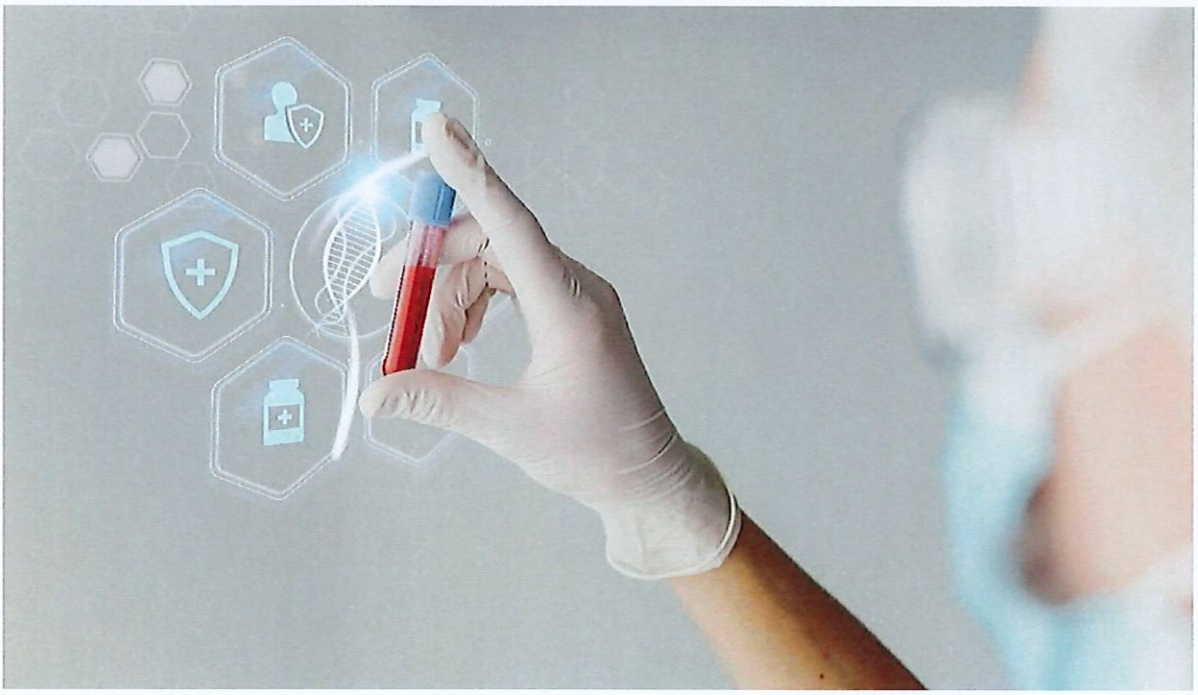
UPDATE ON HIV SCREENING AND CONFIRMATORY TESTING ALGORITHM



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Abbreviations And Acronyms

ART	Antiretroviral Therapy
CCRC	Cure & Care Rehabilitation Centre
CDC	United States Centres For Disease Control And Prevention
FSW	Female Sex Workers
HIV	Human Immunodeficiency Virus
HIV 1	Human Immunodeficiency Virus 1
HIV 2	Human Immunodeficiency Virus 2
HIV 1/2	Human Immunodeficiency Virus 1 Or Human Immunodeficiency Virus 2
HIVST	HIV Self-Testing
MOH	Ministry Of Health Malaysia
MDA	Medical Device Authority
MSM	Men Who Have Sex With Men
PCR	Polymerase Chain Reaction
PEP	Post-Exposure Prophylaxis
PrEP	Pre-Exposure Prophylaxis
PWID	People Who Inject Drugs
RDT	Rapid Diagnostic Test
RNA	Ribonucleic Acid
STI	Sexually Transmitted Infections
TB	Tuberculosis
TG	Transgender Persons

Content

UPDATE ON HIV SCREENING AND CONFIRMATORY TESTING ALGORITHM

1.0 PURPOSE

This circular serves to inform on the updated HIV screening and confirmatory testing algorithm, to be used as an implementation guide by healthcare personnel in public and private health facilities, including health clinics, hospitals, medical institutions, and HIV screening centres.

2.0 BACKGROUND

The current HIV testing algorithm in use is based on the Circular of the Director-General of Health Malaysia No. 10/2020 (Ref. IMR/IDRC/VIRO/23/2301/05(65)). In line with advancements in laboratory technology and changes in HIV testing methodologies, the algorithm has been revised according to the latest recommendations issued by the United States Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO).

It is noted that the Serodia HIV-1/2 test, which employs the particle agglutination method for detecting HIV-1 and HIV-2 antibodies, is no longer widely used in current practice. Accordingly, the HIV-1/2 Antibody Differentiation Assay will be adopted as the primary confirmatory method, in accordance with current guidelines and internationally recommended best practices.

This guide outlines several key changes and improvements as follows:

(i) **Change in confirmatory test technique** from the Particle Agglutination method to the HIV-1/2 Antibody Differentiation Assay for adults and children aged over 18 months (Algorithm 1).

(i) **Amendments to Algorithm 2**, with emphasis on the requirement for two negative HIV-1 RNA tests in infants. Follow-up HIV Ag/Ab Immunoassay may be performed at the nearest hospitals when the infant reaches 18 months of age or three months after cessation of breastfeeding, whichever is later.

