 species of atypical mycobacteria. Non-tuberculosis mycobacterium is an opportunistic pathogen that can cause non-tuberculosis mycobacterium infection with symptoms such as fever, weight loss, night sweats and loss of energy. M. avium is the most common atypical mycobacteria that significant, when associated with acquired immunodeficiency syndrome (AIDS)
Specimen	Sputum, gastric lavage, and bronchial samples
Transportation & Storage	Transport on ice with three layer packaging. Unprocessed patient samples can be kept at 4°C for

	long-term storage.
Perform / Test Method	Per request/RT-PCR
LTAT (completion time - sample registration to result reporting)	24 Hours

Pertussis (Whooping Cough)	
Description	It is a highly contagious respiratory disease that is caused by bacterium <i>Bordetella pertussis</i> . This is a toxin-mediated disease that manifests symptoms similar to a common cold: runny nose, sneezing, mild cough, and low-grade fever.
Specimen	Aspiration or swabbing the posterior nasopharynx. Nasopharyngeal (NP) aspirates that flush the posterior nasopharynx with a saline wash are preferred over swabs because this results in a larger quantity of bacterial DNA in the sample Minimum Volume Required: 0.5 mL (nasopharyngeal aspirates)
Transportation & Storage	Unprocessed patient samples can be kept at 4°C for long-term storage. transport on ice 2-8 degrees.
Perform / Test Method	Per request/RT-PCR
LTAT (completion time - sample registration to result reporting)	24 Hours

Dengue Test	
	Dengue virus (DENV) is categorized into four serotypes, DENV1-4. All four dengue serotypes produce clinically

Description	similar symptoms, and all can cause dengue hemorrhagic fever and dengue shock syndrome in decreasing order of frequency: serotype 2, 3, 4 and 1.
Specimen	Whole blood/serum/plasma The blood should be collected in a red-top or tiger-top tube. After blood is allowed to clot, separate serum by centrifugation and keep refrigerated at 4 °C if shipped within 72 hours of collection; otherwise, specimen should be kept frozen at -20 °C. Citrate (collected in yellow top tubes) and heparin plasma (collected in green top tubes) can be tested by real-time polymerase chain reaction (RT-PCR) Minimum Volume Required: 0.5 mL (1.0 mL preferred) Note: Samples obtained during the first 5 days of illness are likely to contain viruses, whereas samples collected after 5 days of illness may contain antibodies against the virus.
Transportation & Storage	Serum or plasma samples are kept frozen at -20°C and sent on dry ice to the lab/ If dry ice is unavailable, the separated serum or plasma is maintained on ice or in a refrigerator within 2 hours before it is either frozen at -20°C or tested. Transport on ice 2-8 degrees
Perform / Test Method	Per request/RT-PCR
LTAT (completion time - sample registration to result reporting)	24 Hours

Chikungunya fever	
Description	Chikungunya virus (CHIKV) consists of three different strains: the East, Central and South African strain; West African strain; and Asian strain. It is transmitted by mosquitoes that causes sudden onset of fever, a characteristic rash, severe and incapacitating joint pain.
Specimen	-Serum or Blood collected in a serum separator (typically tiger/speckled-top). The blood should be allowed to coagulate and tubes should be spun to separate the serum from the clot prior to shipping -Plasma. If a red-top is used, the blood must be allowed to coagulate, the tube should be centrifuged and the serum drawn off into a clean tube prior to shipping. Heparin

	(green top) and EDTA (purple top) are unsuitable for chikungunya testing All specimens should be acute (0-7 days post onset date). Minimum Volume Required: 0.5 mL
Transportation & Storage	Serum or plasma samples are kept frozen at -20°C and sent on dry ice to the lab/ If dry ice is unavailable, it is the separated serum or plasma is maintained on ice or in a refrigerator within 2 hours before it is either frozen at -20°C or tested. Transport on ice 2-8 degrees.
Perform / Test Method	Per request/RT-PCR
LTAT (completion time - sample registration to result reporting)	24 Hours

Zika virus	
Description	Zika is spread mostly by the bite of an infected Aedes species that can be passed from a pregnant woman to her fetus which causes certain birth defects or it can be sexually transmitted. This viral infection can be range from asymptomatic to dengue-like symptoms such as fever, headache, arthralgia, conjunctivitis, muscle and joint pain, malaise and rash.
Specimen	-Serum: at least 1.0 mL is needed. Serum shall be transferred to a plastic tube measuring approximately 50 mm tall and 15 mm in diameter with screw cap and secure with a small piece of thermoplastic, self-sealing lab film -Plasma: Transportation and Storage: specimens should be kept cold at 2-8°C and for long term storage, kept at -70°C All specimens should be acute (0-7 days post onset date) Minimum Volume Required: 0.5 mL
Transportation & Storage	Serum or plasma samples are kept frozen at -20°C and sent on dry ice to the lab. If dry ice is unavailable, separated serum or plasma is maintained on ice or in a refrigerator within 2 hours before it is either frozen at -20°C or tested.
Perform / Test Method	Per request/RT-PCR

