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MEDIVEN
MEDICAL INNOVATION VENTURES

JKN Johor PMTCT Online Course

Hands On- POCT RTK HIV and Syphilis

Presenter:

Wallace Chee, Application Specialist

MEDIVEN®
MEDICAL INNOVATION VENTURES

Company Profile

About Us

Medical Innovation Ventures Sdn. Bhd. (Mediven®) specialises in the design, development and manufacturing of infectious disease *in vitro* diagnostics products.

Company	**Medical Innovation Ventures Sdn. Bhd.**
Founded in	2012
Address	1st Floor, Plot 88f, Lintang Bayan Lepas 10, Bayan Lepas Industrial Park, Bayan Lepas Free Industrial Zone Phase 4, 11900 Bayan Lepas, Pulau Pinang, Malaysia.
Website	www.mediven.com.my

About Us

Manufacturing & Production

BUATAN MALAYSIA

Design & Development

We design, develop, manufacture and distribute our own diagnostic solutions worldwide

Quality Control

Clinical needs

Sales & Marketing

Customer service/ After sale support

About Us

- One of the few fully integrated IVD specialists based in ASEAN.
- Our products are validated by independent International External Quality Assessment (EQA) from the UK and Australia.

Key Milestones

- CE-IVD granted for 32 immunoassays (ProDetect®).
- CE-IVD marks obtained for 18 molecular diagnostics (GenoAmp®).
- Sole supplier of HIV rapid tests to Malaysia government hospitals
- Sole supplier of Dengue rapid tests to Brunei government hospitals

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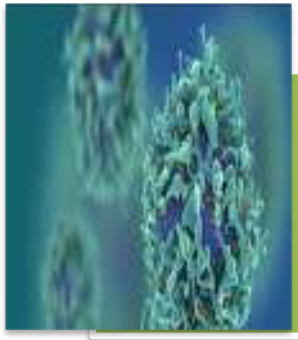
Our Products

Infectious Diseases

- Respiratory infection
- Tropical fever
- Sexually Transmitted Infection
- Liver

Toxicology

- Workplace
- Government
- Reference Lab

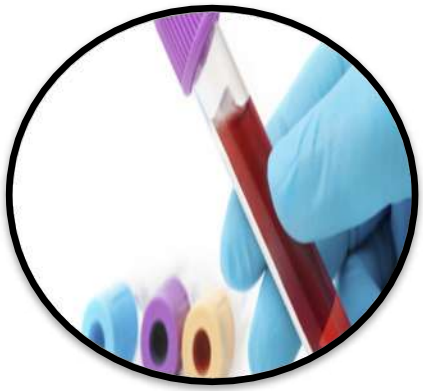
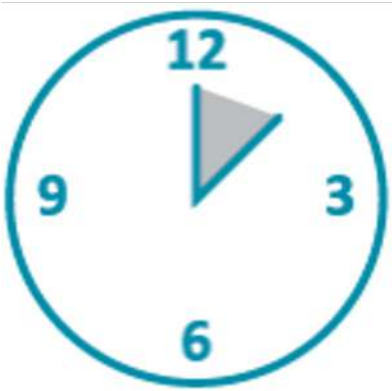
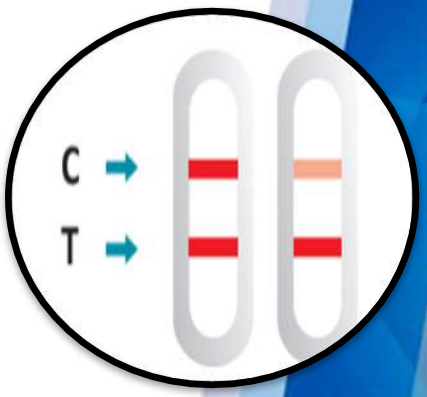


Family Health

- Women's Health
- Oncology

ProDetect® Rapid Test Platform

- Immunoassay-based rapid detection technology
- Rapid and qualitative detection platform

Sample	Sample loading	Wait & read	Data interpretation & result
			
Samples are collected in appropriate containers	Load sample onto the well of test kit	Read the test	Data interpretation and result

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ProDetect® Rapid Test Platform


COVID-19 (Ag/Ab)


hCG Pregnancy (Strip/Cassette)


Flu A/B/RSV


Rota/Adenovirus


Drug of Abuse


Syphilis


HbsAg


Mycoplasma pneumoniae


Dengue


Zika

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GenoAmp® Platform

Real-Time PCR

- Multiplex detection of pathogens in a single tube
- Detection through real-time PCR
- Easy reaction setup