(ii) **Updates to the use of Rapid Diagnostic Tests (RDTs)** for HIV in Algorithm 3, with emphasis on case management aspects. This aligns with the increasing use of RDTs in healthcare facilities as well as the implementation of HIV self-testing, accessible via https://testnow.com.my.

(iii) **Introduction of Algorithm 4**, a new algorithm covering HIV testing among blood donors and its implementation in blood centres.

With these updates, HIV screening and confirmatory testing are expected to be more accurate, efficient, and based on current scientific evidence. This will further strengthen the delivery of comprehensive healthcare, encompassing prevention, control, treatment, monitoring, social support, and integrated clinical referral.

3.0 TARGET GROUPS FOR HIV TESTING

HIV testing shall be conducted for the following groups:

(i) High-risk individuals: people who inject drugs (PWID), female sex workers (FSW), transgender persons (TG), and men who have sex with men (MSM).

(ii) Pregnant women and infants born to HIV-positive mothers.

(iii) Contacts of HIV-positive individuals.

(iv) Patients with sexually transmitted infections (STIs)

(v) Patients with tuberculosis (TB).

(vi) Residents of Cure & Care Rehabilitation Centres (CCRC).

(vii) Prison inmates.

(viii) Blood donors and blood transfusion recipients (pre-transfusion).

(ix) Individuals requesting testing, including for pre-marital purposes.

4.0 IMPLEMENTATION METHODS

4.1 Updated HIV Testing Algorithm

The updated HIV testing algorithms attached to this circular are as follows:

(i) HIV diagnostic algorithm for adults and children (paediatric) aged over 18 months (Annex 1 – Updated).

(ii) HIV diagnostic algorithm for paediatric patients aged under 18 months (Annex 3 – Updated).

(iii) HIV screening algorithm using RDTs by healthcare workers (Annex 5 – Updated).

(iv) HIV laboratory testing algorithm for blood donors and implementation in blood centres (Annex 6 – New).

4.2 Confirmatory Testing

For any individual who tests reactive in the HIV screening test, confirmatory testing must be performed as soon as possible, and no later than one (1) week from the date of the screening test.

If a reactive individual fails to present for confirmatory testing, the responsible party must notify the nearest District Health Office for follow-up tracing and confirmatory testing.

5.0 SPECIFICATIONS FOR HIV-1/2 RAPID DIAGNOSTIC TESTS (RDTs)

5.1 Sensitivity and Specificity

The performance of HIV RDTs must meet the technical specifications recommended by the Ministry of Health Malaysia.

The sensitivity of HIV-1/2 RDTs shall be no less than 99.0% for blood samples. Sensitivity is defined as the ability of the RDT to accurately detect HIV-1/2 antibodies and/or HIV-1 p24 antigen in individuals infected with HIV.

The specificity of HIV-1/2 RDTs shall be no less than 98.0% for blood samples. Specificity is defined as the ability of the RDT to accurately identify individuals who are free from HIV infection.

RDTs meeting these criteria may detect antibodies alone or both antigens and antibodies.

All RDTs must registered with the Medical Device Authority (MDA) Malaysia.

6.0 DEFINITIONS OF TERMS

6.1 HIV Screening Test:

An initial test conducted to detect the presence of HIV antibodies and/or antigen in blood or body fluid samples, to determine whether an individual's HIV status is reactive or non-reactive. A reactive result requires confirmatory testing.

6.2 HIV Confirmatory Test:

A follow-up test conducted to confirm a reactive result from the HIV screening test. It uses a more specific method to ensure an accurate and reliable HIV diagnosis.

6.3 Rapid Diagnostic Test (RDT):

A rapid screening test for HIV using a portable diagnostic kit that provides results within 15 to 20 minutes. RDTs can be used by healthcare workers, trained NGO personnel, or self-administered, depending on the type of test and setting.

6.4 HIV Antigen/Antibody Combination Immunoassay:

A fourth-generation immunoassay capable of detecting both HIV-1 p24 antigen and HIV-1/2 antibodies simultaneously. This test improves detection sensitivity during the HIV infection window period.

