Kursus Pengurusan Kes Prevention Mother-To-Child Transmission (PMTCT) HIV Dan Sifilis Peringkat Negeri Johor 2023

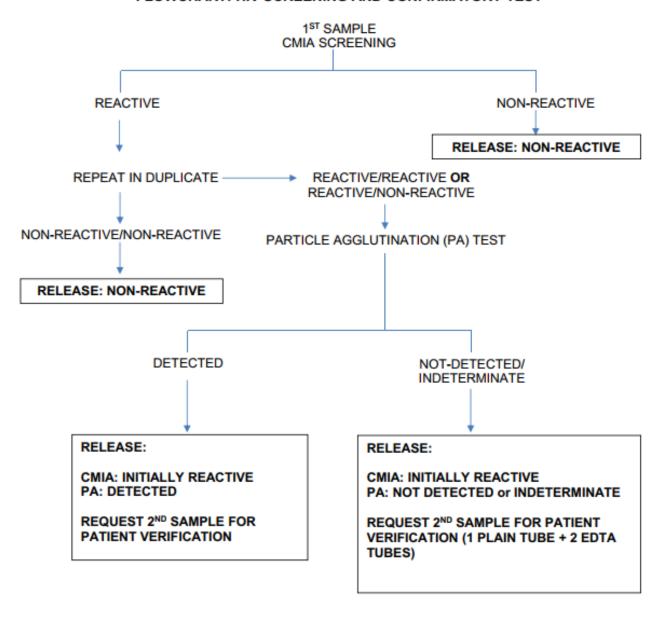




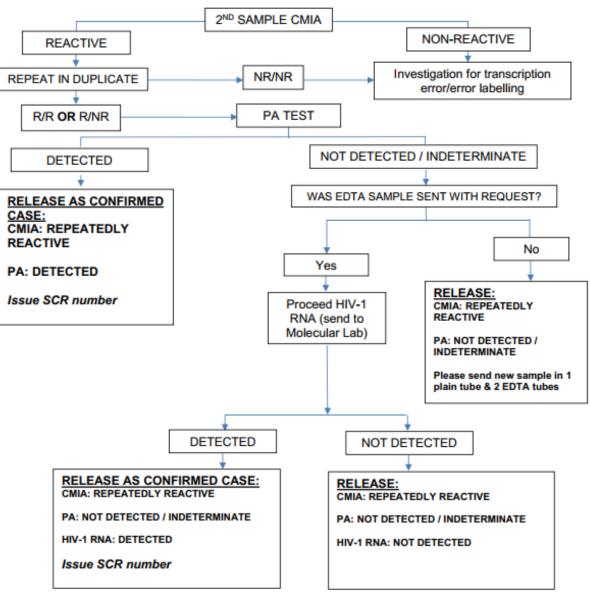
District	Sample Receiving Hospital
Johor Bharu Pontian Kulai Kota Tinggi Mersing	Hospital Sultanah Aminah
Cases in HSI	Hospital Sultan Ismail
Segamat	Hospital Segamat
Muar Tangkak	Hospital Pakar Sultanah Fatimah
Kluang	Hopital Enche' Besar Hajjah Khalsom
Batu Pahat	Hospital Sultanah Nora Ismail

HIV Diagnostic Tests

FLOWCHART: HIV SCREENING AND CONFIRMATORY TEST



HIV SCREENING AND CONFIRMATORY TEST (CONTINUE) 2ND SAMPLE CMIA



WHO recommends that all HIV testing algorithms achieve PPV of at least 99% and use a combination of tests with ≥99% sensitivity and ≥98% specificity.

Rajah 4: Carta alir pengurusan dan rawatan bayi yang dilahirkan oleh ibu HIV positif Bayi dilahirkan oleh ibu HIV positif 1. Mulakan profilaksis untuk HIV sejurus selepas 2. Ujian: HIV DNA/RNA PCR (bersama dengan ujian darah ibu) pada usia 0 – 2 minggu, FBC semasa lahir dan pada usia 6 minggu 3. Mulakan profilaksis PCP selepas melengkapkan profilaksis untuk HIV hingga status HIV dikenalpasti Negatif Positif HIV-1 RNA Ulang HIV-1 RNA PCR pada usia 4-6 minggu Positif HIV-1 RNA Ulang HIV-1 RNA PCR pada PCR1 sampel darah yang baru dengan kadar segera Ulang HIV-1 RNA Negatif pada usia ≥ 3 bulan HIV-1 RNA PCR1 HIV-1 RNA

Nota:

Tidak reaktif

PCR1

HIV Ag/Ab EIA

HIV Negatif

Negatif

Ulang HIV Ag/Ab EIA pada usia 18 bulan ATAU 3 bulan selepas penyusuan susu badan dihentikan (mana-mana yang terkemudian).

Reaktif

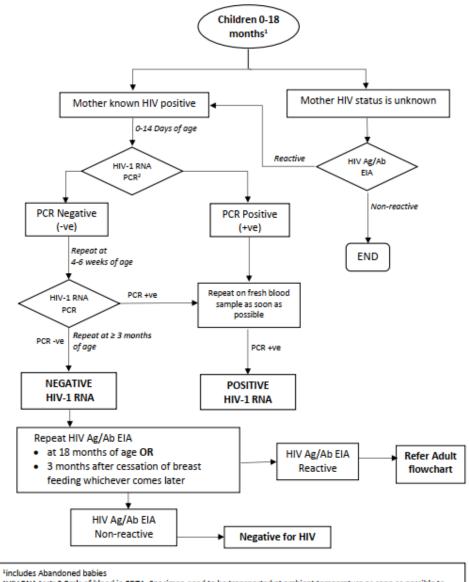
Ujian ¹HIV RNA PCR: 2.5mls darah dalam botol EDTA. Spesimen hendaklah ditransport pada suhu yang bersesuaian secepat mungkin ke Makmal Virologi, IMR Kuala Lumpur. Jika tidak dapat dihantar dalam tempoh 24 jam, simpan spesimen pada suhu 2-8°C (maksimum 3 hari sahaja). JANGAN DIBEKUKAN.