LTAT (completion time - sample	24 Hours
registration to result reporting)	

Tropical fever test	
Description	Tropical fevers were defined as infections that are prevalent in tropical and subtropical regions. Testing includes detection of <i>Leptospira</i> spp., <i>Burkholderia</i> <i>pseudomallei</i> , <i>Salmonella</i> spp. and <i>Plasmodium</i> spp. These infections are associated with animal contacts, vectors or contaminated environment.
Specimen	Whole blood. Collect using an EDTA tube. Collect within 10 days of illness onset. Minimum Volume Required: 0.25mL (whole blood)
Transportation & Storage	Specimens can be kept refrigerated at 4°C if shipped in less than 72 hours of collection; otherwise specimen should be kept frozen at -20°C.
Perform / Test Method	Per request/RT-PCR
LTAT (completion time - sample registration to result reporting)	24 Hours

Malaria	
Description	Malaria is a mosquito-borne disease that caused by intracellular parasite known as Plasmodium which infects the liver cells and red blood cells of its human host. There are several species that cause human malaria which are <i>P.</i> <i>Vivax, P. Falciparum, P. Ovale</i> and <i>P. Knowlesi.</i> Symptoms of malaria include fever and flu-like illness, including shaking chills, headache, muscles ache and tiredness usually begin 10-15 days after being bitten.
Specimen	Whole blood. Collect using a EDTA or sodium citrate tube. Minimum Volume Required: 0.2 mL
Transportation & Storage	Store blood samples at 4°C temporarily or at - 20°C or -80°C for long-term storage.

Perform / Test Method	Per request/ Real time/nested PCR.
LTAT (completion time - sample registration to result reporting)	24 Hours

Leptospirosis	
Description	Leptospirosis is a blood infection caused by the bacteria <i>Leptospira</i> (pathogenic spirochetes) that is typically transmitted to humans through water or soil contaminated by the urine of infected animals or by direct contact with affected animals. Leptospires enter the broken skin or the mucous membrane and disseminate into the organism. Signs and symptoms can range from none to mild (headache, muscle pains and fever) to severe (bleeding in the lungs or meningitis).
Specimen	Whole blood. Collect using an EDTA or sodium citrate tube. Urine. Collect in a universal bottle
Transportation & Storage	Whole Blood : If the samples are not processed immediately, they should be frozen at -20°C or -80°C and shipped on dry ice. Urine : If the samples will not be processed immediately, they should be pelleted down and stored at -20°C or -80°C. To pellet down, centrifuge 1 mL urine sample at 13,000 xg for 30 mins. Discard the supernatant, then add again 1mL of urine sample to the pellet and centrifuge at 13,000 xg for 30 mins. Repeat this step for the third time.
Perform / Test Method	Per request/ Leptospira DNA detection. Nucleic acid extraction, PCR amplification and detection.
LTAT (completion time - sample registration to result reporting)	1-5 days upon receipt at the reference laboratory.

# HIV-1 antibodies

Description	HIV-1 is the virus that causes AIDS. Symptoms of an HIV-1 infection are flu-like and also include fever, sore throat, muscles and joint aches.
Specimen	Plasma in EDTA (centrifuged within 6 hours of collection) Minimum Volume Required: 1mL plasma or serum (1.5mL preferred)
Transportation & Storage	Shipment of serum or plasma stored at 2-8°C within 7 days of collection should be on cold pack and frozen specimens on dry-ice. Freeze (-70°C is optimal, -20°C acceptable) sera/plasma as soon as possible after separation.
Perform / Test Method	Per request/ RT PCR.
LTAT (completion time - sample registration to result reporting)	1 - 2 days, but additional time should be allowed for the testing schedule.

