



# GUIDELINES FOR THE IMPLEMENTATION OF **THE HIV SELF-TESTING IN MALAYSIA**



**PUBLISHED BY**

Disease Control Division  
Ministry of Health Malaysia

December 2023  
First Edition

# THE GUIDELINES FOR THE IMPLEMENTATION OF THE HIV SELF-TESTING IN MALAYSIA

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## Foreword

The Guidelines for the Implementation of HIV Self-testing in Malaysia has been published for the first time, and this is another effort made by the Ministry of Health Malaysia to enhance the HIV testing program in Malaysia.

Malaysia has faced the HIV/AIDS epidemic for three decades since the detection of first case in 1986. The change in the HIV infection landscape from needle-sharing to sexual transmission has made the disease prevention and control challenging. The rising trend in HIV infection amongst the youth is worrying, as approximately 77% of reported cases involved youths aged from 20 to 39 years.

The latest data also shows that almost 40% of HIV patients were diagnosed late with very low CD4 counts below 200 cells/mm<sup>3</sup>. Only 82.2% of people living with HIV were diagnosed and knew their HIV results. Although 66.2% of them received antiretroviral therapy (ART), only 85% achieved viral load suppression (Malaysia Progress Report on Global AIDS Monitoring 2022). Stigma and discrimination have also affected the uptake of HIV screening tests at health facilities and treatment seeking.

Therefore, HIV detection through the scale-up of screening tests is the first step to achieving the '95-95-95' target of ending AIDS by the year "2030". The World Health Organization (WHO) has recommended that **HIV Self-Testing (HIVST)** be implemented to increase access to HIV testing and complement existing screening services.

We hope that all health personnel at both government and private health facilities, NGO community workers, and any related medical device suppliers will benefit from the Guidelines for the Implementation of HIV Self-testing in Malaysia. This will enhance the country's HIV screening test program. Last, I would like to thank all parties involved in developing the guidelines.

Thank you.

**DATUK DR. MUHAMMAD RADZI ABU HASSAN**

Director General of Health  
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## *Preface*

Ministry of Health Malaysia has launched several initiatives to address HIV/AIDS infection in the country since the first case was detected in 1986. One of which is the introduction of HIV self-testing (HIVST) as a critical approach for testing and treating HIV/AIDS. This initiative aims to encourage a larger segment of key populations and their partners to undergo screening and receive necessary treatment, which is in line with the global target to end AIDS by 2030.

In 2022-2023, the Ministry of Health Malaysia held a series of meetings and workshops to produce the first edition guideline and standardise the implementation of online HIV self-testing initiatives. Participants included representatives from the Disease Control Division, the Malaysian Medical Device Authority, the National Public Health Laboratories, the Institute of Medical Research, the Family Health Development Division, the Pharmacy Practise and Development Division, the State Health Department, the Malaysian Pharmacy Society and Non-Governmental Organisation namely the Malaysian AIDS Foundation.

The Disease Control Division has put much effort into ensuring the accuracy and completeness of this guideline document. The Disease Control Division also reserves the right to amend the guideline document.

This guideline document shall be read in conjunction with the Guideline on the placement of HIV-self test (HIVST) kits in the Malaysia market prepared by Medical Device Authority, Ministry of Health Malaysia, dated 24 August 2023, first edition.

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## *Acknowledgement*

Thank you to all those who have contributed directly or indirectly to making the publication of these guidelines a success.

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## *Abbreviations and acronyms*

ARV	Antiretroviral (drugs)
CHW	Community Health Worker
HIV	Human Immunodeficiency Virus
HIVST	HIV Self-Testing
MOH	Ministry of Health Malaysia
MAF	Malaysian AIDS Foundation
MDA	Medical Device Authority
NGO	Non-Governmental Organization
PLHIV	People living with HIV
PEP	Post-Exposure Prophylaxis
PrEP	Pre-Exposure Prophylaxis
RDT	Rapid Diagnostic Test
WHO	World Health Organization

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# **GUIDELINES FOR THE IMPLEMENTATION OF HIV SELF-TESTING IN MALAYSIA**

## **1. PURPOSE**

- 1.1 The purpose of this guideline is to explain the necessity for implementing the program, objectives, target groups, general policies, guiding principles, test-kit criteria and standards, procedures for conducting the HIV self-testing, as well as the steps to be taken after interpreting the results. The overall goal is to increase the uptake of HIV testing among those at risk and facilitate linkage to prevention services, treatment and care.
- 1.2 This guideline is intended to be used as a reference guide for healthcare providers in public and private health facilities. It must also be used by community pharmacies, community-based organisations, non-governmental organisations (NGOs) and any medical device suppliers who will assist in providing services related to HIV-self testing in Malaysia.

## **2. BACKGROUND**

- 2.1 Since the first case was detected in 1986, Malaysia has been dealing with the HIV/AIDS epidemic for thirty years. Prevention and control efforts in Malaysia have become more challenging due to the changing landscape of HIV transmission, which has moved from needle-sharing to sexual transmission. The increasing trend of HIV infections among youth is becoming a growing concern, with an approximately 77% of reported cases involved youths aged from 20 to 39 years.
- 2.2 Current data also indicates that almost 40% of HIV patients were diagnosed late with very low CD4 counts below 200 cells/mm<sup>3</sup>, while 20% diagnosed with CD4 counts between 200-500 cells/mm<sup>3</sup>. The Malaysia Progress Report on Global AIDS Monitoring 2022 shows that only 82.8 % of those living with HIV/AIDS (PLHIV) have been diagnosed and are aware of their HIV test results. As of now, only 66.2% have received antiretroviral treatment (ART) and out of them, 85% have achieved viral load suppression. Additionally, stigma and discrimination contribute to high-risk individuals not attending HIV screening tests at healthcare facilities and delaying treatment.
- 2.3 Hence, implementing HIV-self testing (hereafter referred to as 'HIVST') in Malaysia is in line with the WHO's recommendations to achieve the '95-95-95' targets to end AIDS by "2030". HIVST will also serve as a gateway to referral for HIV prevention packages and pre-exposure prophylaxis (PrEP) for those who test negative for HIV, as well as antiretroviral treatment (ARV) for those diagnosed as HIV-positive.