Rujuk carta alir untuk dewasa Positif

HIV Positif

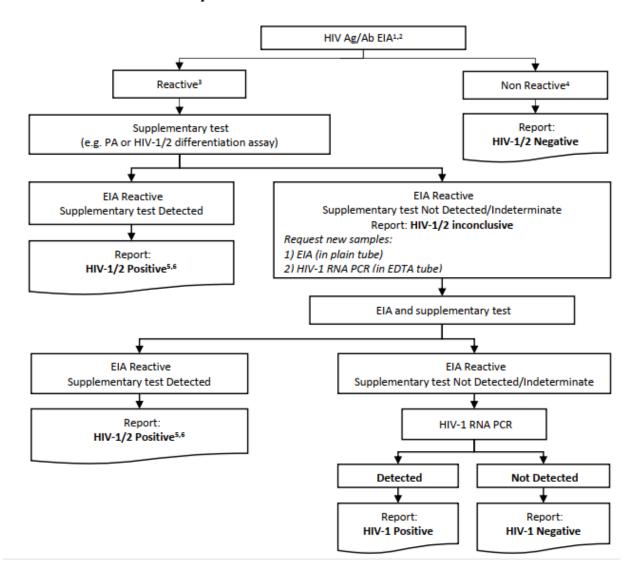
Rujukan: Surat pekeliling Ketua Pengarah Kesihatan Malaysia Bil 10/2021- Kemaskini carta alir ujian saringan dan pengesahan HIV.

Algorithm for diagnosis of HIV infection in children less than 18 months



²HIV RNA test: 2.5mls of blood in EDTA. Specimen need to be transported at ambient temperature as soon as possible to IMR KL (Virology). If unable to send within 24 hours, keep specimen at 2-8°C (maximum of 3 days).

Algorithm for HIV testing using HIV antigen / antibody combination immunoassay for adults and children more than 18 months

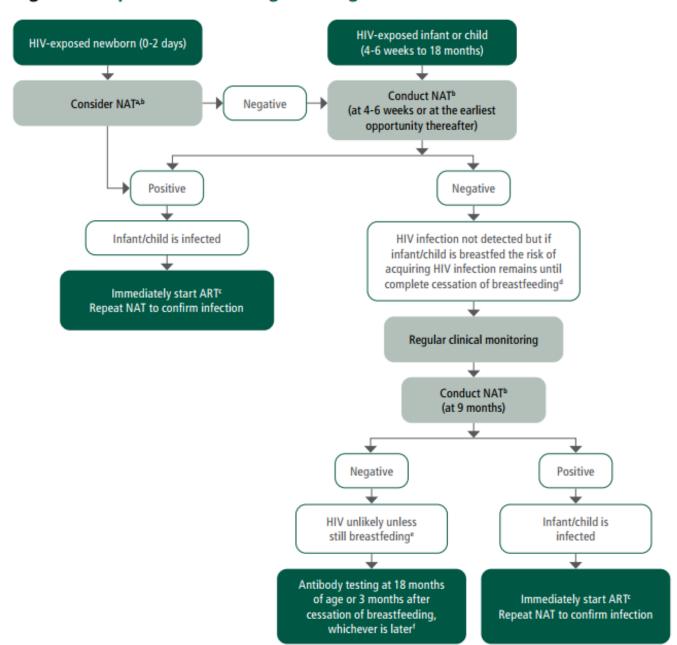


- ¹ HIV Ag/Ab EIA: HIV antigen-antibody enzyme immunoassay (latest available version).
- ² Specimen is considered as first specimen if there is NO previous RDT result. Specimen is considered as second specimen if there is previous positive RDT result (first specimen).
- ³ To be performed as duplicate or more following the manufacture product inserts.
- ⁴ 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.
- Request second sample for patient verification if no previous positive result documented. This is applied for EIA and supplementary testing only.
- ⁶ Suggest: to send fresh blood sample in EDTA tubes for HIV-1 RNA PCR

References:

- World Health Organization (WHO). Consolidated Guidelines on HIV Testing Services for A Changing Epidemic. Policy Brief. November 2019.
- 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. Accessed 6 February 2020.