Hepatitis B	
Description	Hepatitis B is a serious liver infection that causes inflammation that can lead to liver damage. Symptoms may be minor to intense and may include mild fever, having yellow skin or eyes (jaundice), stomach pain and loss of appetite.
Specimen	Plasma (EDTA) (preferred) or serum (plain tube). Separate serum from the clot within 6 hours of collection Minimum Volume Required: 2 mL
Transportation & Storage	Specimens should be kept frozen at -20 °C. Specimens can be kept refrigerated at 4 °C if shipped in less than 72 hours of collection.
Perform / Test Method	Per request/ RT PCR.
LTAT (completion time - sample registration to result reporting)	7 days

Hepatitis C				
<b>Description</b> The hepatitis C virus is the cause of hepatitis some cancers such as liver cancer and lympho humans.				
Specimen	Serum or EDTA Plasma Minimum Volume Required: 2 mL			
Transportation & Storage	Plasma frozen, -20°C to -80°C. Plasma or whole blood (EDTA) may also be transported at 2-8 °C.			
Perform / Test Method	Per request/ RT PCR.			
LTAT (completion time - sample registration to result reporting)	7 days			

Hepatitis D				
<b>Description</b> Hepatitis D is an infection that causes the litbecome inflamed. This swelling can impair function and cause long-term problems.				
Specimen	Serum or EDTA Plasma Minimum Volume Required: 2 mL			
Transportation & Storage	Specimens should be kept frozen at -20 °C. Specimens can be kept refrigerated at 4 °C if shipped in less than 72 hours of collection.			
Perform / Test Method	Per request/ RT PCR.			
LTAT (completion time - sample registration to result reporting)	7 days			

# LIST OF RAPID TESTS OFFERED

Rapid tests are tests that can be done in a short period of time so that the results can be given to the patient while they are still at the centre. Rapid tests can be performed for HIV, syphilis and malaria according to national guidelines.

Chikungunya IgG/IgM Antibodies				
Description	Chikungunya virus (CHIKV) consists of three different strains: the East, Central and South African strain; West African strain; and Asian strain. It is transmitted by mosquitoes that causes sudden onset of fever, a characteristic rash, severe and incapacitating joint pain.			
Specimen	Serum			
Transportation & Storage	<ul> <li>For serum separator tubes: centrifuge sample prior to placing in biohazard bag.</li> <li>Place each specimen type in an individual biohazard bag and seal. Insert the corresponding requisition in the pocket on the outside of each sealed biohazard bag.</li> <li>Clotted blood/serum specimens should be stored at 2-8°C following collection and shipped to the lab on ice packs.</li> </ul>			
<b>Rejection Criteria</b>	Hemolyzed, icteric, lipemic or microbially contaminated serum or plasma are not recommended for testing.			
Perform / Test Method	Per request/ Rapid Test			
LTAT (completion time - sample registration to result reporting)	24 Hours			

Covid-19 Antigen				
Description	Antigen tests are immunoassays that detect the presence of specific viral antigen, which implies current viral infection.			
Specimen	Nasopharyngeal swab, oral fluid			
Transportation & Storage	The sample should be sent in a plain container (in ice box) and not in VTM.			
<b>Rejection Criteria</b>	Heavily blood stain swabs shall be rejected as it may give false results.			

Perform / Test Method	Per request/ Rapid Test Antigen Testing. The specimens are placed directly into the assay's extraction buffer.
LTAT (completion time - sample registration to result reporting)	30 Min - 1 Hour

Covid-19 IgG/IgM Antibodies				
Description	Covid-19 antibody testing is done to determine previous infection of SARS-COV-2.			
Specimen	Blood (EDTA)			
Transportation & Storage	In an ice box.			
<b>Rejection</b> Criteria	Insufficient volume, inappropriate sample type.			
Perform / Test Method	Per request/ Rapid Test Antibody Testing.			
LTAT (completion time - sample registration to result reporting)	30 Min - 1 Hour			

Dengue Antigen					
Description	Dengue fever is a viral infection transmitted to humans by mosquitoes that live in tropical and subtropical climates and carry the virus. Blood testing detects the dengue virus or antibodies produced in response to dengue infection.				
Specimen	Whole blood, serum, plasma. Red top tube, 0.5ml.				
Transportation & Storage	If shipment will be delayed within 7 days, freeze serum specimens until shipment on dry ice				
Rejection Criteria	Insufficient volume, inappropriate sample type.				
Perform / Test Method	Per request/ Rapid Test, Detection: IgG and IgM antibodies.				
LTAT (completion time - sample registration to result reporting)	24 - 48 Hours				

Influenza				
Description	This rapid test is for the qualitative detection of influenza A and I viruses in the nasal swab, throat swab and nasal aspirate as an aid in the diagnosis of influenza infection.			
Specimen	Nasal swab, throat swab and nasal aspirate.			
Transportation & Storage	Transport cold on ice packs within 4 days of collection or freeze at - 70° C and ship on dry ice.			
<b>Rejection</b> Criteria	Specimen collected with a non-approved swab. Duplicate specimen collected: collected the same day.			
Perform / Test Method	Per request/ Rapid Test, Test is performed by applying the extracted sample to the sample well of the cassette and observing the formation of colored lines. Detection: Influenza A virus, Influenza B virus.			
LTAT (completion time - sample registration to result reporting)	24 Hours			