6.5 HIV-1/2 Antibody Differentiation Assay:

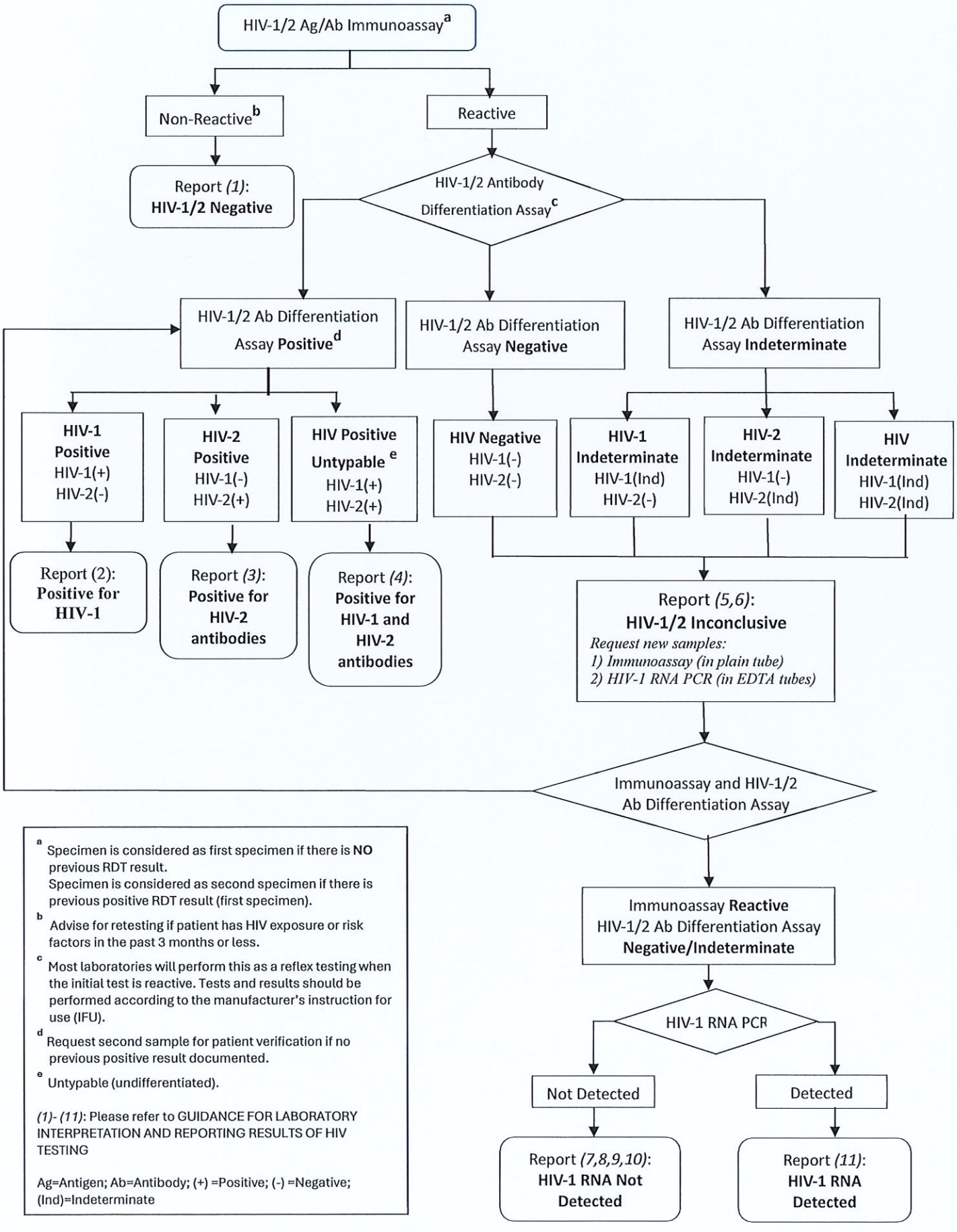
A confirmatory test that differentiates between HIV-1 and HIV-2 antibodies in individuals who test reactive in screening. It is used to determine the type of HIV infection present.

6.6 HIV-1 RNA Assay PCR / HIV-2 RNA Assay PCR:

A test for detecting HIV-1 or HIV-2 ribonucleic acid (RNA) using the polymerase chain reaction (PCR) technique. This test directly detects the virus and is especially useful for early diagnosis of infection (including in newborns) and for monitoring the viral load of HIV patients.

ANNEX 1

ALGORITHM 1: HIV LABORATORY TESTING IN ADULTS AND CHILDREN ABOVE 18 MONTHS OLD



[a] 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).

[b] Advise for retesting if patient has HIV exposure or risk factors in the past 3 months or less.

[c] Most laboratories will perform this as a reflex testing when the initial test is reactive. Tests and results should be performed according to the manufacturer's instruction for use (IFU).

[d] Request second sample for patient verification if no previous positive result documented.

[e] Untypable (undifferentiated).

(1)- (11): Please refer to GUIDANCE FOR LABORATORY INTERPRETATION AND REPORTING RESULTS OF HIV TESTING

Ag=Antigen; Ab=Antibody; (+) =Positive; (-) =Negative; (Ind)=Indeterminate

ANNEX 2

LABORATORY GUIDANCE FOR HIV TEST INTERPRETATION AND REPORTING (ADULTS AND CHILDREN ABOVE 18 MONTHS OLD)

I. There are several elements of reports of test results and interpretation that can help the requestor and avoid interpretive errors. Reports for the persons who ordered HIV testing should specify: all the assays that were used, the results of each assay and interpretation of the results. If the laboratories use a testing sequence other than the recommended algorithm or other/additional assays than those currently recommended, reports should describe the limitations associated with the testing sequence.

II. False-positive test results can occur due to technical issues associated with the test or biological causes:

   a. Technical issues include pre-analytical factors e.g., specimen mix-up, mislabelling, transport conditions and analytical factors, such as interpretation of a visually read rapid test result.

   b. Biological causes include autoimmune disorders, other medical conditions such as chronic infections i.e., tuberculosis; end stage renal failure, pregnancy and participation in an HIV vaccine study.