### **3. OBJECTIVES**

#### **3.1 General:**

HIVST implementation aims to provide an additional option to the existing HIV screening services in Malaysia.

#### **3.2 Specific:**

- i) To enhance the availability of HIV tests, particularly for young individuals from the targeted groups.
- ii) To ensure that individuals who have undergone HIVST are linked to prevention, treatment, and support measures.

### **4. TARGET GROUPS**

- a) High-risk populations include key populations like men who have sex with men (MSM), transgender individuals (TG), people who inject drugs (PWID), and female sex workers (FSW).
- b) Individuals who are contacts or partners of HIV-positive index cases.
- c) Individuals who perceive themselves as at risk and have never undergone HIV screening or been diagnosed with HIV.

### **5. POLICY DECISION, GUIDING PRINCIPLES AND GENERAL POLICIES**

#### **5.1 Policy decision**

The Exco Committee Meeting for Policy in Public Health Program (No. 3/Year 2022, held on 22nd November 2022) and the Director General of Health Special Meeting (No. 1/Year 2023, held on 21st February 2023) have approved the policy for the implementation of HIV self-testing in Malaysia.

#### **5.2 Guiding principles**

The guiding principles of HIVST are based on the '5C' introduced by the WHO, which are Consent, Confidentiality, Counselling, Correct results, and Connection, as follows:

##### **5.2.1 Consent**

Individuals conduct HIVST voluntarily without any form of coercion. However, informed consent must be obtained before conducting HIVST if it is done with the help of another individual or partner.

### 5.2.2 Confidentiality

Since HIV testing is conducted privately, confidentiality is ensured. Maintaining confidentiality is important when performing HIVST with assistance. In the event that the HIVST result is reactive, individuals are advised to report it and undergo confirmatory test at a nearby healthcare facility.

### 5.2.3 Counselling

Intensive HIV pre-screening counselling is no longer conducted. All individuals undergoing HIVST will receive pre-screening information through brochures, digital media or relevant online platforms. Post-HIV screening counselling can be obtained from trained healthcare personnel or community health workers after individuals interpret their HIVST results.

### 5.2.4 Correct Result

Individuals should understand and perform HIVST in accordance with the usage instructions given in the product brochure or provided video to guarantee accurate and precise results.

### 5.2.5 Connection

Individuals undergoing HIV testing should be linked to or referred to the appropriate preventive, treatment, and follow-up care services regardless of whether their test results are "reactive" or "non-reactive."

## 5.3 General Policies

### 5.3.1 Definition

HIVST is a voluntary process in which individuals collect their sample (either oral fluid or blood), then perform a screening test and interpret the results themselves. However, as a screening test, HIVST will not replace the diagnostic functions of laboratory tests to confirm or diagnose.

### 5.3.2 Voluntary

HIV testing is done voluntarily and not under coercion. It can be done either alone or with a trusted person. According to WHO, HIVST can be performed through two (2) approaches, namely:

- (i) **Unassisted:** Individuals perform HIVST on their own and interpret the results based on product instructions, video tutorials, or other reference materials without assistance from anyone.
- (ii) **Directly assisted:** Individuals perform HIVST with the assistance of trained healthcare personnel, pharmacists, or community health workers, physically

or virtually (e.g., online consultation) to guide, conduct HIVST, and interpret the results.

### **5.3.3 Age**

- (i) Individuals 18 years of age and older are eligible for HIVST. If HIV testing is to be performed on individuals under the age of 18, prior consent must be obtained from the parent or guardian.
- (ii) WHO does not recommend HIVST for infants less than two (2) years of age because it may provide inaccurate results due to maternal antibodies in the infant's body.
- (iii) WHO also does not recommend HIVST for individuals receiving ARV treatment because of the greater likelihood of false negative results.

### **5.3.4 Additional Options**

Implementing HIVST is an additional option to existing screening services. It will not replace any existing HIV screening programs running effectively (i.e., antenatal HIV screening programs, pre-marital screening, blood donation, TB patients, STI, Hepatitis C, prison inmates, PUSPEN drug-rehab trainees and others).

## **6. CRITERIAS AND STANDARDS FOR TEST KITS**

- 6.1 HIVST kits that can be used must be registered and approved by the Malaysian Medical Devices Authority (MDA) under Section 5 of Act 737.
- 6.2 HIVST kits placed on the market should be specifically for HIVST and not for professional use, should be easily handled by the general public without scientific or medical training, and should be safe to use.
- 6.3 HIVST kits should be of high quality and performance, with a sensitivity of at least 99.0% for blood samples and 92.0% for oral fluid samples. The sensitivity of the HIVST kit refers to the test kit's ability to detect HIV-1/2 antibodies and/or HIV-1 p24 antigen in an HIV-infected person's blood or oral fluid sample.
- 6.4 Meanwhile, the HIVST kit's specificity for both blood and oral fluid samples should be at least 99.0%. The specificity of the HIVST kit refers to the test kit's ability to detect samples from HIV-free individuals correctly.
- 6.5 The performance of the HIVST kit mentioned above is achieved using the detection of antibodies only or antigens and antibodies.
- 6.6 HIVST kits use the immunoassay chromatography technique, where test results can be obtained visually within 15-20 minutes.