Adenovirus and Rotavirus				
Description	This test is a rapid immunochromatographic test for qualitative detection of adenovirus and rotavirus in human feces samples. The test utilizes specific antibodies to selectively detect the respective viruses.			
Specimen	Feces			
Transportation & Storage	Put the container in a sealed plastic bag. Stool samples should be transported cold and stored immediately at 2–4°C upon arrival.			
<b>Rejection Criteria</b>	Unlabelled samples, leaky container, delayed transport time and duplicate samples received on the same day are unacceptable and should not be processed.			
Perform / Test Method	Per request/ Rapid Test, The test is performed by applying the patient sample to the sample well of the cassette and observing the formation of colored lines. Detection: Adenovirus and rotavirus			
LTAT (completion time)	24 Hours			

# PATIENT PREPARATION AND INFORMATION

Preparation prior to sample collection should be informed to the patient as to fulfill the need of sample integrity such as fasting, special dietary consumption, or other requirements. For self-collection samples (eg: urine), the patients should be provided with a specific instruction and sample container.

Patients should be addressed with their full name and identification number such as IC or given Lab ID from the lab that will also be labelled to their respective collected sample. All the information is recorded and documented in the system. Sample labelling should be done in the presence of the patient him/herself. Consent letter should be filled up by the patient for confidential tests such as HIV testing.

Medilabz Sdn. Bhd.				Medilabz So	In. Bhd.		
Request for examination		Rev.	SD/01 No. 00	1	Request for examination		F/CSD/02 Rev. No. 00 Page No. 1 of 1
KELANTAN BRANCH PT207, Ground floor, Taman Kenangan, Jalan Hospital, I20 Kota Bharu Kelantan Teë Ote-47973 JOHOR BRANCH 118, Jalan Serampang, Taman Tebrau Jaya, 80400 Johor Bahnu, Johor		Page No LAB ID			KELAMTAN BRANCH PTR07, Ground For, Taman Kenangan, Jalan Hospital, 120Ko ta Bharu Kelantan Tel: 0164 4879330 JOHODE BRANCH 118, Jalan Serampang, Taman Tebrau Jaya, 80400 Johor Bahru, Johor. Tel: 016-4879330	LAB The specimen request forr with the sp	m must be accompany
Tel: 016-4879330		with the specimen			PATIENT INFORMATION	TEST REQ	UEST
PATIENT INFORMATION		TEST REQUEST			PATIEN T ID:	MOLECULAR TEST	SAMPLE X
PATIENT ID:	MOLECULAR	SAMPLE	x		FULL NAME:	Influenza A (H1N1/ H3N2	) BAL/ TASP/ SP/ NASP/ NWS/
FULL NAME:	TEST				BIRTH DATE: GENDER: F M	Influenza B	OASP/ OWS/
BIRTH DATE: GENDER: F M		Bronchoalveolar lavage			PHONE NUMBER:	MERS-COV	NSB/ OSB
PHONE NUMBER:		Tracheal aspirates	-		ADDRESS:	MTBC	SP/ GAL/ BRC
ADDRESS:	1	Sputum Nasopharyngeal aspirates	-			NTM	SP/ GAL/ BRC NASP-P/NSB-P
	SARS-COV	Nasopharyngeal washes	·		MEDICAL FACILITY	Pertussis	EDTA/PT
MEDICAL FACILITY	SARS-COV	Oropharyngeal aspirates	+		CENTRE:	Dengue Chikungunya	EDTA/PT
		Oropharyngeal washes	+	1		Zika	EDTA/ PT
CENTRE:		Nasopharyngeal swabs	+		REPORTING PHYSICIAN :	Tropical fever	EDTA
REPORTING PHYSICIAN :		Oropharyngeal swabs	+	1	PHONE NUMBER:	Malaria	EDTA/ SC
PHONE NUMBER:	RAPID TEST	SAMPLE	x		EMAIL:	Leptospirosis	EDTA/ URINE
EMAIL:	RAPID TEST		-	1	ADDRESS:	HIV -1 A/B	EDTA/ PT
ADDRESS:	COVID-19	Nasopharyngeal swabs	-		ADDRESS.	Hepatitis B	EDTA/ PT
ADDRESS:	ANTIGEN	Nasal swabs				Hepatitis C	EDTA/ PT
		Deep throat saliva/ Sputum	<u>۱</u>		CLINIC STAMP	Hepatitis D	EDTA/PT
CLINIC STAMP	CO VID-19	EDTA Tube			AND DOCTOR	RAPID TEST	SAMPLE X
AND DOCTOR	ANTIBODY	Plain Tube			SIGNATURE :	Chikungunya A/B	EDTA/ PT
SIGNATURE :	*Kindly circle sa	mple type accordingly		-	SPECIMEN	Mycoplasma Pneumonia	e EDTA
SPECIMEN					SPECIIVIEN	Zika	EDTA/ PT
CLINICAL HISTORY:	RECEIPT	VERIFIED BY			CLINICAL	Influenza	NASP/ NSB
COLLECTED BY:					HISTORY:	Adenovirus/Rotavirus	STOOL
TIME/DATE OF COLLECTION:					COLLECTED BY:	Dengue A/B	EDTA/ PT
					TIME/DATE OF COLLECTION:	Dengue A/G	EDTA/PT
SAMPLE STATUS: FASTING NON FASTING					SAMPLE STATUS: FASTING NON FASTING	*Kindly circle sample type	e accordingly
URGENT : YES NO	MLT	LAB MANAGE	ER		URGENT : YES NO	RECEIP T BY:	VERIFIED BY :
					Bronchoalveolar Javage (BAL), Tracheal sopirates (TASP). Sputum (RF), Na ophangeal aspirates (IVASP). Natophangeal washte (IVASS). Orophange aspirates (OSSP). Orophangeal washte (OVA). Natophangeals wash (SB). Orophangeal washte (SB). (Sa stric Lawge (GAL), Bronchal samples (BRC), Appiration posterior masphangen (NATSP -/), Swabiting orapication ras sophangen. (SB: PF), Nasal swab(NASB), EDIA Tube (EDTA), Plain Tube (PT), Sodium Otraa Vashter().		LAB MANAGER