III. A negative HIV-1 RNA result and repeatedly HIV-2 indeterminate or HIV indeterminate antibody differentiation immunoassay result should be referred for testing with a different validated supplemental HIV-2 test (antibody test or NAT) if available. Alternatively, advise to repeat test in 2-4 weeks.

IV. Laboratories shall report final results, including the laboratory algorithm interpretation, upon completion of all testing. Whenever possible and applicable, the report should also provide recommendations for appropriate next steps, though this may not be feasible in all reporting scenarios.

V. The diagnosis of acute HIV infection highlights the need for potential public health interventions, as the risk of transmission to uninfected partners is heightened during this stage. Laboratories should establish protocols to promptly report test results and notification, indicative of acute HIV infection to both the healthcare provider and the public health department, ensuring timely access to treatment.

VI. There has been an increase in the use of antiretrovirals (ARVs) for pre-exposure prophylaxis (PrEP) and for treatment that begins earlier in the course of infection. ARVs can impact the normal development of HIV markers (RNA, antigen, antibodies) in an infected person and may lead to negative test results that fluctuates between negative and positive in subsequent specimens.

LABORATORY GUIDANCE FOR HIV TEST INTERPRETATION AND REPORTING (ADULTS AND CHILDREN ABOVE 18 MONTHS OLD)

No	Step 1 HIV-1/2 Ag/Ab Immunoassay	Step 2 HIV-1/2 Antibody Differentiation Assay	Step 3 HIV-1 RNA Assay	Step 4 HIV-2 RNA Assay	Interpretation for Laboratory	Final report
1	NR	N/A	N/A	N/A	Negative for HIV-1 antigen and HIV-1/HIV-2 antibodies. No laboratory evidence of HIV infection.	HIV-1/2 Negative. If recent HIV exposure is suspected, kindly repeat test after 2-4 weeks.
2	R	HIV-1 Positive	N/A	N/A	Positive for HIV-1 antibodies. Laboratory evidence of HIV-1 infection is present.	Positive for HIV-1 antibodies.
3	R	HIV-2 Positive	N/A	N/A	Positive for HIV-2 antibodies. Laboratory evidence of HIV-2 infection is present.	Positive for HIV-2 antibodies.
4	R	HIV positive Untypable (HIV-1 and HIV-2 Positive)	N/A	N/A	Positive for HIV-1 and HIV-2 antibodies. Laboratory evidence of HIV-1 and/or HIV-2 infection is present.	Positive for HIV-1 and HIV-2 antibodies. Suggest to send for HIV-1 RNA if warranted by clinical evaluation or risk factors.

No	Step 1 HIV-1/2 Ag/Ab Immunoassay	Step 2 HIV-1/2 Antibody Differentiation Assay	Step 3 HIV-1 RNA Assay	Step 4 HIV-2 RNA Assay	Interpretation for Laboratory	Final report
5	R	HIV Negative	N/A	N/A	HIV infection is not confirmed.	HIV-1/2 Inconclusive. Send new samples for immunoassay (plain tube) and HIV -1 RNA PCR (EDTA tubes) for retesting.
6	R	HIV Indeterminate (HIV-1 Ind, HIV-2 Ind, HIV Ind)	N/A	N/A	HIV infection is not confirmed.	HIV-1/2 Inconclusive. Send new samples for immunoassay (plain tube) and HIV -1 RNA PCR (EDTA tubes) for retesting.
7	R	HIV Negative	ND	N/A	HIV antibodies are not confirmed, and HIV-1 RNA is not detected. No Laboratory evidence of HIV-1 infection.	HIV-1 antibodies Inconclusive and HIV-1 RNA Not Detected. Further testing is recommended if warranted by clinical evaluation or risk factors.