Fig. 2.7 Simplified infant diagnosis algorithm

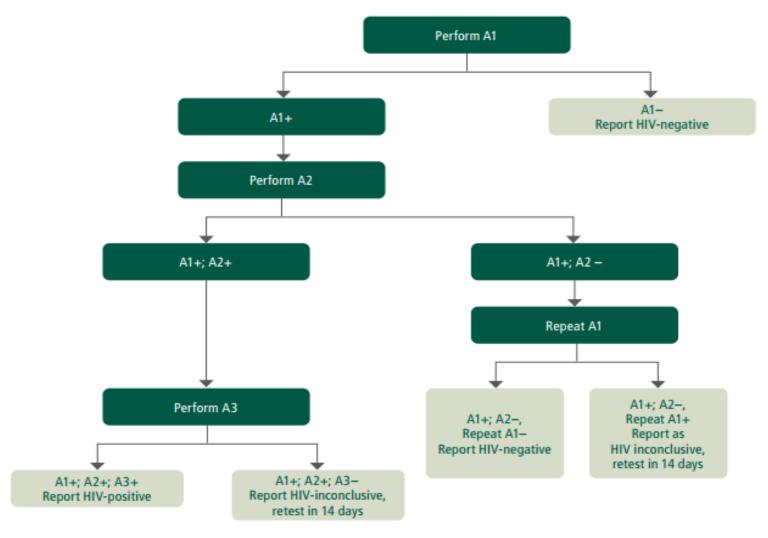


- *Based on 2016 WHO Consolidated ARV Guidelines (3), addition of NAT at birth to the existing testing algorithm can be considered.
- ^b Point-of-care NAT can be used to diagnose HIV infection as well as to confirm positive results.
- Start ART without delay. At the same time, retest to confirm infection. As maternal treatment is scaled up and MTCT transmission rates decrease, false-positive results are expected to increase: retesting after a first positive NAT is hence important to avoid unnecessary treatment, particularly in settings with lower transmission rates. If the second test is negative, a third NAT should be performed before interrupting ART.
- ^dFor children who were never breastfed, additional testing following a negative NAT at 4–6 weeks is included in this algorithm to account for potential false-negative NAT results.
- The risk of HIV transmission remains as long as breastfeeding continues. If the 9-month test is conducted earlier than 3 months after cessation of breastfeeding, infection acquired in the last days of breastfeeding may be missed. Retesting at 18 months or 3 months after cessation of breastfeeding (whichever is later) should be carried out for final assessment of HIV status.
- 'If breastfeeding extends beyond 18 months, the final diagnosis of HIV status can only be assessed at the end of breastfeeding.

 If breastfeeding ends before 18 months, the final diagnosis of HIV status with antibody testing can only be assessed at 18 months.

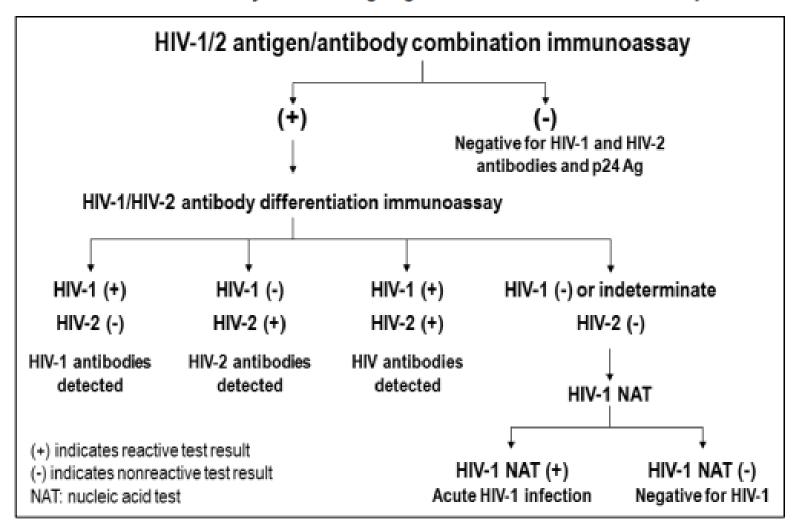
 Antibody testing should be undertaken at least 3 months after cessation of breastfeeding (to allow for development of HIV antibodies). For infants younger than 18 months of age NAT should be performed to confirm infection. If the infant is older than 18 months, negative antibody testing confirms that the infant is uninfected; positive antibody testing confirms infant is infected.

Fig. 2.4 WHO standard testing strategy for HIV-1 diagnosis (among people ≥18 months of age)



A1:Assay 1 (first test); A2: Assay 2 (second test); A3: Assay 3 (third test). Assay (test) are HIV rapid diagnostic tests (RDTs) or enzyme immunoassays (EIAs).

Recommended Laboratory HIV Testing Algorithm for Serum or Plasma Specimens



Tests Offered for HIV

Diagnosis

- HIV Rapid Test
- HIV Ag/Ab Serology
- HIV Particle Agglutination
- HIV RNA PCR

Disease Monitoring

- HIV Viral Load
 - PCR
 - Genexpert
- CD4 and CD8 Enumeration

HIV Rapid Test

- The HIV rapid test is a qualitative, membrane-based immunoassay for the detection of antibodies to HIV in serum or plasma
- The membrane is coated with recombinant HIV antigens on the test line region of the cassette
- When the serum or plasma specimen is applied at one end of the membrane, it reacts with Anti-Human IgG Monoclonal antibody coated particles
- The mixture then migrates chromatographically towards the other end of the membrane and reacts with the recombinant HIV antigens on the membrane in the test line region
- If the plasma or serum contains antibodies to HIV-1 or HIV-2, a colored line will appear in the test line region, showing a positive result

- The absence of the colored line indicates that the whole blood Plasma or serum does not contain the anti-HIV antibodies, showing a negative result
- A colored line will always appear in the control region to serve as a procedural control indicating that proper volume of specimen has been added and membrane wicking has occurred
- KKM recommends 99.9% sensitivity and 99.8% specificity for rapid test
- Regular External Quality Assuarance by IMR dan Inter-laboratory Comparison (ILC) by JKN performed

Test	Type of Specimen	Specimen Container	Volume of Specimen	LTAT
HIV Ag/Ab screening	Serum	Plain Tube	3-5 ml	1-3 working days
HIV 1&2 Mix Particle agglutination (PA)	Serum	Plain Tube	3-5 ml	3-5 working days
HIV Viral Load PCR	Plasma (EDTA)	EDTA	5-10 ml Blood (EDTA) / 1.5 ml plasma	2-4 weeks
HIV-1 RNA RtPCR for Babies (HIV PCR)	Blood	EDTA (Child)	3-5 ml	IMR 5 days
HIV Drug Resistance Genotyping Test	Blood	EDTA	5-10 ml	IMR 40 days
CD4 / CD8 Enumeration	Blood	K2/K3 EDTA	3 ml	5 days