- 6.7 HIVST kits must have clear user instructions to reduce errors during testing. User instructions for HIVST kits should be written in at least two languages: Bahasa Malaysia and English.
- 6.8 HIVST kits should also provide instructions for safe disposal and plastic bags for disposal.
- 6.9 The Medical Device Authority (MDA) is in charge of market control and enforcement of HIVST kits. Companies or establishments selling HIVST kits must have a valid MDA establishment certificate issued under Section 15 of Act 737. This establishment certificate should encompass the scope of in-vitro diagnostics within the Good Distribution Practice for Medical Devices (GDPMD) certification.
- 6.10 Establishments must also comply with post-market obligations, according to Chapter 3 of the Medical Device Act 2012 (Act 737) and the Medical Device Regulations (Duties and Obligations of Establishments) 2019.
- 6.11 HIVST test kits can only be sold or supplied to the general public by:
- (i) Community pharmacies licenced under the Pharmacy Services Programme, Ministry of Health Malaysia;
  - (ii) Healthcare Facilities, both public and private; and
  - (iii) Non-Governmental Organisations Collaborating with the Ministry of Health Malaysia and its affiliated organisations.
- 6.12 HIVST can be sold or supplied online by 6.11 (i) and (iii). However, a suitable logistics service provider must carry out the delivery activity with assurances regarding the safety and performance of medical devices.
- 6.13 Sales of HIVST by individuals, physically and online, are strictly prohibited.
- 6.14 HIVST kit distributors must provide information that can be supplied with the test kits or display instructions on how to execute the HIVST procedure (e.g., posters, videos) that depict how HIVST is performed. End-users must have access to reference information and links.
- 6.15 Suppliers of HIVST kits must display a QR code or the link to the website '[www.testnow.com.my](http://www.testnow.com.my)' to customers/users. The '[www.testnow.com.my](http://www.testnow.com.my)' website is an online platform developed through a smart partnership between the Ministry of Health Malaysia, the Malaysian AIDS Foundation, and the Global Fund. This website provides services for supplying HIVST kits, pre-screening information, risk assessment, testing procedures, links to the MDA website, links to the MySejahtera health facility appointment system, a directory of community health workers, and a directory for psychosocial support assistance.

## 7. PROCEDURE FOR HIV SELF-TESTING

### 7.1 Guidance for the supply/sales of HIVST kits

7.1.1 The guidance for the supply/sales of HIVST kits is as follows:

Period	Actions for HIVST Kit Suppliers/Sellers
<b>Before supplying/selling</b>	<ul style="list-style-type: none"> <li>i) To ensure that HIVST Kit products comply with the specified criteria and standards: <ul style="list-style-type: none"> <li><input type="checkbox"/> Must be registered and approved by the Malaysian Medical Device Authority (MDA) under Section 5 of Act 737.</li> <li><input type="checkbox"/> HIVST kit sensitivity <ul style="list-style-type: none"> <li>- Blood sample: <math>\geq 99.0\%</math>.</li> <li>- Oral fluid sample: <math>\geq 92.0\%</math>.</li> </ul> </li> <li><input type="checkbox"/> HIVST kit specificity <ul style="list-style-type: none"> <li>- Blood and oral fluid samples: <math>\geq 99.0\%</math>.</li> </ul> </li> <li><input type="checkbox"/> Test results can be obtained visually within 15-20 minutes.</li> <li><input type="checkbox"/> Not expired and still valid.</li> </ul> </li> <li>ii) To ensure the HIVST kit has user instruction leaflets regarding the testing procedure. The user instruction leaflets should be written in at least two languages: Bahasa Malaysia and English.</li> <li>iii) To ensure that the HIVST kit states a safe disposal procedure and provides plastic bags for disposal.</li> <li>iv) To display the QR code or the link to the website 'www.testnow.com.my'.</li> </ul>
<b>During the supply/ Distribution/ Sale to customers/ users of HIVST Kits</b>	<ul style="list-style-type: none"> <li>v) To explain the HIVST procedure to customers/users using the user instruction leaflets.</li> <li>vi) To inform customers/users to scan the QR Code or link to the website 'www.testnow.com.my.'</li> <li>vii) To advise customers/users to properly dispose of used kits as stated in the instruction leaflets.</li> </ul>



- 7.1.2 The Ministry of Health Malaysia (MOH) will provide briefings/ training and the latest information to community pharmacies regarding the supply/sale of HIVST kits and the implementation of HIVST, including the responsibilities of the supplier/seller.

## 7.2 Guidance for customers/users who will purchase and use HIVST kits.

The guidance for customers/users will include:

- 7.2.1 Guidance prior to and during the purchase/acquisition of HIVST kits.
- 7.2.2 Guidance prior to, during, and after the customers/users perform the HIVST tests, whether unassisted or directly assisted; and
- 7.2.3 Guidance on follow-up actions that need to be taken by the customers/users after obtaining the results of the HIVST tests.

Please refer to '**Appendix 1**' for the HIVST implementation flowchart.