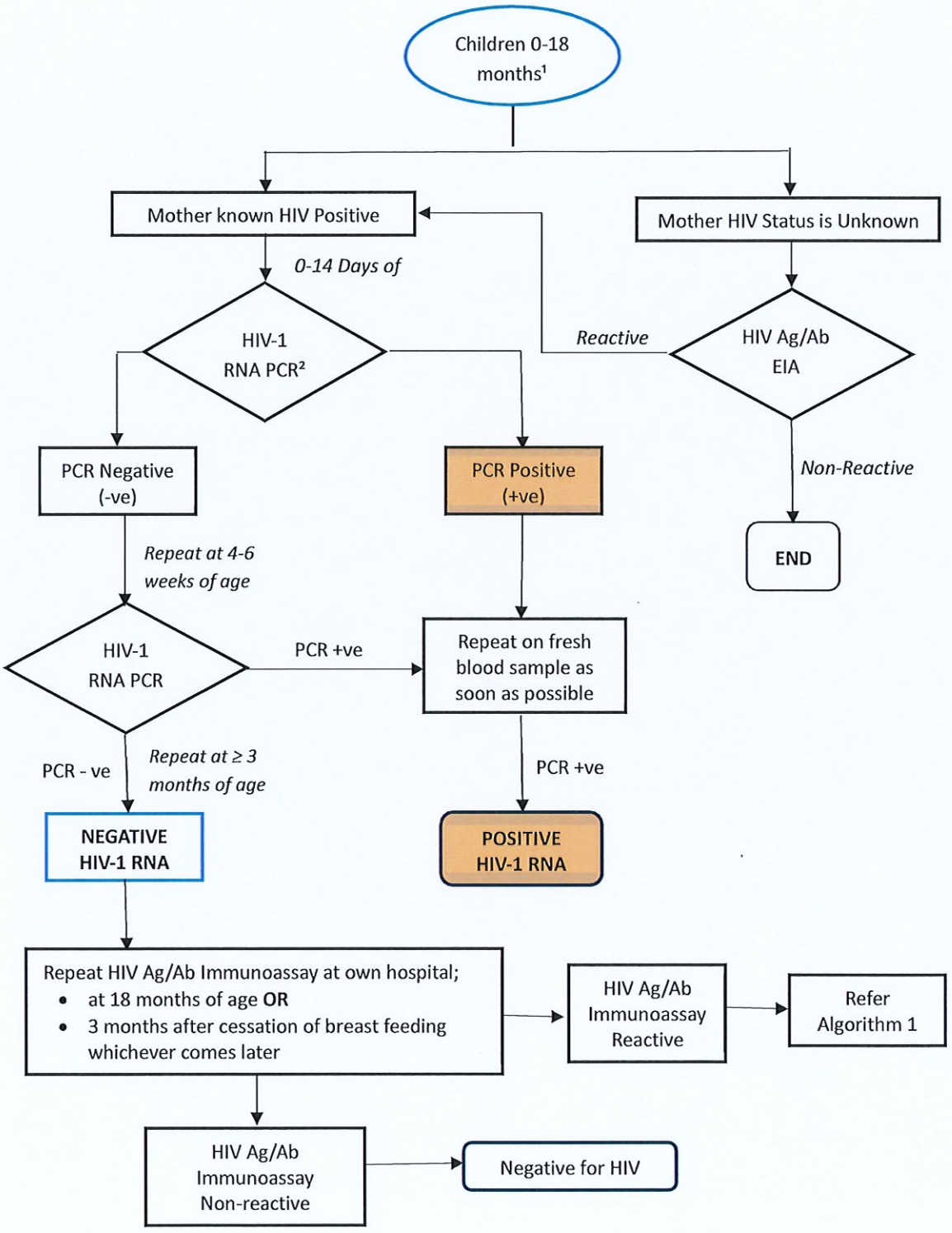
No	Step 1 HIV-1/2 Ag/Ab Immunoassay	Step 2 HIV-1/2 Antibody Differentiation Assay	Step 3 HIV-1 RNA Assay	Step 4 HIV-2 RNA Assay	Interpretation for Laboratory	Final report
8	R	HIV-1 Indeterminate	ND	N/A	HIV-1 antibodies are not confirmed, and HIV-1 RNA is not detected.	HIV-1 antibodies Inconclusive and HIV-1 RNA is not detected. Further testing is recommended if warranted by clinical evaluation or risk factors.
9	R	HIV-2 Indeterminate	ND	N/A	HIV-2 antibodies are not confirmed, and HIV-1 RNA is not detected.	HIV-2 antibodies Inconclusive and HIV-1 RNA is not detected. Further testing is recommended if warranted by clinical evaluation or risk factors.
10	R	HIV Indeterminate (HIV-1 Ind, HIV-2 Ind)	ND	N/A	HIV antibodies are not confirmed, and HIV-1 RNA is not detected.	HIV-1/2 antibodies Inconclusive and HIV-1 RNA is not detected. Further testing is recommended if warranted by clinical evaluation or risk factors.

No	Step 1 HIV-1/2 Ag/Ab Immunoassay	Step 2 HIV-1/2 Antibody Differentiation Assay	Step 3 HIV-1 RNA Assay	Step 4 HIV-2 RNA Assay	Interpretation for Laboratory	Final report
11	R	HIV Negative	D	N/A	HIV-1 RNA detected. Laboratory evidence of HIV-1 infection.	HIV-1 RNA Detected.
12	R	HIV-2 Indeterminate	ND	D	HIV-2 RNA Detected. Laboratory evidence of HIV-2 infection.	HIV-2 RNA Detected.

Abbreviations: Ag=antigen; Ab=antibody; R=reactive; NR=non-reactive; D=detected; ND=not detected; Ind=indeterminate

ANNEX 3

ALGORITHM 2: HIV LABORATORY TESTING IN PAEDIATRICS AGE GROUP < 18 MONTHS

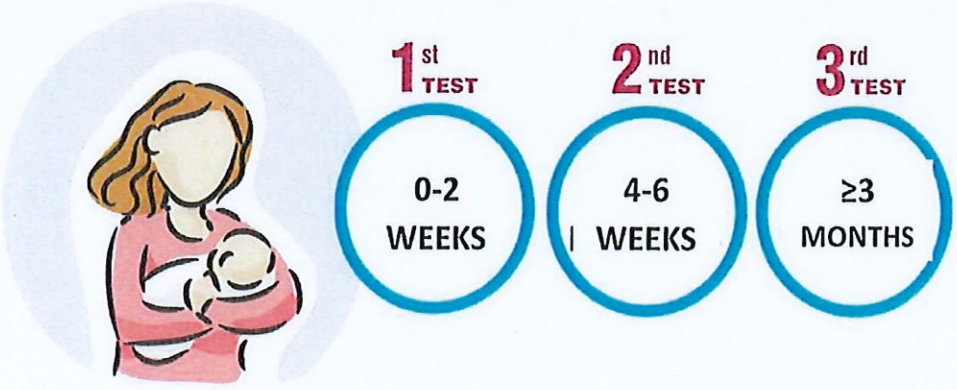


[1] Includes abandoned babies
[2] HIV RNA test: 2.5mls of blood in EDTA. Specimens need to be transported at 2-8°C to Virology Unit, IMR, NIH, Setia Alam. If delay in transporting the specimen, the specimens should be kept at 2-8°C (maximum of 3 days).