# **TEST REQUISITION FORM**

All specimens sent shall be attached with the Test Requisition Form that contains essential information as listed below:

#### i. Patient Information

Kindly fill in the patient's full name with NRIC (or Passport), patient's date of birth & gender, phone number and address for accurate sample identification with the patient and result reporting particulars.

#### ii. Medical Facility

Do provide us the name of the medical facility, phone number, address signature of the requesting doctor, and clinic stamp for us.

#### iii. Specimen

Please write the type of specimen taken, date and time specimen was taken from the patients for proper results evaluation. Write down the name of personnel collecting specimens as well. Please indicate whether the patient has been fasting/not fasting before the test and indicate if the results for this test(s) are needed urgently by ticking the URGENT box. For 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.

#### iv. Test

Please tick the relevant test in the provided box using 'X' mark.

#### v. Lab ID

This field will be used by our Lab Personnel for barcodes and assigning Lab ID. Leave the section blank.

#### **TEST REQUEST AND CANCELLATION**

We will respond immediately to **urgent requests** during our routine hours. Please tick the urgent box on the request form. To arrange urgent specimen collection, please call us at the number provided in this service guide.

Additional or follow-up tests can be ordered on previously submitted specimens as long as there is sufficient volume and the specimen is in viable condition. Written verification must be provided by filling up the request form with an appropriate note. Please call the laboratory to enquire about the condition of the specimen before ordering an additional or follow-up test.

# COLLECTION AND HANDLING OF SPECIMEN

Proper specimen collection and handling is vital in obtaining accurate and precise laboratory test results. Specimens must be obtained using proper techniques and guidelines. Medilabz reserves the right to reject specimens when there is failure to comply with these guidelines.

# **General Guidelines**

- Identify the patient prior to specimen collection, using at least two patient identifiers and label at the specimen container.
- Select specimen containers suitable to requested test and use sterile containers and aseptic technique to obtain specimen.
- Collect the correct type and an adequate amount of specimen.
- Clearly label specimen containers with waterproof ink at the point of specimen collection, place in a biohazard plastic bag and attach a Test Requisition Form.
- All specimens from high risk patients (HIV, Hep B, TB, and others) must be clearly marked as high risk
- Indicate the source of specimens on containers for anatomical pathology and microbiology specimens.
- Do not pre-label the empty specimen containers before attend to the patient
- Swabs shall be transported in suitable media
- Transport specimens to the lab as soon as possible and preferably within the same day.

# **Special Instructions**

# A. BLOOD COLLECTION

Laboratory tests are performed on anticoagulated whole blood, plasma or serum. Practicing proper phlebotomy techniques need to be implemented in order to ensure accurate test results:

1. Tourniquets should not be left for more than 1 minute to prevent haemolysis. Hemoconcentration condition prompt to happen in prolonged tourniquet time may whereby there will be blood pooling at the venipuncture site. Hemoconcentration shall cause falsely elevated results, mostly in the potassium level.