HIV Ag/Ab Serology

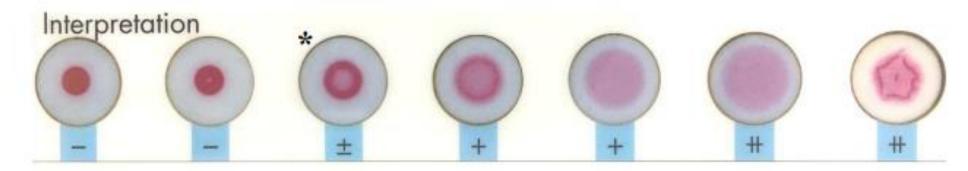
Architect CMIA Assay

- This is a two-step immunoassay, using Chemiluminescent Microparticle Immunoassay (CMIA) technology, with flexible assay protocols referred to as Chemiflex, for the quantitative determination of target antigen or antibody in human serum or plasma
- The resulting chemiluminescent reaction is measured as Relative Light Units (RLUs)
- A direct relationship exists between the target amount of target antigen/antibody in the sample and the RLUs detected by the architect optical system
- The concentration of target antigen/antibody in the specimen is determined using a previously generated Architect target antigen/antibody calibration curve

HIV Particle Agglutination

SERODIA®-HIV 1/2 MIX PA

- The test is an in-vitro diagnostic test for the detection of antibodies towards HIV-1 and/or HIV-2
- It is manufactured using gelatine particles sensitized with recombinant HIV-1 antigens (HIV-1/gp41 and HIV-1/p24) and HIV-2/gp36
- The test is based on the principle that sensitized particles agglutinated by the presence of antibodies towards HIV-1 and/or HIV-2 in human serum/plasma
- If HIV PA is Not Detected / Indeterminate, new samples in 1 plain tube and 2 EDTA tubes for HIV Confirmatory Test must be sent
- For second samples, if PA remains Not Detected/Indeterminate, send EDTA tubes and request form to Molecular Laboratory, Microbiology Unit, HSAJB to proceed with HIV-1 RNA PCR for confirmation



* - Indeterminate

HIV PA Pattern Interpretation

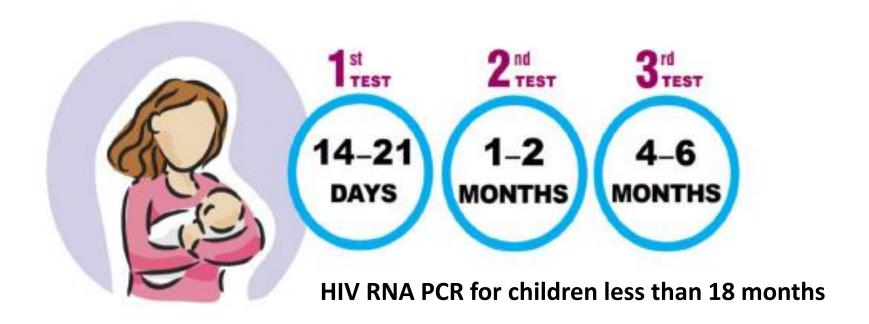
HIV RNA PCR

Mother/ Child above 18 months of age

- Test done in HSAJB
- Abbott RealTime HIV-1 Assay used to detect Human Immunodeficiency Virus Type 1 (HIV-1) nucleic acids from human plasma
- Only for cases with indeterminate/not detected PA with reactive HIV Ag/ab serology

Child less than 18 months of age

- Test outsourced to Virology, IMR
- Abbott real-time HIV-1 Qualitative performs qualitative detection of Human Immunodeficiency Virus Type 1 (HIV-1) nucleic acids from human plasma
- To send sample with latest IMR Virology form
- Mother's sample not required



Blood Test for Children less than 18 months old:

- 1. HIV DNA/RNA PCR: Birth to 2 weeks, 4 to 6 weeks and 4 to 6 months
- 2. FBC, LFT, RFT, HbsAg, Hep C, Syphilis serology: At birth
- 3. In premature babies, blood test should be done after 24 hours
- 4. Cord blood for G6PD and TSH

UJIAN POLYMERASE CHAIN REACTION (PCR) UNTUK HUMAN IMMUNODEFICIENCY VIRUS (HIV) DI KALANGAN BAYI

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MR/Vro/HIV/2 IMEVIRUS/NARL2

UJIAN POLYMERASE CHAIN REACTION (PCR) UNTUK HUMAN IMMUNODEFICIENCY VIRUS (HIV) DI KALANGAN BAYI

Spesimen yang diperlukan: 2.5ml darah EDTA dari bayi

Darah hendaklah dihantar serta-merta kepada Makmal Rujukan Kebangsaan AIDS (NARL), Institut Penyelidikan Perubatan, Institut Keshatan Manara. Rafia Alam Selanger, Tel: (N.3392 8114

Institut Kesihatan	Negara, Setia Alar	m,Selangor. Tel:	03-3362 8	8114			
Hospital:	spital:				Wad/Clinic:		
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	AZT diberikan masa antenatal: OTidak OYa, tarikh diberi dari: hingga						
Untuk Kegunaan NARL Sahaja	Keputusan ujian anti- O Positif Makmal HIV: O Negatif menjala				al yang lankan ujian:		
	Nama Bapa:				No Kad Pengenalan/Passport:		
	Umur:	Keturunan:			Aktivit	i risiko (jika ad	ia):
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Tarikh darah	di ambil:						
Nama doktor	yang minta ujia	in:				egunaan NARL:	
Chop:	Tandatangan		-	Re	eceived m	O EDTA	O Plasma O Serum (ml) (ml) O Clear O Lysed O Turbid

No Tel:

Tarikh



Case definition of HIV infection in child aged less than 18 months

In a child aged < 18 months, a reportable case of HIV infection must meet at least one of the following criteria:

1. Laboratory criteria

Definitive.

Positive result or report of detectable quantity on any of the following HIV virology (nonantibody) tests:

- HIV nucleic acid (DNA or RNA) detection.
- HIV p24 antigen test including neutralization assay,
- HIV isolation (viral culture)

OR

(ii) Presumptive

A child who does not meet the criteria for definitive HIV infection but who has a positive result on only one specimen (excluding cord blood) using the above HIV virology (nonantibody) tests.