ANNEX 4

TEST TO DIAGNOSE HIV IN INFANTS AND CHILDREN BELOW 18 MONTHS OF AGE

- It is strongly recommended that HIV-1 RNA PCR tests to be used to diagnose HIV infection in infants and children below 18 months of age.
- Because of the passage of maternal HIV antibody across the placenta to the baby, HIV serological testing (HIV Ag/Ab EIA) in infancy cannot be used to confirm HIV infection in the infant and does indicate maternal HIV infection and exposure of the infant.
- In order to diagnose HIV infection definitively in children below 18 months of age, HIV-1 RNA PCR tests that detect the virus or its components are therefore required.
- The first HIV-1 RNA PCR test should be performed at 0-2 weeks after birth, the second test at 4-6 weeks of age, and the third rest at 3 months of age.



Confirming HIV Test Results in Infants

1. At least two HIV-1 RNA PCR test results must be negative to be sure that a baby is not infected with HIV.
2. At least two HIV-1 RNA PCR test results must be positive to know for certain that a baby is infected with HIV.

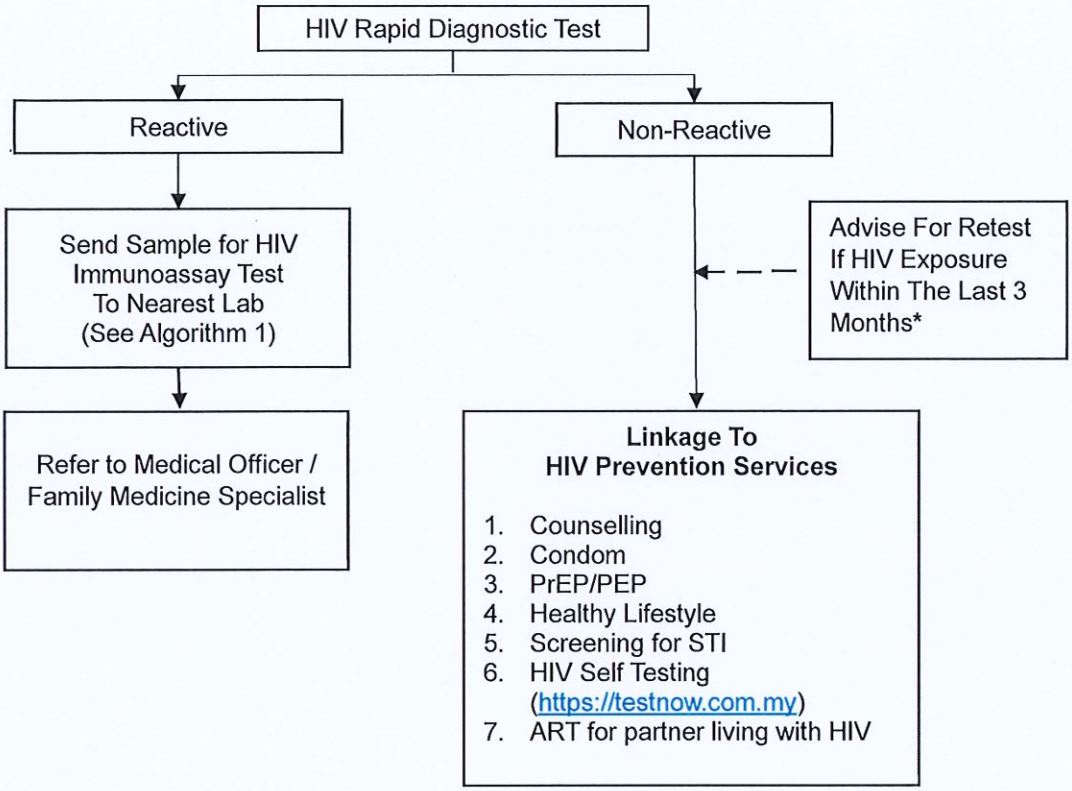
- In infants less than 18 months of age with HIV-positive mother, where it is missed by the recommended age testing algorithm, HIV-1 PCR tests need to be done as soon as possible.

Additional Considerations

- Acute HIV infection during breastfeeding is associated with an increased risk of perinatal transmission of HIV
- Women with possible acute HIV infection who are breastfeeding at or after her infant reaches the age of 18 months, HIV Ag/Ab EIA testing need to be done at 3 months after cessation of breastfeeding.