Viral Respiratory Panel	Bacterial Respiratory Panel	Tropical Fever Panel	TB Panel	Endpoint
• FluA/H1N1/H3 N2/FluB • MERS-CoV • Flu/MERS/ SARS-CoV-2 • SARS-CoV-2	• *Bordetella pertussis*	• Dengue 1-4 • Chikungunya • Zika • Dengue/Chikun gunya/Zika • Leptospirosis • Malaria • Malaria/Leptos pirosis/Salmone lla/*B. pseudomallei*	• MTBC/NTM	• *Vibrio Cholera* • *MTBC/NTM*

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Syphilis: Introduction & Hands-on

Syphilis: Introduction

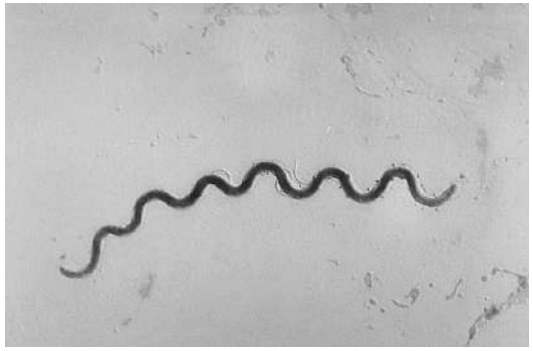
Bacterial infection caused by ***Treponema pallidum***

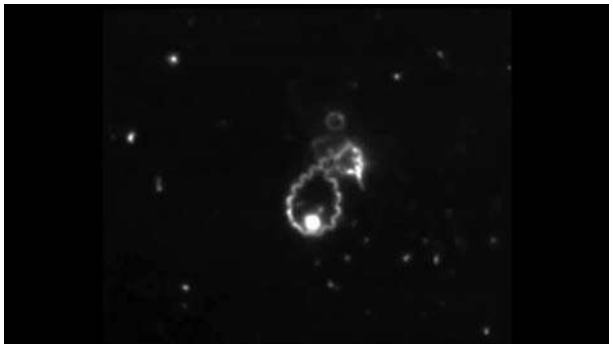
Usually spread via **sexual contact**.

Starts painless sore typically on the genitals, rectum or mouth.

Difficult to differentiate: **Overlapped** clinical presentation with other STIs

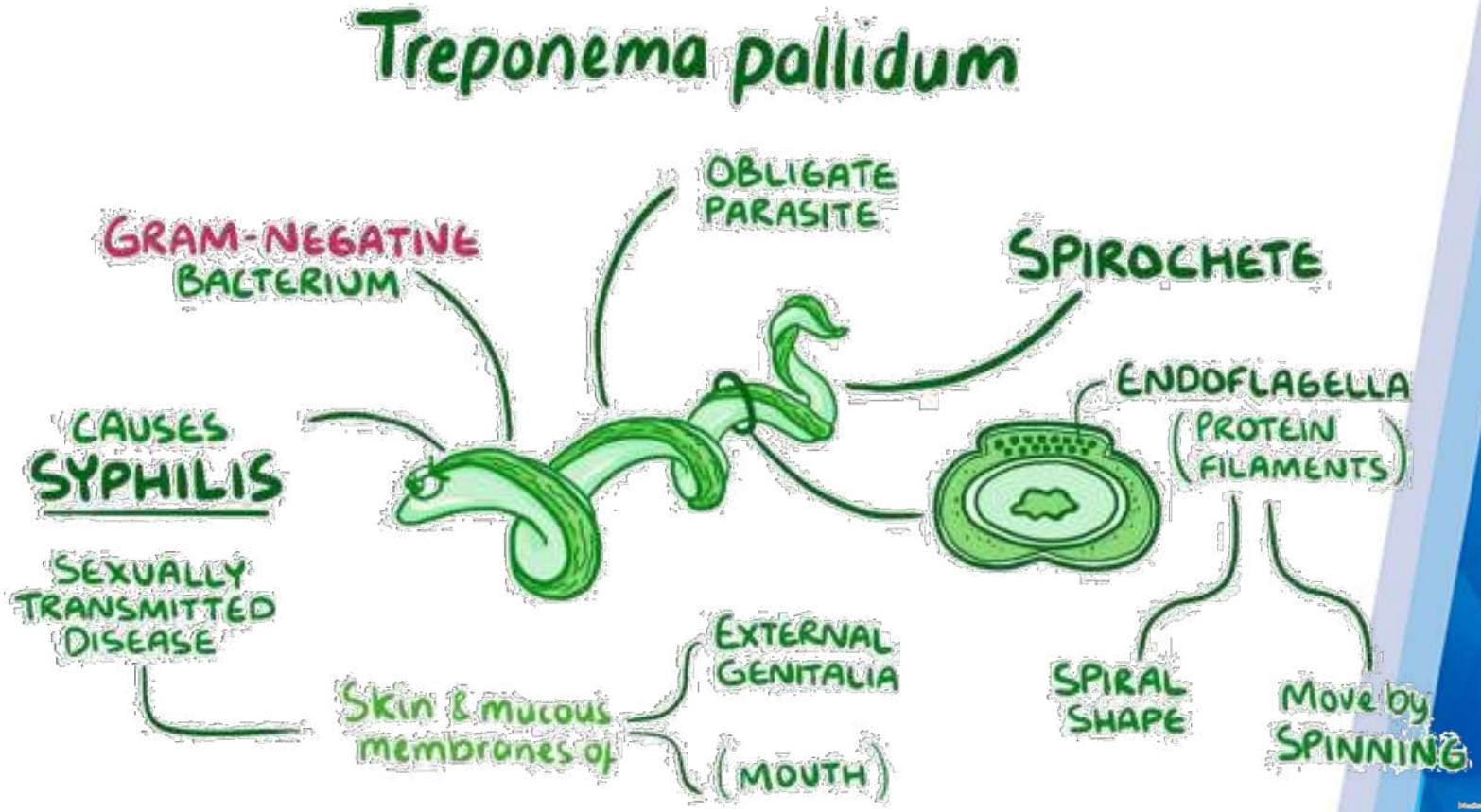
Effective diagnosis: Rapid test for timely diagnosis of infection and medical care.