### 7.2.1 Guidance for Purchasing/Acquiring HIVST Kits.

Period	Customer/User Actions
<b>Before purchasing the HIVST kit</b>	<ul style="list-style-type: none"> <li>i. To inspect and review the HIVST kits for compliance with established criteria: <ul style="list-style-type: none"> <li><input type="checkbox"/> Must be registered and approved by the Malaysian Medical Device Authority (MDA) under Section 5 of Act 737.</li> <li><input type="checkbox"/> HIVST kit sensitivity: <ul style="list-style-type: none"> <li>- Blood sample: <math>\geq 99.0\%</math>.</li> <li>- Saliva sample: <math>\geq 92.0\%</math>.</li> </ul> </li> <li><input type="checkbox"/> HIVST kit specificity: <ul style="list-style-type: none"> <li>- Blood and saliva samples: <math>\geq 99.0\%</math>.</li> </ul> </li> <li><input type="checkbox"/> Test results can be obtained visually within 15-20 minutes.</li> <li><input type="checkbox"/> Not expired and is still valid.</li> </ul> </li> </ul>
<b>During purchasing/acquiring the HIVST kit</b>	<ul style="list-style-type: none"> <li>ii. The customer/user bears payment if the HIVST test kit is purchased at a community pharmacy.</li> <li>iii. Scan the QR code or link to the website 'www.testnow.com.my' to gain access to pre-screening information, risk assessment, testing procedures and others.</li> </ul>



### 7.2.2 Guidance for performing the HIVST test either unassisted or directly assisted.

Period	Client/User Actions
<b>Before performing HIVST</b>	<ul style="list-style-type: none"> <li>i. To read and understand the user instructions for the HIVST kit carefully.</li> <li>ii. To inspect and ensure all items in the HIVST kit are sufficient and not damaged.</li> <li>iii. To provide a timer (e.g., a clock or a phone).</li> <li>iv. To refrain from eating, drinking, or using mouthwash for at least 30 minutes before conducting the HIVST test using the oral fluid product.</li> </ul>
<b>During performing HIVST</b>	<ul style="list-style-type: none"> <li>v. To collect an oral fluid or blood sample and perform the HIVST according to the user instructions or the demonstration video given.</li> <li>vi. To record the starting time of performing the HIVST.</li> <li>vii. To read the HIVST result within 15-20 minutes (or as stated by the manufacturer).</li> <li>viii. To interpret the HIVST result as 'reactive,' 'non-reactive,' or 'invalid.' Please refer to <b>'Appendix 2'</b> and <b>'Appendix 3'</b>.</li> <li>ix. Encourage taking a photo of the HIVST kit and sharing the test result on the website 'www.testnow.com.my' in order to link to the health facility appointment system.</li> </ul>
<b>After performing HIVST</b>	<ul style="list-style-type: none"> <li>x. To wash hands with soap and water</li> <li>xi. To dispose of the used HIVST kit in a plastic bag or a kit box before discarding it in the trash bin.</li> </ul>

### 7.2.3 User action guidance after obtaining HIVST test results.

Period	Clients/Users Action	
	HIVST Result	Action
<b>Customer/ User's Action after obtaining HIVST results</b>	<b>Reactive</b>	<ul style="list-style-type: none"> <li><input type="checkbox"/> It is advised that the test results be reported on the website 'www.testnow.com.my.'</li> <li><input type="checkbox"/> To make an appointment for health assessment and confirmatory test through the MySejahtera online appointment system.</li> </ul>
	<b>Non-Reactive</b>	<ul style="list-style-type: none"> <li><input type="checkbox"/> It is advised that the test results be reported on the website 'www.testnow.com.my.'</li> <li><input type="checkbox"/> Individuals at risk are advised to repeat the test at least 3 to 6 months after being exposed to HIV. They can seek HIV prevention services from the government health clinic or a suitable NGO for HIV, including referrals for PrEP or PEP.</li> </ul>
	<b>Invalid</b>	<ul style="list-style-type: none"> <li><input type="checkbox"/> It is advised that the test results be reported on the website 'www.testnow.com.my.'</li> <li><input type="checkbox"/> It is also recommended to use a different test kit or schedule an appointment for HIV testing at a government health clinic or with an NGO.</li> </ul>

## 8. PROGRAM MONITORING AND EVALUATION

The Ministry of Health (KKM) prioritises the principle of 'do no harm' and preserving patient's/ client's confidentiality. However, to monitor the effectiveness of the HIVST Program, certain data from patients/clients are required (such as age, gender, HIV testing history, risk factors, and test results). Personal data (such as full name and identification number) is only necessary if a referral is needed for further treatment. These data can then be used for program improvement purposes in the future.

<b>8.1</b>	<b>Demographic data of patients/clients</b>
i.	Gender
ii.	Age
iii.	Target groups <ul style="list-style-type: none"> <li><input type="checkbox"/> High-risk populations such as key populations of men who have sex with men (MSM), transgender individuals (TG), people who inject drugs (PWID), and female sex workers (FSW).</li> <li><input type="checkbox"/> Individuals who are contacts or partners of HIV-positive index cases.</li> <li><input type="checkbox"/> Individuals who perceive themselves as being at risk and have never undergone HIV screening or been diagnosed with HIV.</li> </ul>
<b>8.2</b>	<b>Process indicators</b>
i.	Screening status, whether: <ul style="list-style-type: none"> <li><input type="checkbox"/> First-time screening; or</li> <li><input type="checkbox"/> Repeat screening</li> </ul>
ii.	HIVST result: <ul style="list-style-type: none"> <li><input type="checkbox"/> Reactive; or</li> <li><input type="checkbox"/> Non-reactive; or</li> <li><input type="checkbox"/> Invalid</li> </ul>
iii.	The number of HIVST kits distributed. Proxy data will be obtained from the MDA.
iv.	The number of patients/clients accessing the online HIVST platform.
v.	The number of patients/clients referred for the prevention package, confirmatory testing and further treatment.
<b>8.3</b>	<b>Outcome indicators</b>
i.	The percentage of patients/clients detected as reactive, non-reactive, and invalid.
ii.	The percentage of patients/clients who make online appointments for referrals to healthcare facilities.