ANNEX 5

Algorithm 3: Algorithm for HIV Rapid Diagnostic Test



*At risk individuals who tested negative warrant repeat testing (earliest at 4-6 weeks):

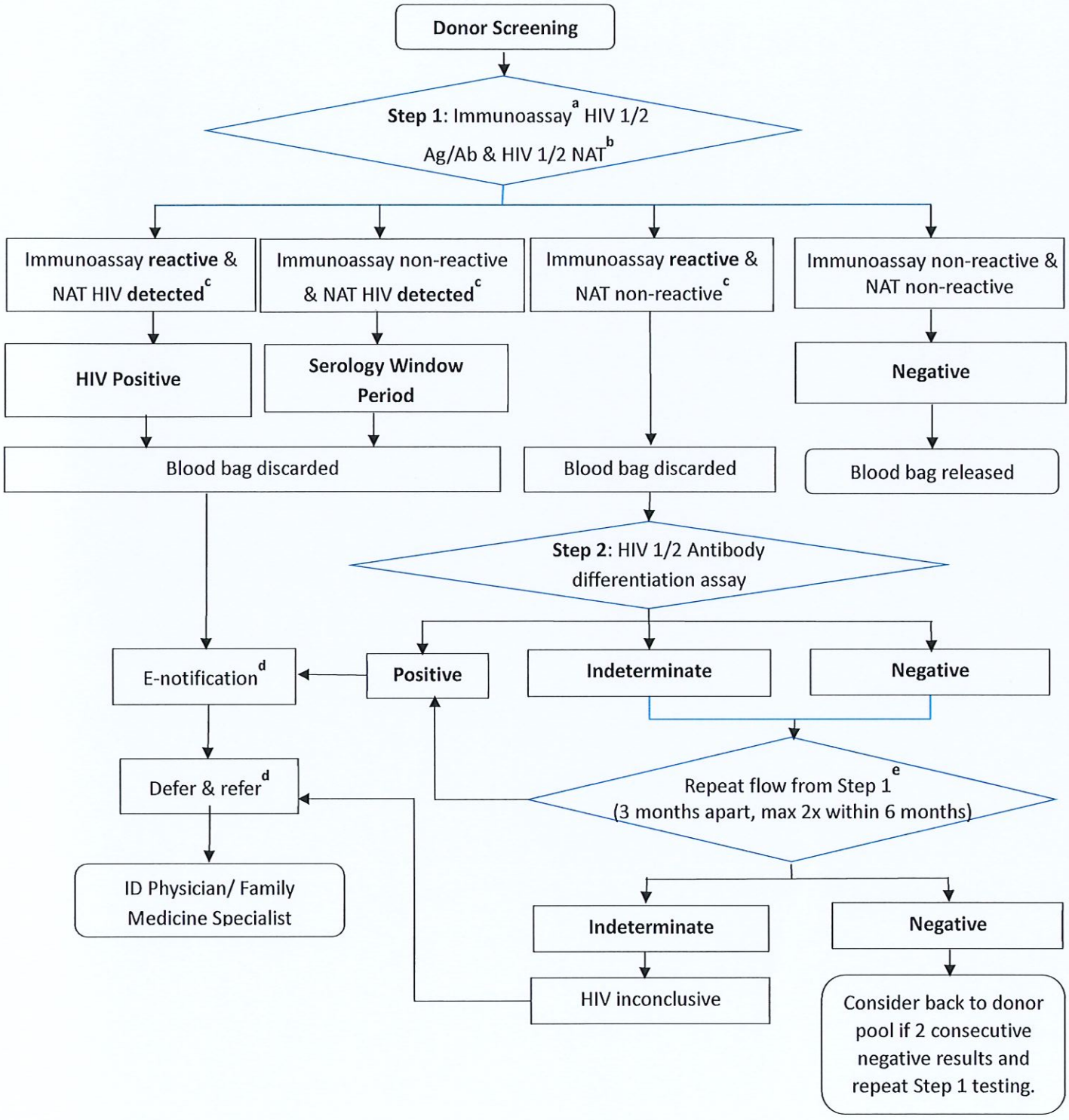
- People from key populations
- People with known HIV partners
- Individuals with known or possible recent HIV exposure
- Individuals who are seen for diagnosis or treatment of recent STI/ Hepatitis B/ Hepatitis C
- Individuals who are taking PrEP or PEP

Format of Reporting for HIV Rapid Diagnostic Tests

REACTIVE	NON-REACTIVE
Report as: Anti-HIV Rapid Test **REACTIVE** Name of Rapid Test Kit: Date of Test: Testing Site: Operator: Kit Lot No: Batch No: Expiry Date:	Report as: Anti-HIV Rapid Test **NON-REACTIVE** Name of Rapid Test Kit: Date of Test: Testing Site: Operator: Kit Lot No: Batch No: Expiry Date:

ANNEX 6

ALGORITHM 4: HIV LABORATORY TESTING IN DONOR SCREENING



Notes:

[a] Immunoassay method in use is chemiluminescent microparticle immunoassay (CMIA) and is subject to change depending on service requirements.

[b] NAT: Nucleic Acid Testing

[c] Donors will be contacted, counseled and followed-up until referred to ID Physician/Family Medicine Specialist.

[d] E-notification, defer and refer is the responsibility of Donor Management.

[e] Repeat the assay as per indication with new sample (at least 3 months apart, max: 2x within 6 months).