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 an EDTA/Heparin/Fluoride anticoagulant tube prior to transferring blood into a Plain tube, definitely will cause anticoagulant contamination into the needle.

Order of Draw

- Blue cap (sodium citrate)
- Red cap (Plain tube)
- Yellow cap (Serum Separator Tube)
- Green Cap (Heparinized tube)
- Purple cap (EDTA tube)
- Royal Blue cap
- 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. Blood Collection Procedure
- Label the tube correctly as following:-
  - Patient's full name
  - Patient's IC number / Passport number.
  - Perform the venipuncture, collecting the sample(s) in the appropriate container(s). The date and time of collection must be indicated on the Test Requisition Form.
- a) Collect in a vacuum tube containing spray coated K2 ethylenediamine tetra acetic acid (EDTA–an anticoagulant and preservative plastic) or K3 EDTA (glass) or a CD4 stabilization tube (if the time to testing will be >72 hours).
- b) Draw this specimen last if drawing multiple tubes. Fill the tube until no additional blood can be drawn in.
- c) Use paediatric tubes for collecting specimens from infants and young children.
- d) Fill up the citrate and EDTA specimens to the volume mark available on the tube to ensure the correct anticoagulant to specimen ratio.

- e) Mix the tube well right after collection by inverting the specimen tubes to stop blood clots from forming. Avoid vigorous shaking to prevent blood specimen haemolysis.
- f) Secure all specimen containers' caps to prevent leakage and cross contamination.
- g) Keep the tube at room temperature (20-25°C) until it is transported to the testing lab.
- h) Avoid drawing blood below or from the infusion side to prevent dilution of blood specimens.

#### **PREVENTION OF HAEMOLYSIS**

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

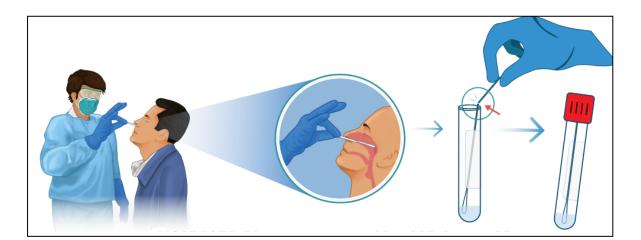
A 21-gauge needle is recommended for collection of blood using non-vacutainer tubes. There is a greater likelihood of haemolysis with smaller gauge needles.

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

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

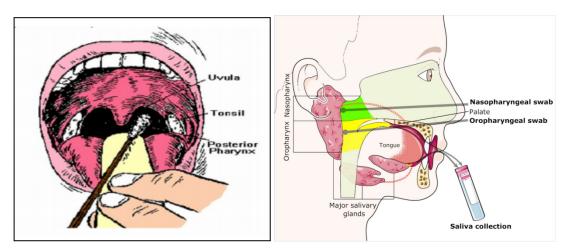
After collecting blood into the blood tube containing anticoagulant, immediately invert the capped blood tube gently for several times to allow blood mixing with anticoagulant thoroughly to prevent clotting. Do not shake the blood tube vigorously as this may cause haemolysis.

#### B. SWAB



Nasopharyngeal Swab Procedure:

- 1. Use a flexible fine-shafted swab designed for sampling the nasopharyngeal mucosa. Swabs with plastic shafts and tips of synthetic material such as Rayon or Dacron are highly recommended
- 2. Tilt patient's head back 70 degrees.
- 3. Gently insert the swab into the patient's nostril until resistance which indicates nasal mucosa is encountered or the distance is equivalent to that from the ear to the nostril of the patient.
- 4. Leave in place for a few seconds.
- 5. Slowly withdraw the swab with a rotating motion.
- 6. Insert swab, tip first, into a vial containing 2-3 ml of Viral Transport Medium and cut the shaft.



Oropharyngeal Swab Procedure:

- 1. Depress the tongue
- 2. Insert swab into posterior pharynx and tonsillar areas.
- 3. Rub swab back and forth over posterior oropharynx behind the tonsils.
- 4. Avoid touching the tongue and nostrils.
- 5. Insert swab, tip first, into a vial containing 2-3 ml of Viral Transport Medium and cut the shaft.

Lower Respiratory Tract - Sputum, bronchoalveolar lavage, tracheal aspirate:

- Collect 3–5ml specimen into a sterile, leak-proof, screw cap container.
- For sputum specimen, patient needs to rinse mouth with water and then expectorate deep cough sputum into the container instead of saliva.
- If required, educate the patient on the difference between sputum and saliva.