Treponema pallidum

Syphilis Causative Agent



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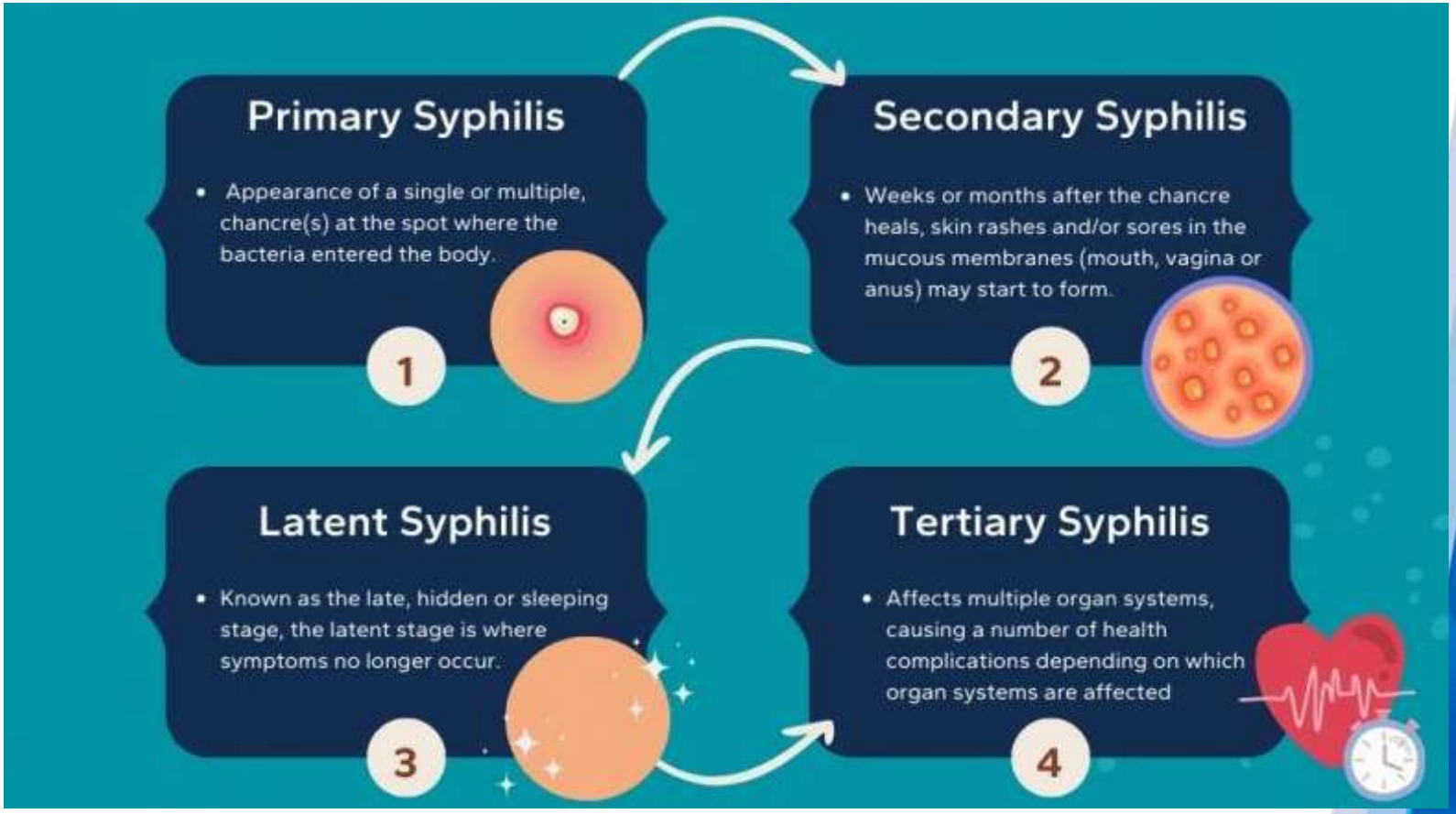