ANNEX 7

GUIDE TO TRANSFUSION MEDICINE: HIV SCREENING ALGORITHM OF DONORS

I. It is compulsory to screen all blood donations for Human Immunodeficiency Virus (HIV), Hepatitis B (HBV), Hepatitis C (HCV) and syphilis.

II. Current method of donation screening by National Transfusion Medicine Service under Ministry of Health Malaysia is by immunoassay (chemiluminescent microparticle immunoassay, CMIA) and molecular (nucleic acid testing, NAT).

III. If **any** immunoassay or molecular screening result is **reactive**, the donated blood bags shall be **discarded**.

IV. Donated blood bags can only be released for use if screening results for immunoassay **and** molecular are non-reactive.

V. False-positive test results can occur due to technical issues associated with the test or biological causes.

VI. All donors who are under investigation for reactive HIV screening results (immunoassay or/and NAT) is deferred from donation.

VII. All donors who are under investigation for reactive HIV screening results shall be contacted, counselled and followed-up by Donor Management Unit of the blood collection centre. All inconclusive and confirmed HIV positive donors shall be referred to ID Physician / Family Medicine Specialist.

VIII. **E-notification shall be done within 7 days** in accordance to Act 342 Prevention and Control of Infectious Diseases Act 1988, Act A1742 Prevention and Control of Infectious Diseases (Amendment) Act 2025 and related subsidiary legislations and guidelines by the Ministry of Health Malaysia.

IX. E-notification, deferral and referral of a donor, is the responsibility of Donor Management Unit of the blood collection centre.

X. A donor who are under investigation for reactive HIV screening results can be considered to be allowed back to donor pool if **ALL** these criteria are met:
   a. No high-risk behaviours.
   b. 2 consecutive negative results and repeat HIV screening test (negative) with each testing at least 3 months apart.

XI. Any uncertainties regarding the algorithm, interpretation of results or management of the donors can be discussed with the in-house Transfusion Medicine Specialist (or nearest hospital with Transfusion Medicine Specialist).

ANNEX 8

LIST OF MINISTRY OF HEALTH HOSPITALS PROVIDING HIV ENZYME IMMUNOASSAY (EIA) AND HIV-1/2 DIFFERENTIATION TESTING (as of Aug 2025)

STATE	HOSPITAL	
Perlis	1	Hospital Tuanku Fauziah
Kedah	2	Hospital Sultan Abdul Halim
	3	Hospital Sultanah Bahiyah
	4	Hospital Kulim
Pulau Pinang	5	Hospital Pulau Pinang
	6	Hospital Seberang Jaya
Perak	7	Hospital Raja Permaisuri Bainun
	8	Hospital Seri Manjung
	9	Hospital Taiping
	10	Hospital Teluk Intan
Kelantan	11	Hospital Raja Perempuan Zainab II
Terengganu	12	Hospital Kemaman
	13	Hospital Sultanah Nur Zahirah
Pahang	14	Hospital Tengku Ampuan Afzan
	15	Hospital Sultan Haji Ahmad Shah
Selangor	16	Hospital Tengku Ampuan Rahimah
	17	Hospital Selayang
	18	Hospital Serdang
	19	Hospital Sungai Buloh
	20	Hospital Ampang
	21	Hospital Shah Alam
	22	Hospital Tengku Permaisuri Norashikin
	23	Hospital Cyberjaya

STATE	HOSPITAL	
Wilayah Persekutuan	24	Hospital Kuala Lumpur
	25	Hospital Putrajaya
	26	Hospital Labuan
Negeri Sembilan	27	Hospital Tuanku Ja'afar Seremban
Melaka	28	Hospital Melaka
Johor	29	Hospital Sultanah Aminah
	30	Hospital Sultan Ismail
	31	Hospital Sultanah Nora Ismail
	32	Hospital Pakar Sultanah Fatimah
	33	Hospital Segamat
	34	Hospital Enche' Besar Hajjah Kalsom, Kluang
Sabah	35	Hospital Queen Elizabeth
	36	Hospital Wanita dan Kanak-Kanak Sabah
	37	Hospital Tawau
	38	Hospital Duchess of Kent
Sarawak	39	Hospital Umum Sarawak
	40	Hospital Miri
	41	Hospital Sibu
	42	Hospital Bintulu

ANNEX 9

LIST OF MINISTRY OF HEALTH HOSPITALS PROVIDING HIV-1 RNA PCR TEST (as of Aug 2025)

STATE	HOSPITAL	
Kedah	1	Hospital Sultanah Bahiyah
Pulau Pinang	2	Hospital Pulau Pinang
Perak	3	Hospital Raja Permaisuri Bainun
Kelantan	4	Hospital Raja Perempuan Zainab II
Terengganu	5	Hospital Sultanah Nur Zahirah
Pahang	6	Hospital Tengku Ampuan Afzan
Selangor	7	Hospital Tengku Ampuan Rahimah
	8	Hospital Sungai Buloh
Wilayah Persekutuan	9	Hospital Kuala Lumpur
Negeri Sembilan	10	Hospital Tuanku Ja'afar Seremban
Melaka	11	Hospital Melaka
Johor	12	Hospital Sultanah Aminah
Sabah	13	Hospital Queen Elizabeth
Sarawak	14	Hospital Umum Sarawak

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