## **9. ROLES AND RESPONSIBILITIES**

### **9.1 Disease Control Division**

- ☐ Planning, monitoring, and evaluating the implementation of the HIVST program at the national level.
- ☐ Coordinating data collection and program achievement analysis for HIVST at the national level.
- ☐ Planning and organising briefings/ training for healthcare professionals, community pharmacists, and community healthcare workers on the procedures for implementing the HIVST programme on a nationwide scale.

### **9.2 State Health Departments**

- ☐ Promoting the HIVST program and monitoring its implementation at the state level.
- ☐ Planning and organising briefings/ training on the procedures for implementing the HIVST program at the state level among healthcare professionals, community pharmacists, and NGO healthcare workers.
- ☐ Ensuring that HIV confirmation testing services, post-confirmation counselling, treatment for HIV-positive cases, and prevention packages such as condoms, PrEP, and PEP are offered to those who self-refer to Health Clinics that provide these services.
- ☐ Ensuring that control measures are executed and that HIV-positive cases diagnosed are registered in the National AIDS Registry (NAR).

### **9.3 Medical Device Authority (MDA)**

- ☐ Approval and issuance of establishment licenses to HIVST test kit manufacturers or suppliers.
- ☐ Monitoring and enforcing compliance with HIVST test kits in the market.

### **9.4 Community Pharmacies**

- ☐ Only sell HIVST kit products from MDA-licensed and registered establishments.
- ☐ Adhere to the manufacturer's instructions for storing HIVST kits.
- ☐ Monitor the expiration dates of the products sold.
- ☐ Sell HIVST kits at market prices.

- ☐ Explain to clients the different types of HIVST kits available in the market.
- ☐ Provide a space for customers to perform HIVST if necessary.
- ☐ Pharmacists aid in the explanation of HIVST procedures, particularly to those who require assistance (directly assisted), such as those who do not understand the HIVST method or have difficulties interpreting test results.

### **9.5 Non-Governmental Organizations (NGOs)**

- ☐ Provide HIVST kits to clients as needed.
- ☐ Promote the 'www.testnow.com.my' platform online to key population groups and their partners.
- ☐ NGO healthcare workers assist in explaining HIVST procedures, particularly to those who require assistance (directly assisted), such as those who do not understand the HIVST procedure or have difficulties interpreting test results.

### **9.6 Customers/Users**

- ☐ The cost of purchasing HIVST kits is borne by the customers/users if bought directly from pharmacies or online.
- ☐ Customers/users are responsible for ensuring that the MDA has approved the HIVST kit by comparing the HIVST kit registration number to the list of registered medical devices on the MDA website, which is updated on a regular basis.
- ☐ HIVST kits must be stored properly and should not be used beyond their expiration date. The recommended environmental temperature for storing HIVST kits should follow the requirements.
- ☐ Perform HIVST according to the provided usage instructions.
- ☐ Customers/ users are advised to report their HIVST results and make appointments with healthcare facilities. This enable customers/ users to obtain the appropriate preventive, treatment, and follow-up care based on whether they are reactive, non-reactive, or invalid test results.

## 10. REFERENCES/ SOURCES

- i) Consolidated guidelines on HIV testing services; WHO (2016)
- ii) Consolidated Guidelines on HIV Prevention, Testing, Treatment, Service Delivery, and Monitoring: Recommendations for a Public Health Approach; WHO (2021)
- iii) Integrated Biological and Behavioral Surveillance Survey in Malaysia; Ministry of Health (2022)
- iv) Global AIDS Monitoring Country Progress Report- Malaysia; Ministry of Health Malaysia (2021)
- v) Global AIDS Monitoring (UNAIDS/WHO/UNICEF) and Global HIV, Hepatitis and STIs Programmes; WHO (2022)
- vi) Guidelines on HIV self-testing and partner notification: Supplement to consolidated guidelines on HIV testing services; WHO (2019)
- vii) Monitoring, Evaluation, and Reporting Indicator Reference Guide; PEPFAR (2021)
- viii) WHO and partners urge countries to fast-track implementation and scale-up of HIV self-testing and other innovative HIV testing approaches in Asia and the Pacific; WHO (2021)
- ix) Surat Pekeliling Ketua Pengarah Kesihatan Malaysia Bil 10/2020: Kemaskini Carta Alir Ujian Saringan dan Pengesahan HIV.
- x) Surat Pekeliling Pihak Berkuasa Peranti Perubatan Bil 1/2023: Pelaksanaan dan Penguatkuasaan di bawah Akta Peranti Perubatan 2012 (Akta 737) Kebenaran Peletakan Dalam Pasaran Kit Ujian Kendiri bagi Penyakit Human Immunodeficiency Virus (HIV).