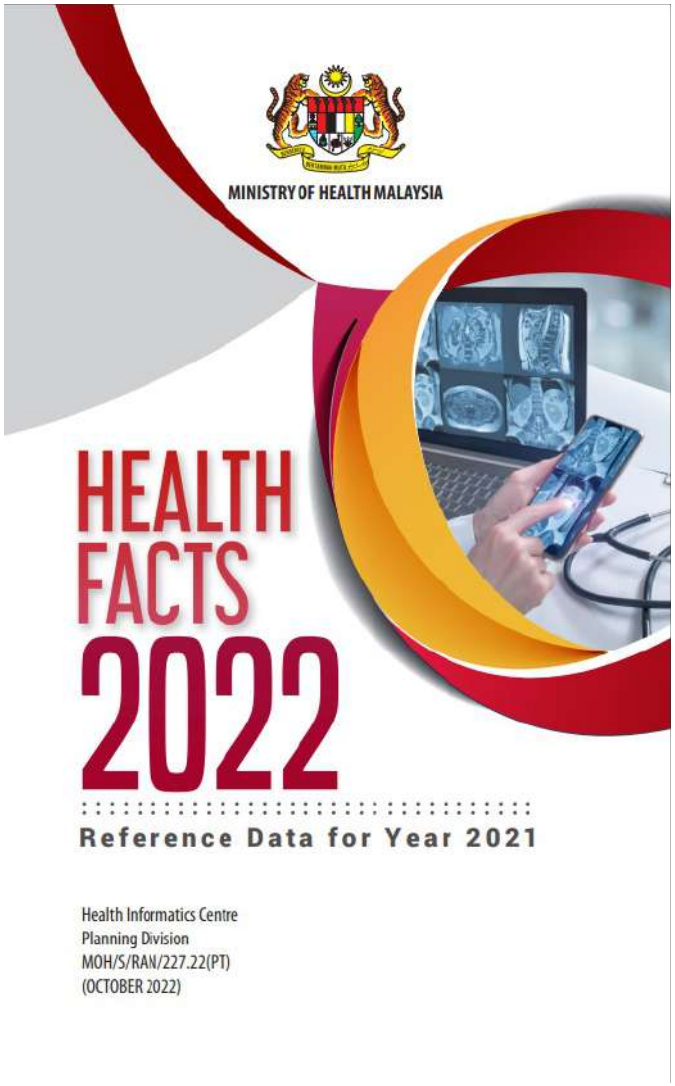
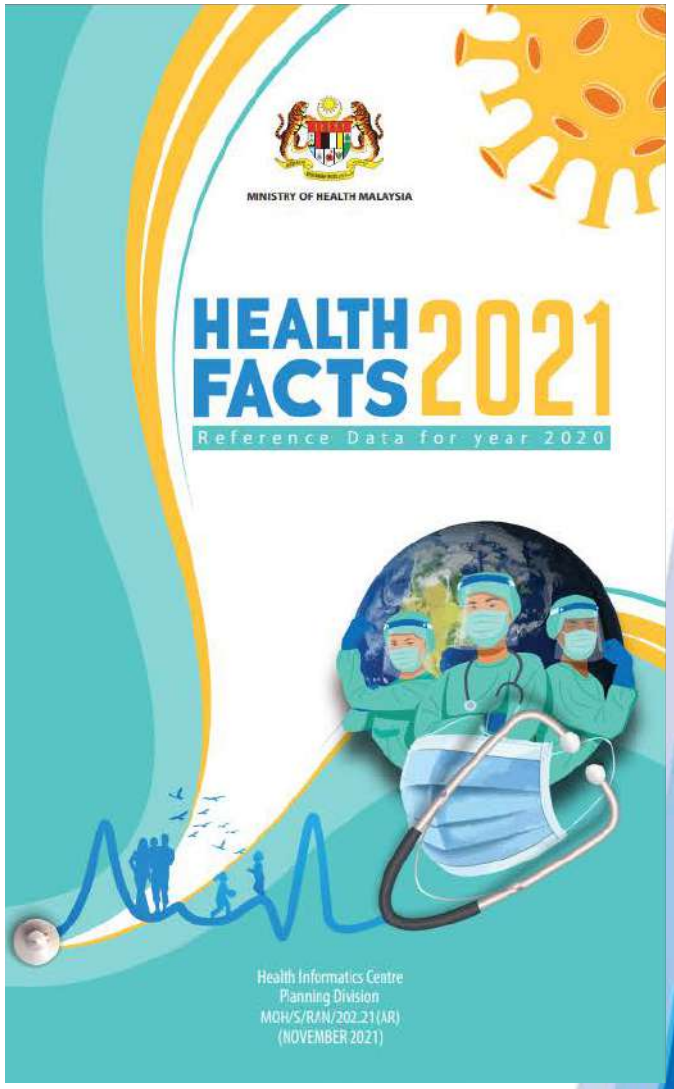
Stages and Symptoms of Syphilis