OR

Clinical or other criteria (if the above laboratory criteria are not met and no other causes of immune suppression)

Condition that meets criteria included in the 1987 paediatric surveillance case definition for AIDS which are:

- Candidiasis of the oesophagus, trachea, bronchi, or lungs
- Cryptococcosis, extrapulmonary
- Cryptosporidiosis with diarrhoea persisting >1 month
- Cytomegalovirus diseases of an organ other than liver, spleen, or lymph nodes in patient >1 month of age
- Herpes simplex virus infection causing a mucocutaneous ulcer persisting >1 month; or bronchitis, pneumonitis, or oesophagitis for any duration in a patient >1 month of age
- Kaposi sarcoma
- · Lymphoma of the brain (primary).
- Mycobacterium avium complex or M. kansasii disease, disseminated (site other than/in addition to lungs, skin, cervical or hilar lymph nodes)
- Pneumocystis carinii pneumonia
- · Progressive multifocal leukoencephalopathy
- · Toxoplasmosis of the brain in a patient >1 month of age
- Two or more bacterial infections within a 2-year period (septicaemia, pneumonia, meningitis, bone or joint infections) or abscess of an internal organ or body cavity excluding otitis media or superficial abscesses.

HIV Viral Load PCR

Abbott RealTime HIV-1 Assay

- It is an in vitro reverse transcription polymerase chain reaction (RT-PCR) assay for the quantitation of Human Immunodeficiency Virus type 1 (HIV-1) in human plasma from HIV-1 infected individuals
- It is intended for use in conjunction with clinical presentation and other laboratory markers as an indicator of disease prognosis and for use as an aid in assessing viral response to antiretroviral treatment as measured by changes in plasma HIV-1 RNA levels
- Indication:
- ❖ In pregnancy, to be done between 32 to 36 weeks of gestation to decide on mode of delivery
- ❖ Pre-HAART (not during diagnosis, except certain cases such as after pregnancy/ discussion with FMS and ID specialist)
- 4 months after HAART treatment is started
- ❖ 6 months intervals (after 4 months of HAART treatment for 2 years)
- ❖ Once a year after 2 years of HAART treatment

HIV Viral Load Genexpert

- Xpert HIV-1 Viral Load automates the test process including RNA extraction, purification, reverse transcription and cDNA real time quantitation in one fully integrated cartridge
- Point of Care Test (POCT) HIV viral load service at Makmal Klinik Dada Kluang and KK Batu Pahat

Bil	Fasiliti Kesihatan Yang Boleh Menghantar Sampel
	Ujian HIV Viral Load Ke Makmal Klinik Dada Kluang
1.	Hospital Enche Besar Hajah Kalsom(HEBHK)
2. 3.	KK Mengkibol
3.	KKIA Kluang
4.	Klinik Dada Kluang/Methadone
5.	KK Paloh
6.	KK Kahang Bt22
7.	KK Kahang Timur
8.	KK Ulu Belitong
9.	KK Layang-Layang
10.	KK Renggam
11.	KK Simpang Renggam
12.	Penjara Kluang
13.	Penjara Simpang Renggam

- Sample processed on working Sundays to Wednesdays, sample must reach
 Makmal Klinik Dada by 11am
- Sample must be sent in 2 EDTA bottles, volume 2.5-3ml of blood plasma
- Blood sample should be centrifuged to separate plasma
- Cold chain maintained during transportation
- LTAT 3-5 days



CD4 CD8 Enumeration

- Direct immunofluorescence method for enumerating percentages of mature human helper/inducer (CD4+) and suppressor/cytotoxic (CD8+) lymphocytes in erythrocyte-lysed whole blood (LWB)
- Request form must include :
- Latest date of CD4 CD8 Count/ HIV Viral Load
- II. Date of specimen collection
- III. Date of commencement of HAART
- Transport samples within 4 hours of blood collection at room temperature or within 24 hours for District Hospital/Klinik Kesihatan with ice pack. Avoid direct contact with ice
- CD4/CD8 test is available from Sunday to Wednesday only
- Request form requires Specialist's signature.

Indication:

- In pregnancy, as soon as diagnosed with HIV
- New HIV case
- Patients with no CD4 CD8 results in 6 months upon being diagnosed with HIV
- Patients who rejected anti-retroviral therapy
- CD4 request once a year if CD4 count > 350
- CD4 request 6 monthly if CD4 count < 350
- In patients who just started anti-retroviral therapy, CD4 CD8 request can be made after 4 months of stable HAART intake
- CD4 CD8 request 6 monthly during the first 2 years of HAART intake (Performed together with HIV Viral Load)
- CD4 CD8 request yearly after 2 years of HAART intake (Performed together with HIV Viral Load)

Results

HIV results both positive/negative and HIV Viral Load PCR

- To collect results from microbiology laboratories
- Results would be placed in sealed envelopes

HIV Genexpert

Hardcopy, email sent to PKD

CD4 CD8

Traced via LIS Cobas





HOSPITAL SULTANAH JOHOR BAHR	
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CMIA TEST FOR HIV Ag & Ab: Reactive

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PATHOLOGY DEPARTMENT HOSPITAL SULTANAH AMINAH 80100 JOHOR BAHRU

Lab ID Name

RN/IC

Sample Type : Plasma

Sample Status : Dk

Date & Time Spec. Collect 19/03/2023

Date & Time Spec. Received 19/03/2023

Lab Order Date & Time 22/03/2023 11:46:30

Location OPD, JUN MAHMOODIAH

Requesting Doctor DR DAYANI

Molecular Laboratory: EXT 2222 / Direct Line: 072257222 Authorised Personel: Dr Dayangku Seriful Akmar, Clinical Pathologist (Micro.), Head of Unit

Sex: Male

HIV VIRAL LOAD Restult.

HIV VIRAL LOAD Detected

HIV VIRAL LOAD VALUE 12365 cooles/

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Unit

Validated By: DR HENG PAO YING Report Date & Time 27/03/2023 10:32:11

Current Date & Time 27/03/2023 12:17:09

^{*} This is a computer generated report. No signature is required.