## Flowchart for the Implementation of HIVST Screening

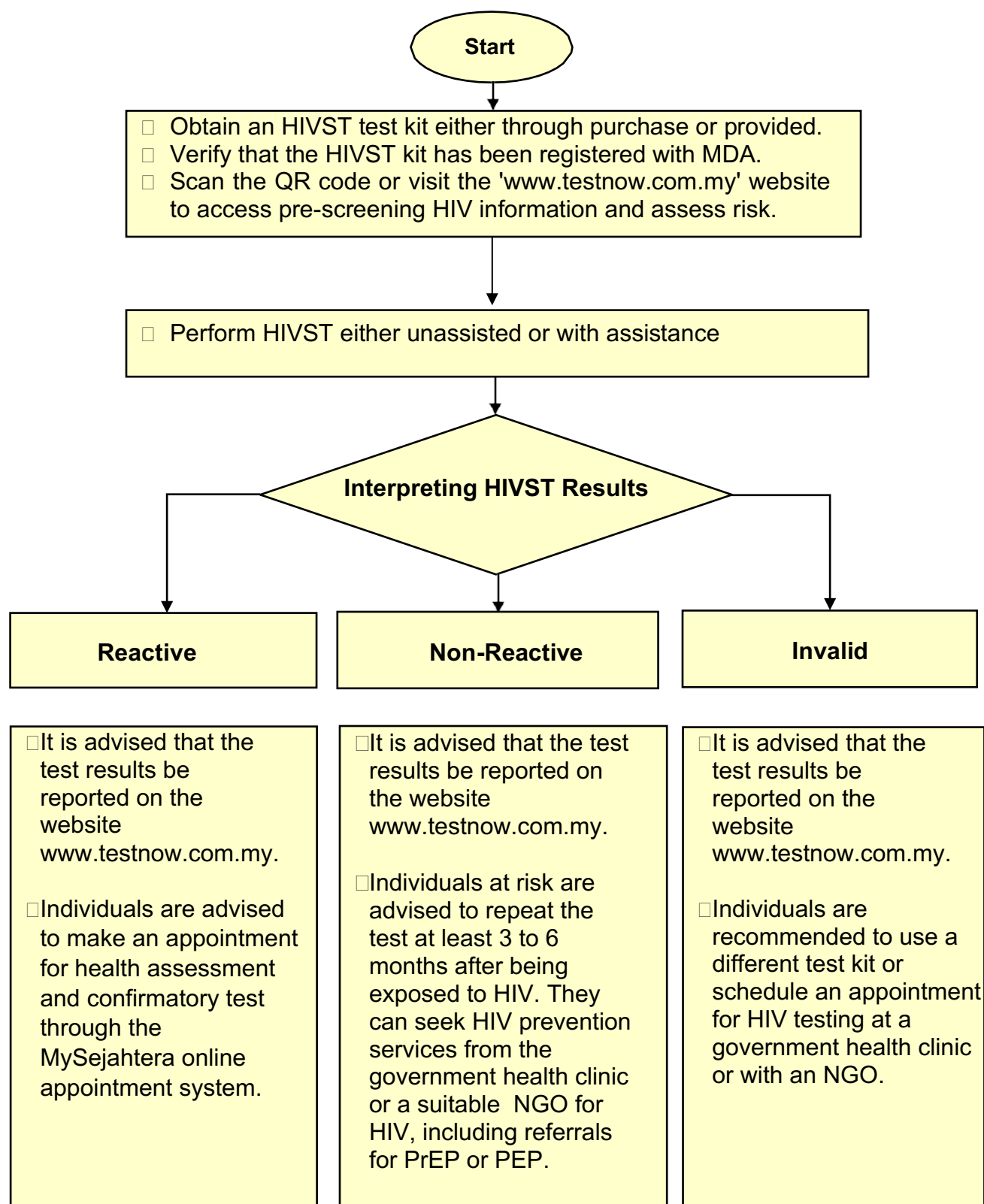
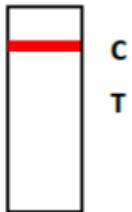
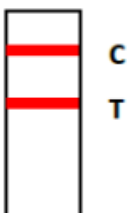
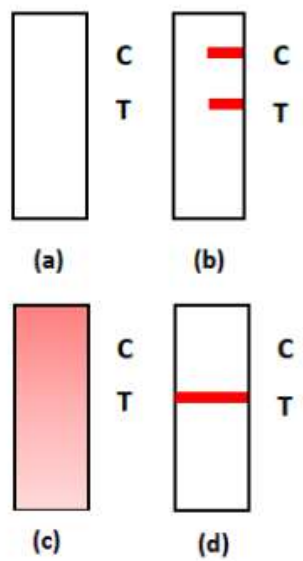


Table 1: Examples of HIVST Rapid Test Result Interpretation

<p><b>Non-reactive result</b></p> 	<p><b>The result of the rapid test is 'non-reactive':</b></p> <ul style="list-style-type: none"> <li>- One complete line appears in the "C" section, and no line appears in the "T" section.</li> </ul>
<p><b>Reactive result</b></p> 	<p><b>The result of the rapid test is 'reactive':</b></p> <ul style="list-style-type: none"> <li>- Two complete lines appear in the "C" and "T" sections.</li> <li>- If the line that appears in the "T" section is faint or blurry, the test result is still considered reactive.</li> </ul>
<p><b>Invalid result</b></p> 	<p><b>The result of the rapid test is 'invalid':</b></p> <ul style="list-style-type: none"> <li>- No line appears in the "C" section; or</li> <li>- Only a partial line appears; or</li> <li>- A red background appears, making the result unreadable; or</li> <li>- Only the "T" line appears.</li> </ul>

**a) What does a 'non-reactive' rapid test mean?**

A 'non-reactive' result means that the test kit could not detect the presence of antibodies to the HIV in the examined sample. There are two possibilities:

- (i) If the individual is not at risk, a 'non-reactive' rapid test result means that the individual is not infected with HIV. Testing can be repeated as needed.
- (ii) However, if the individual has risk factors, a 'non-reactive' rapid test result DOES NOT mean that the individual is free from HIV infection because they may still



be in the 'window period.' The 'window period' refers to the time from exposure to HIV until the test can detect antibodies. During this period, someone can infect others but may have a false-negative result.

**Action:**

- Individuals are advised to stop risky behaviours and repeat the test at least 3 to 6 months after exposure to HIV (window period).
- Individuals at risk can contact the health clinic or any relevant NGO for HIV prevention packages, including PrEP referrals. Additionally, if individuals believe they have been exposed to HIV within 72 hours, they should immediately consult a medical specialist to discuss PEP treatment.