# **SPECIMEN STORAGE**

# I. 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

#### **II. 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 ( $<25^{\circ}$ C).

NOTE: PLEASE DO NOT STORE UNSPUN SERUM/PLASMA TUBES IN REFRIGERATOR. TUBES MUST BE CENTRIFUGED BEFORE STORAGE TO ENSURE SPECIMEN INTEGRITY.

Please do not send samples that are not urgent after normal office hours.

# SPECIMEN TRANSPORT

- On normal working days, our courier will make the routine specimen collection twice a day in the morning and afternoon.
- If these hours are not suitable for you, kindly contact us to set up a different arrangement for routine specimen collection.
- If specimens cannot be delivered to the laboratory immediately, please keep specimens under a suitable temperature.

Specimen Type	Container	Storage and Transportation	Precaution
<b>Respiratory</b> <b>Tract,</b> <b>Upper</b> Nasal Oral Throat	Cotton/Dry/Rayon Dacron Swab Both swabs in one VTM and fully immersed	If transportation is within 72 hours, store at $2^{\circ}$ C - $8^{\circ}$ C and transport in ice. If transportation is more than 72 hours, store in between -20°C to -80°C.	Not applicable
Respiratory Tract, Lower Sputum, Bronchial, Alveolar Lavage, Bronchial Lavage, Bronchial Aspirate, Bronchial Washing, Nasopharyngeal	Sterile Leak-Proof Container		Specimens must be brought to the laboratory as soon as possible after collection.

Aspirate, Trachea Aspirate			
Gastrointestinal Tract Fecal specimens	Sterile Leak-Proof Container	Refrigerate at 2°C-8°C	All stool specimens must be brought to the laboratory as soon as possible
Urine	Sterile urine container	Refrigerate at 2°C-8°C. If delay is expected, keep in the refrigerator at 4°C for a maximum of 24 hours.	Send samples to the lab immediately in ice packs.
Plain Serum/Edta Plasma	Plain Tube/EDTA Tube	Refrigerate serum/plasma at 2°C-8°C for 3 days. Freeze serum/plasma in -20°C or cooler if more than 3 days	Not applicable

# SPECIMEN REJECTION CRITERIA

To ensure good analytical results, our laboratory personnel will inspect the condition of specimens received. Inappropriate specimens or test requests will be rejected based on the following criteria:

# 1. Unsuitable sample condition

Such conditions could be clotted EDTA/Citrate specimen, haemolysed sample or collection swab has dried out for microbiology specimens. 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 Lab Manager who will then advise whether the degree of hemolysis will significantly interfere with the particular test requested

# 2. Broken / Leaking / Inappropriate containers

Example are specimen received in unsuitable containers e.g. blood still in syringe and citrate tube is not correctly filled

# 3. Inadequate / Incorrect amount of specimen

# 4. Improper packaging

Improper packaging that is used for transporting the specimen will affect the sample integrity and stability which causing wrong lab test result

# 5. Sample without accompanying Test Requisition 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.

# 6. Test Requisition Form with missing information

# 7. Wrong usage or Expired collection container for specimen collection

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

# 8. Discrepancies between specimen and request form

The party that wrongly collects specimen type for requested test is 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.

# 9. Unlabeled 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

Specimen rejection will be notified by phone to discuss the appropriate corrective actions. A follow-up Specimen Request Form will be sent to the referring party.

Specimen Type	Rejection Criteria	Precaution
<b>Respiratory Tract</b> (Upper) Nasal Oral Throat	Swab without VTM Swab using calcium alginate swabs type and swabs with wooden or aluminum shafts and/or cotton tips as these are potentially inhibitory. They may impair the PCR and in the worst case lead to false negative results. The usage of bacteriological swabs containing jelly agar is unsuitable.	Not applicable
Respiratory Tract	Salivary sample	To ensure sampling quality is not

(Lower) Sputum, Bronchial, Alveolar Lavage, Bronchial Lavage, Bronchial Aspirate, Bronchial Washing, Nasopharyngeal Aspirate, Trachea Aspirate		affected, patient should refrain from drinking, eating or gargling for at least 30 minutes before sampling.
Gastrointestinal Tract Fecal specimens	Not applicable	Do not scoop specimen from the toilet bowl. Do not freeze specimen prior to testing.
Urine	Insufficient specimen	Ensure to collect 1st void urine Send samples to the lab immediately in ice packs. If delay is expected, keep in the refrigerator at 4°C for a maximum of 24 hours.
Plain Serum/EDTA Plasma	Lysed specimen	Not applicable

# FACTOR AFFECTING RESULTS

1. Incorrect Order of Draw

Lithium heparin, ammonium heparin or sodium heparin are the additives that act as anticoagulants in the blood tube which will contaminate and interfere with the result if order of draw is violated. EDTA contamination occurs when the blood is drawn into EDTA tubes first before other tubes

2. 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. Besides, the blood should not be collected on the same vein where drug IV is given and the pace should not be too slow to prevent clotting and too fast to prevent haemolyse.