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PATHOLOGY DEPARTMENT HOSPITAL SULTANAH AMINAH 80100 JOHOR BAHRU Date & Time Spec Collect 21/03/2023 08:00:00 Lab ID Date & Time Spec. Received 21/03/2023 11:28:00 Name Lab Order Date & Time 22/03/2023 10:49:34 RN/IC Location Sample Type OPD, JEN MAHMOODIAH Sample Status Ok Requesting Doctor DR LIM GEOK SEIM Referral Lab HEMATO PATHOLOGY UNIT EXT 2362/DIRECT LINE: 07-2257362 Authorised Personnel Dr Indhira, Hernato Pathologist CD4/CD8 ABSOLUTE COUNT Result Reference Range Unit Flag 951.00 cells/µL CD4 404.00 - 1612.00 %CD4 23.00 - 50.00 37.00 cells/µL 220.00 - 1129.00 CDS 845.00 %CD8 33.00 15.00 - 45.00 1.13 RATIO 0.37 - 2.21 CD4/CD8 RATIO STARTED HAART : 19/6/2017 PREVIOUS CD4/CD8 TEST DONE 19/1/2022 NEXT CD4/CD8 TEST TO BE SENT ON: 21/3/2024

Rejection Criteria



MICROBIOLOGY UNIT DEPARTMENT OF PATHOLOGY HOSPITAL SULTANAH AMINAH JOHOR BAHRU

Patient's Name:	. Barco	ode:	
IC No:RN:		Ward:	
			*
Date: Time			
Fest requested:	Specir	men Type:	
Part Alex Cabada	Mark (X)	Rejection Criteria	Mark (X)
Rejection Criteria	(//)	Specimen not labelled/unclear	
lotted/hemolyzed/lipemic specimen	_	No form/specimen received.	
sufficient specimen	-	Wrong container/transport medium used	
eaking specimen elayed specimen/Specimen received beyond the ptimum time		Information in the form and specimen doesn't tally	
pecimen/form is contaminated		Test not offered	
complete form: No Patient data (Name/IC)		Broken slide/container	
complete form: No Ward/Clinic/Hospital		Repeated test orders	
complete form: No relevant clinical history		Inappropriate specimen type for testing	
complete form: No clinician's		Poor/Wet smear (BFMP)	
complete form: No date and time of specimen		Forms not in duplicate	
o specialist's name/signature/stamp for ecial/outsourced tests		Others:	
ecimen rejection informed via phone: Yes/No			
yes:			
ard/Unit/Clinic/Hospital:			
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ite:	Time	e:	
marks:	.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	****	
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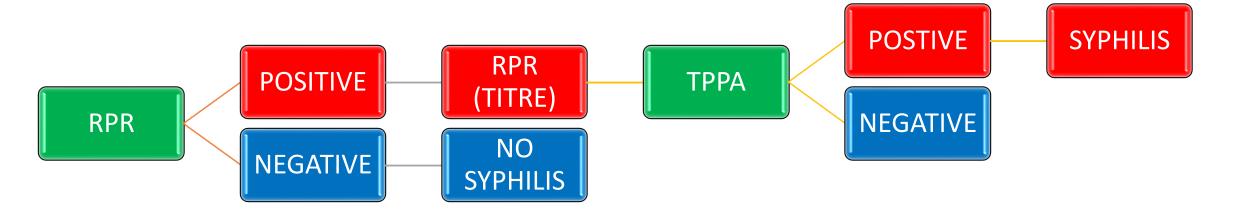


LABORATORY REJECTION FORM MICROBIOLOGY UNIT

DEPARTMENT OF PATHOLOGY
HOSPITAL SULTANAH AMINAH ADHOR BAHRU

Patient's	. Baro	ode:	
IC No:		_	
Date: al 03 203 Time			
HIV			
Test requested:	Speci	men Type:	
Rejection Offeria	Mark (X)	Rejection Criteria	Mark (X)
Clotted/hemolyced/lipemic specimen	101	Specimen not labelled/unclear	
Insufficient specimen		No form/specimen received.	
Leaking specimen		Wrong container/transport medium used	
Delayed specimen/Specimen received beyond the optimum time		Information in the form and specimen doesn't tally	
Specimen/form is contaminated		Test not offered	
Incomplete form: No Patient data (Name/IC)		Broken slide/container	- 0
Incomplete form: No Ward/Clinic/Hospital		Repeated test orders	
Incomplete form: No relevant clinical history		Inappropriate specimen type for testing	-
incomplete form: No clinician's name/signature/date/stamp		Poor/Wet smear (BFMP)	1
Incomplete form: No date and time of specimen collection		Forms not in duplicate	1
No specialist's name/algorature/stamp for		Others Staff - no Osha/447	-11
Special/outseurced tests Specianen rejection informed via phone Yes No If yes:		Hamp.	
454			
Ward/Unit/Ciris/Incolnion		ormed by: Dr Odelia	
Informed to: Pr Meah	1001	8-26 am	
Date: 21/3/13	- Tin	ne:	
Remarks: prev. informed on yo	ti on	12-3-2013 .	
Verified by: DR. ODELIA TAN WAN XIN Pegawai Perubatan UD41 No. JEMC: 99609			

Syphilis Diagnostic Test



Tests Offered for Syphilis

Routine

- RPR (non-treponemal)- screening
- RTK (treponemal)- screening
- TPPA/ TPHA (treponemal)confirmation

Others

- Dark field microscopy
- Treponemal Antibody (FTA-ABS)
- Microhemagglutination test (MHA-TP)
- Treponemal Pallidum Enzyme Immunoassay (TP-EIA)
- •PCR