**b) What does a 'reactive' rapid test mean?**

A 'reactive' result means that the test kit detected the presence of antibodies to the HIV in the examined sample, and the individual is suspected to be infected with the HIV.

**Action:**

- The individual is advised to promptly make an appointment with a nearby Health Clinic for health assessment and confirmation testing.
- The procedures for confirming HIV testing are outlined in the circular letter from the Director-General of Health Malaysia No. 10/2020, Update on the HIV Screening and Confirmation Flowchart.

**c) What does an 'invalid' mean in a rapid test?**

An 'invalid' result may be due to problems with the test kit or incorrect testing techniques.

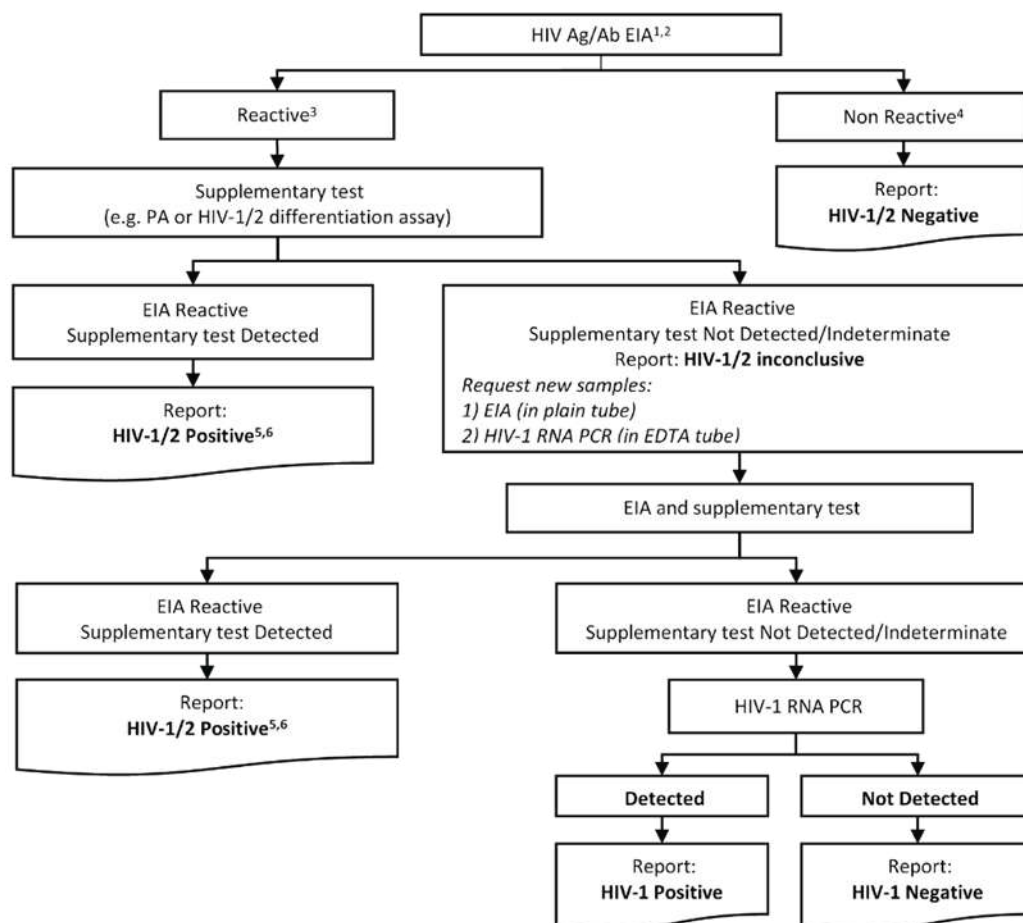
**Action:**

- Individuals are advised to use another test kit or schedule an appointment for HIV screening at the Health Clinic or with a relevant NGO.

Table 2: Summary of Actions After Interpreting HIVST Rapid Test Results

HIVST result (rapid test)	Risk	
	Yes	No
<b>Reactive</b>	The individual is likely to have been infected with HIV. It is advised to make an appointment with a nearby Health Clinic for health assessment and confirmation testing.	The individual is likely to have been infected with HIV. It is advised to schedule an appointment with a nearby Health Clinic for health assessment and confirmation testing.
<b>Non-Reactive</b>	<p>The individual is likely still within the 'window period.'</p> <p>Please stop risky behaviours and repeat the test at least 3 to 6 months after exposure to HIV.</p> <p>You can contact a Health Clinic or a relevant NGO for HIV prevention package.</p>	The individual is not infected with HIV. Testing can be repeated as needed.

## Flowchart for Confirmatory HIV Testing



<sup>1</sup> HIV Ag/Ab EIA: HIV antigen-antibody enzyme immunoassay (latest available version).

<sup>2</sup> Specimen is considered as first specimen if there is NO previous RDT result. Specimen is considered as second specimen if there is previous positive RDT result (first specimen).

<sup>3</sup> To be performed as duplicate or more following the manufacture product inserts.

<sup>4</sup> If there is possibility of very early infection leading to a non-reactive on the initial antigen/antibody immunoassay, such as when recent HIV exposure is suspected or reported, request for a new specimen and repeat the algorithm after 2-4 weeks or to conduct an HIV-1 RNA PCR.


<sup>5</sup> Request second sample for patient verification if no previous positive result documented. This is applied for EIA and supplementary testing only.