# SAMPLE LABELLING AND PACKAGING

- Specimens that are collected should be put in hazard bag that is double bag to prevent the requisition form from getting wet if any leakage happens.
- Place specimens in the inner pocket of the specimen carrier bag and seal the zip.
- Place the Test Requisition Form at the outer pocket of the specimen carrier bag.
- Promptly send the specimens with the Test Requisition Form to the laboratory.
- Place the request form and specimen containers, from a single patient, in an individual specimen. Do not combine different patients' samples in the same bag.
- For Anti-HIV1/HIV2 (Human Immunodeficiency Virus) test, please indicate the patient's Nationality, NRIC Number (for resident) or Passport Number (for non-resident) on the request form.

Please note that a minimum of 5mL plain/SST blood is required for HIV testing.

If the patient is a foreign national, you are required to indicate whether the patient

(a) is a Singapore permanent resident; OR

(b) holds a work permit, long term social visit pass or a student pass; OR

(c) is applying for a work permit, long term social visit pass, student pass or permanent residency

Equivocal/Reactive results will be sent to the National HIV Reference Laboratory (subject to additional charges) as stipulated by MOH regulations.

- For Malaria Parasites (MP) test, please indicate the patient's Nationality on the request form as stipulated by the Ministry of Health (MOH).
- For Dengue NS1 Antigen, or Dengue Blot (IgG & IgM Antibody) test, please indicate the patient's address on the request form as stipulated by the National Environment Agency.

Specimens tested need to be sent in a way that protects them from high or low temperatures and/or humidity. They should be packed to protect both the specimens and the people transporting them

- Packaging of specimens for shipment must be designed to minimize breakage such as in ice box or bag.
- Ensure the samples are tightly capped and no leakage may happen.
- Rough handling of blood specimens may cause haemolysis and compromise test results.
- Transfer of specimens to the laboratory should occur within as short a time period as possible.

# **RESULT REPORTING**

- All test results will be computer printed/email 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 range which are appropriate for the patients, age and sex.

• Summary comment and clinical interpretation by Pathologist will be included for clinical significant results

#### a) URGENT RESULTS

Urgent results will be reported to the requesting clinician via phone call/fax as provided on the test requisition form. A printed report will follow

#### **b) ROUTINE TEST**

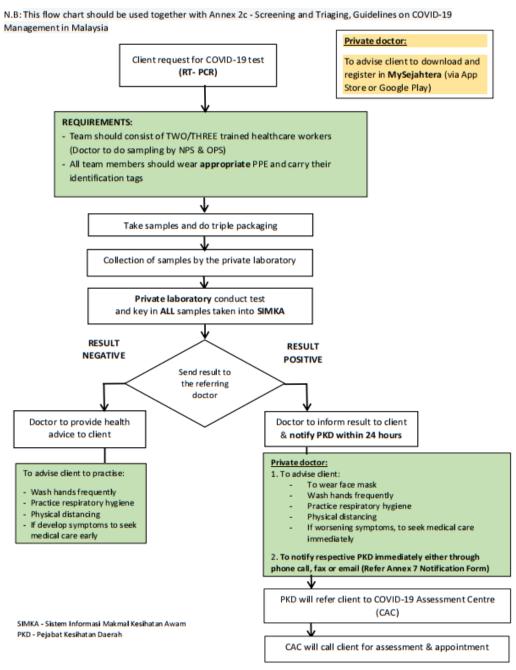
Laboratory reports are usually completed within 24 hours upon specimen receiving. Quantitative laboratory results will be reported together with reference ranges to the requesting clinician.

#### c) SPECIAL REQUEST TEST

Reports are usually completed within 24 hours upon specimen receiving except for tests that are required to run in batches. For further inquiry regarding the turnaround time, please contact the respective laboratory.

# **Appendix**

Appendix 1.1: Flow Chart For Sampling Of Covid-19 By Private Health Facilities



FLOW CHART FOR SAMPLING OF COVID-19 BY PRIVATE HEALTH FACILITIES

Ministry of Health Malaysia Updated 15 February 2021 Appendix 1.2: Workflow : Rejection of Test Request