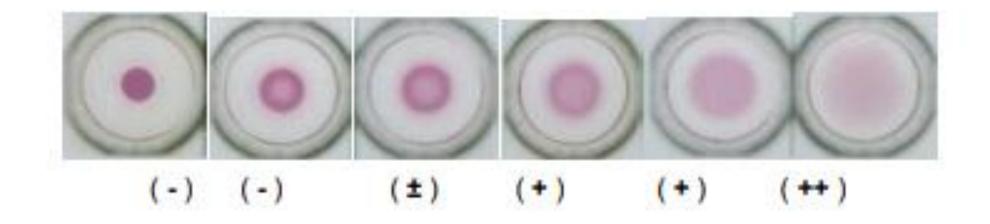
Test	Type of Specimen	Specimen Container	Volume of Specimen	LTAT
Rapid Plasma Reagin (RPR) test	Serum	Plain Tube	3-5 ml	1-3 working days
Treponema pallidum Particle Agglutination	Serum	Plain Tube	3-5 ml	1-3 working days
Rapid Diagnostic Test (RDT)	Serum Plasma Whole blood	Plain tube/ Finger prick	According to manufacture's guidelines	10-30 minutes

Rapid Plasma Reagin (RPR)

- The test qualitatively and semi-quantitatively determine the presence or absence of Reagin (antibodies against Syphilis) in the serum or plasma of patients
- When used by the recommended techniques, the reagent will agglutinate (clump) in the presence of reagin. No agglutination usually indicates the absence of regain
- Dilutions performed in reactive specimen and titre read
- RPR carbon test is non-specific for syphilis. All Reactive samples should be retested with treponemic methods such as TPPA/TPHA and FTA-Abs to confirm the results
- A non reactive result by itself does not exclude a diagnosis of syphilis. Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data
- Look out for false positives, ie infectious mononucleosis, viral pneumonia, toxoplasmosis, pregnancy and autoimmune diseases
- RPR Carbon Kit by Lorne Laboratories is widely used
- External Quality Assurance Programme (EQA) and Inter-Laboratory Comparison (ILC) conducted by Makmal Kesihatan Awam Kebangsaan (MKAK)/ Makmal Kesihatan Awam Johor Bahru (MKAJB)

Treponema Pallidum Particle Agglutination (TPPA) Test

- TPPA is a qualitative assay for diagnosis of infection by Treponema Pallidum in serum or plasma specimens. The TPPA kit is manufactured using gelatin particle carriers sensitized with purified pathogenic Treponema pallidum
- The test is based on the principle that the sensitized particles are agglutinated by the presence of antibodies to Treponema pallidum in human serum/plasma
- **SERODIA-TPPA** is widely used in the laboratories



TPPA Pattern Interpretation

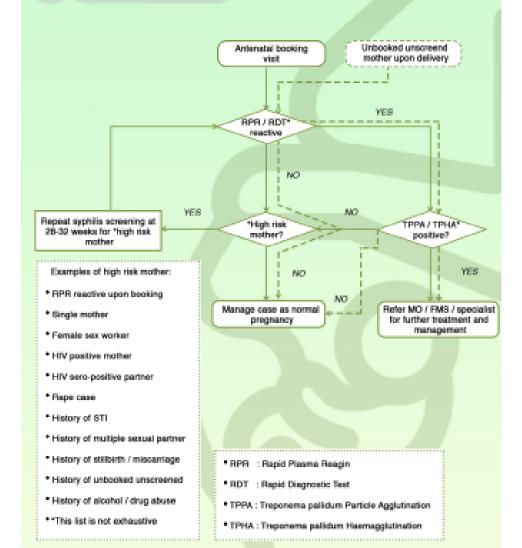
Rapid Diagnostic Test (RDT)

- Syphilis Rapid Diagnostic Test (RDT) is a qualitative rapid immune-chromatographic assay for the detection of IgG and IgM antibodies to Treponema pallidum in human whole blood, serum or plasma
- The assay is used as a screening test for Syphilis in certain groups of pregnant mothers
- RDT has to be registered under Akta dan Peraturan Peranti Perubatan Malaysia (Medical Device Authority Act -MDA)
- KKM recommends 98% sensitivity and 98% specificity



SYPHILIS SCREENING FOR PREGNANT WOMEN ATTEMDING ANTENATAL CARE AND PRESENTING WITH UNKNOWN SYPHYLIS STATUS IN LABOUR













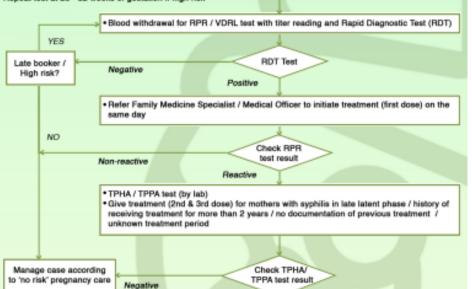
SYPHILIS SCREENING FOR PREGNANT WOMEN ATTENDING ANTENATAL CARE (RAPID DIAGNOSTIC TEST)



RDT screening for following cases or situation:

- 1. Hard to reach population for example Orang Asil, Sabah or Sarawak rural areas, etc.
- 2. Klinik kesihatan / Klinik Ibu dan Anak without lab facilities to perform RPR / VDRL tests.
- 3. Late bookers at third trimester (> 28 weeks pregnant)
- 4. High risk mothers
- · Repeat test after 1 month if late booker OR
- . Repeat test at 28 32 weeks of gestation if high risk

- Health Education
- Informed consent



Refer Specialist Hospital (O&G specialist / Dermatologist / Infectious Disease specialist / Pediatrician) for Syphilis treatment plan during pregnancy and for delivery Notify and contact tracing

Positive

High risk pregnancy:

* Unmarried pregnant ladies

. History of abortion / stillbirth

* Sex worker

Rape case

* History of HIV

* History of alcohol and drug consumption

History of STI

. Having sexual partners with Syphilis / HIV

* History of multiple sexual partner

* Other criteria deemed necessary based

WHO Guideline on Syphilis screening and treatment for pregnant women (2017). Strategy C : On-site rapid syphilis test followed (if positive) by first dose and RPR test (pg.24).