<sup>6</sup> Suggest: to send fresh blood sample in EDTA tubes for HIV-1 RNA PCR

## References:

- 1) World Health Organization (WHO). Consolidated Guidelines on HIV Testing Services for A Changing Epidemic. Policy Brief. November 2019.
- 2) Centers for Disease Control and Prevention (CDC). 2018 Quick Reference Guide: Recommended Laboratory HIV Testing Algorithm for Serum or Plasma Specimens. CDC website. <https://stacks.cdc.gov/view/cdc/50872>. Updated January 2018.

Director General of Health Malaysia, Circular Letter No 14/2023

	<p><b>KETUA PENGARAH KESIHATAN MALAYSIA</b>          Kementerian Kesihatan Malaysia          Aras 12, Blok E7, Kompleks E,          Pusat Pentadbiran Kerajaan Persekutuan          62590 PUTRAJAYA</p>	<p>Tel.: 03-8000 8000          Faks: 03-8889 5542</p>
<p>Ruj. Tuan :          Ruj. Kami : KKM.500-28/3/3 JLD 3 (14)          Tarikh : 14 Ogos 2023</p>		
<p><b>SEPERTI SENARAI EDARAN</b></p>		
<p><i>YBhg. Datuk /Dato' Indera /Datin Paduka /Dato' /Datin /Tuan /Puan,</i></p>		
<p><b>SURAT PEKELILING KETUA PENGARAH KESIHATAN MALAYSIA          BIL. 14.. /2023 : GARIS PANDUAN PELAKSANAAN UJIAN SARINGAN HIV          KENDIRI DI MALAYSIA</b></p>		
<p><b>1. TUJUAN</b></p>		
<p>Surat Pekeliling Ketua Pengarah Kesihatan Malaysia Bil.14/2023 ini bertujuan untuk menerangkan dasar dan garis panduan pelaksanaan ujian saringan HIV sendiri di Malaysia.</p>		
<p><b>2. LATAR BELAKANG</b></p>		
<p>2.1 Pengesanan melalui ujian saringan merupakan langkah utama untuk mengurangkan penularan kes HIV baru. Pelaksanaan ujian saringan HIV sendiri telah diperakui di peringkat antarabangsa dan disarankan oleh Pertubuhan Kesihatan Sedunia (WHO) semenjak tahun 2016 melalui <i>Consolidated Guidelines on HIV testing services</i>.</p>		
<p>2.2 Selari dengan saranan WHO ini, pelaksanaan ujian saringan HIV sendiri di Malaysia bertujuan untuk meningkatkan akses ujian HIV kepada golongan berisiko tinggi khususnya golongan muda dan pasangan mereka disamping merupakan opsyen tambahan kepada perkhidmatan ujian saringan HIV yang sedia ada.</p>		

**Pre-Screening HIV Information Guide**

- i) Explaining the benefits of undergoing HIV screening and the implications if HIV is not diagnosed.
- ii) Differentiating between screening tests and confirmation tests.
- iii) Explaining what HIVST is and the importance of HIV screening.
- iv) Defining the "window period," HIV-positive and HIV-negative.
- v) Highlighting the advantages of early ARV treatment and achieving and maintaining an undetectable viral load in PLHIV while preventing sexual transmission to partners.
- vi) Stressing the importance of disclosing one's HIV status to healthcare providers.
- vii) Discuss the possibility of getting inaccurate results if someone is currently on ARV treatment and undergoing HIV screening.
- viii) Emphasizing open communication and encouraging partners to undergo HIV screening.
- ix) Providing options for preventive measures, including risk reduction information and harm reduction, focusing on individuals at ongoing high risk.
- x) Explaining the confidentiality of screening results and any information that needs to be shared by clients.
- xi) Allowing clients the opportunity to ask questions.

Reference: *Guidelines on HIV self-testing and partner notification: Supplement to consolidated guidelines on HIV testing services; WHO (2019), page 51*

**Post-Screening Counseling Guide**

- i) Explaining HIVST screening test results.
- ii) Explaining the benefits of knowing one's HIV status and early treatment as prevention.
- iii) Stressing the need to repeat the test if an individual is at high risk. This is because they may be in the window period and are advised to retest after 3 to 6 months.
- iv) Explaining the importance of staying HIV-negative and harm reduction measures.
- v) Explaining the services available for HIV-positive individuals, including where ARV treatment can be obtained.

Reference: *Guidelines on HIV self-testing and partner notification: Supplement to consolidated guidelines on HIV testing services; WHO (2019), page 51*

Table 3: List of Related Website Links

No	Website Name	Link	Organization
1.	Consolidated Guidelines on HIV Testing Services	<a href="https://www.who.int/publications/i/item/978-92-4-155058-1">https://www.who.int/publications/i/item/978-92-4-155058-1</a>	World Health Organization (WHO)
2.	List of government health clinics	<a href="https://www.moh.gov.my/index.php/pages/view/4378?mid=1451">https://www.moh.gov.my/index.php/pages/view/4378?mid=1451</a>	Ministry of Health Malaysia
3.	Guidelines on ARV Treatment	<a href="https://www.mashm.net/guidelines">https://www.mashm.net/guidelines</a>	Malaysian Society of HIV Medicine (MASHM)
4.	My PrEP Locator Directory	<a href="https://myprelocator.com/">https://myprelocator.com/</a>	Centre of Excellence for Research in AIDS (CERiA)
5.	Registered Medical Device Search	<a href="https://mdar.mda.gov.my/frontend/web/index.php?r=carian">https://mdar.mda.gov.my/frontend/web/index.php?r=carian</a>	Medical Device Authority (MDA)
6.	MDA Feedback Management System	<a href="https://femes.mda.gov.my/">https://femes.mda.gov.my/</a>	Medical Device Authority (MDA)