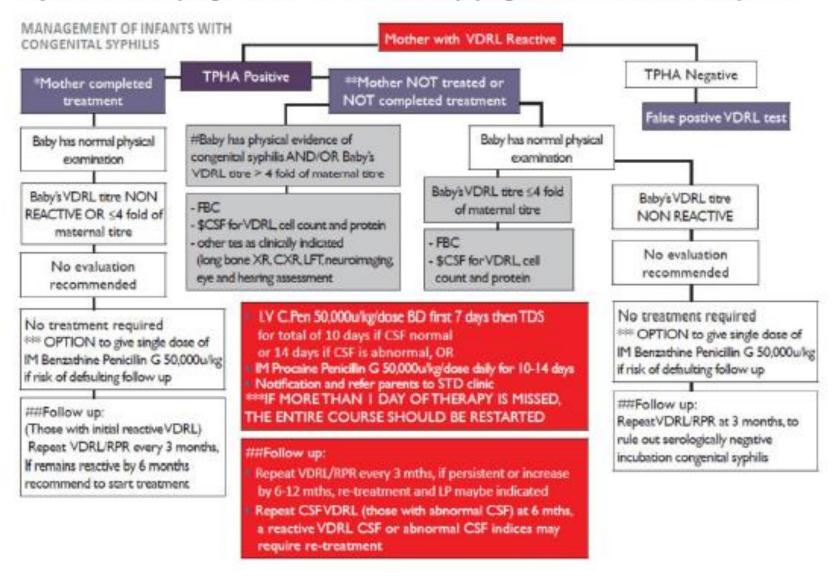


on evaluation by health personnel





Rajah 7: Carta alir pengurusan kes dan rawatan bayi yang dilahirkan oleh ibu Sifilis positif



Results

- Traced via LIS -HSA, Hospital Segamat, HSI
- Hardcopy dispatched to Klinik Kesihatan -HPSF, HSNI
- Via email- HEBHK

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19. Tarikh:

KEMENTERIAN PERKHIDI

RKHIDI

	(PER-PAT 2	90
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Tandatangan dan Cop Doktor

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17. Pengambilan Specimen	Tarikh: [[6 / 2 / 5]	Masa:	
18. Nama Doktor:		***	THE PARTY OF THE P



PATHOLOGY DEPARTMENT HOSPITAL SULTANAH AMINAH 80100 JOHOR BAHRU

: 16/03/2023 00:00:00 Date & Time Spec. Collect Lab ID Date & Time Spec. Received 16/03/2023 10:00:00 Name : 16/03/2023 10:00:00 Lab Order Date & Time RN / IC Age: 53 Sex: Male WEST 4 Location Sample Type Requesting Doctor : DR NUR SABILA Sample Status : Ok Referral Lab : None Serology Laboratory: EXT 2363 / Direct Line: 072257363 Authorised Personel: Dr Dayangku Seritul Akmar, Clinical Pathologist (Micro.), Head of Unit

RAPID PLASMA REAGIN

Result

Unit Ref. Ranges

RAPID PLASMA REAGIN

Non reactive

METHOD: LATEX AGGLUTINATION

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8. Tarikh Masuk Wed: 13/8/2025	9. Pekerjaan	10. Tarof Perkahwinan:	Hayar Percuma
2. No. Laporam Terdahulu:	SidNin no result	13. Buting Penting:	(5564) 12-000 VX
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8. Nama Doktor: D	RFATN SOFTA-	- 11:17	
9. Tarikh: /43/23		- J	

Tandatangan dan Cop Doktor



PATHOLOGY DEPARTMENT HOSPITAL SULTANAH AMINAH 80100 JOHOR BAHRU

Date & Time Spec. Collect 15/03/2023 00:00:00 Lab ID Date & Time Spec. Received 15/03/2023 10:01:00 Name Lab Order Date & Time 15/03/2023 10:01:00 RN/IC Location : OPTHAL CLINIC Sample Type : Serum : DR FATIN Requesting Doctor : Ok Sample Status Referral Lab Serology Laboratory: EXT 2363 / Direct Line: 072257363 Authorised Personel: Dr Dayangku Seritul Akmar, Clinical Pathologist (Micro.), Head of Unit

Unit Ref. Ranges RAPID PLASMA REAGIN Result

RAPID PLASMA REAGIN Reactive

METHOD: LATEX AGGLUTINATION

RPR TITRE 1:8

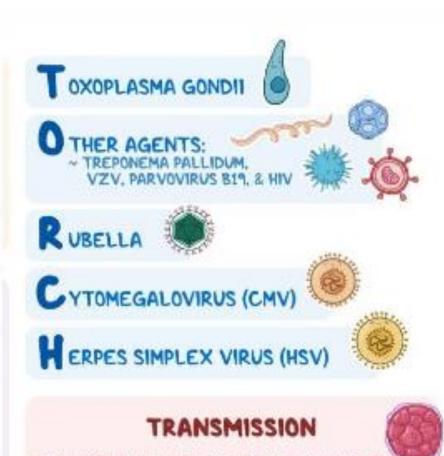
TPPA POSITIVE

METHOD: PARTICLE AGGLUTINATION

Rejections







* TRANSMITTED to FETUS THROUGH PLACENTA

* INFANT MAY CATCH INFECTION WHILE PASSING THROUGH BIRTH CANAL

* MOTHER can PASS INFECTION to INFANT THROUGH BREAST MILK

Reference

- HSAJB Work Instruction
- HSAJB Pathology Handbook 2022
- Garis Panduan Pengukuhan Program Pencegahan Jangkitan HIV dan Sifils dari Ibu ke Anak, KKM, Jun 2021
- WHO Consolidation Guidelines on HIV Prevention, Testing, Treatment, Service. Delivery and Monitoring: Recommendation for a Public Health Approach, July 2021
- WHO Guideline on Syphilis Screening and Treatment for Pregnant Women, 2017
- RPR Carbon Kit: For Detection Of Syphilis, Lorne Laboratories



Thank You