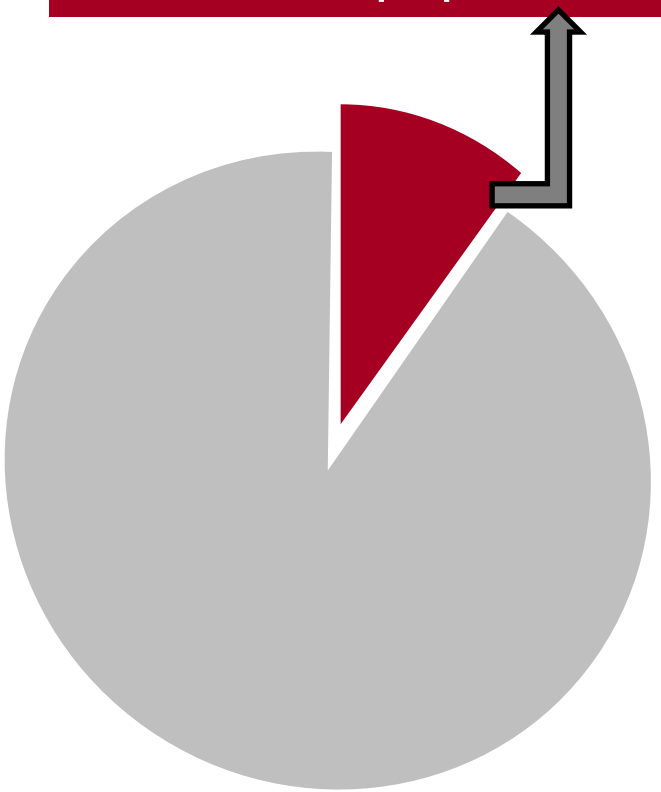
Current Trend of Syphilis in Malaysia



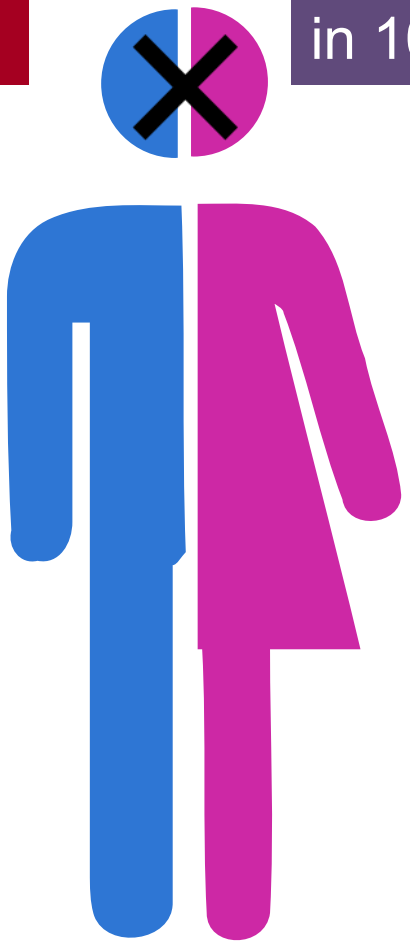


Incidence Rate of Syphilis in Malaysia

10.60 ⟷ 10.63 (2021)
in 100, 000 population



0.06
in 100, 000 population

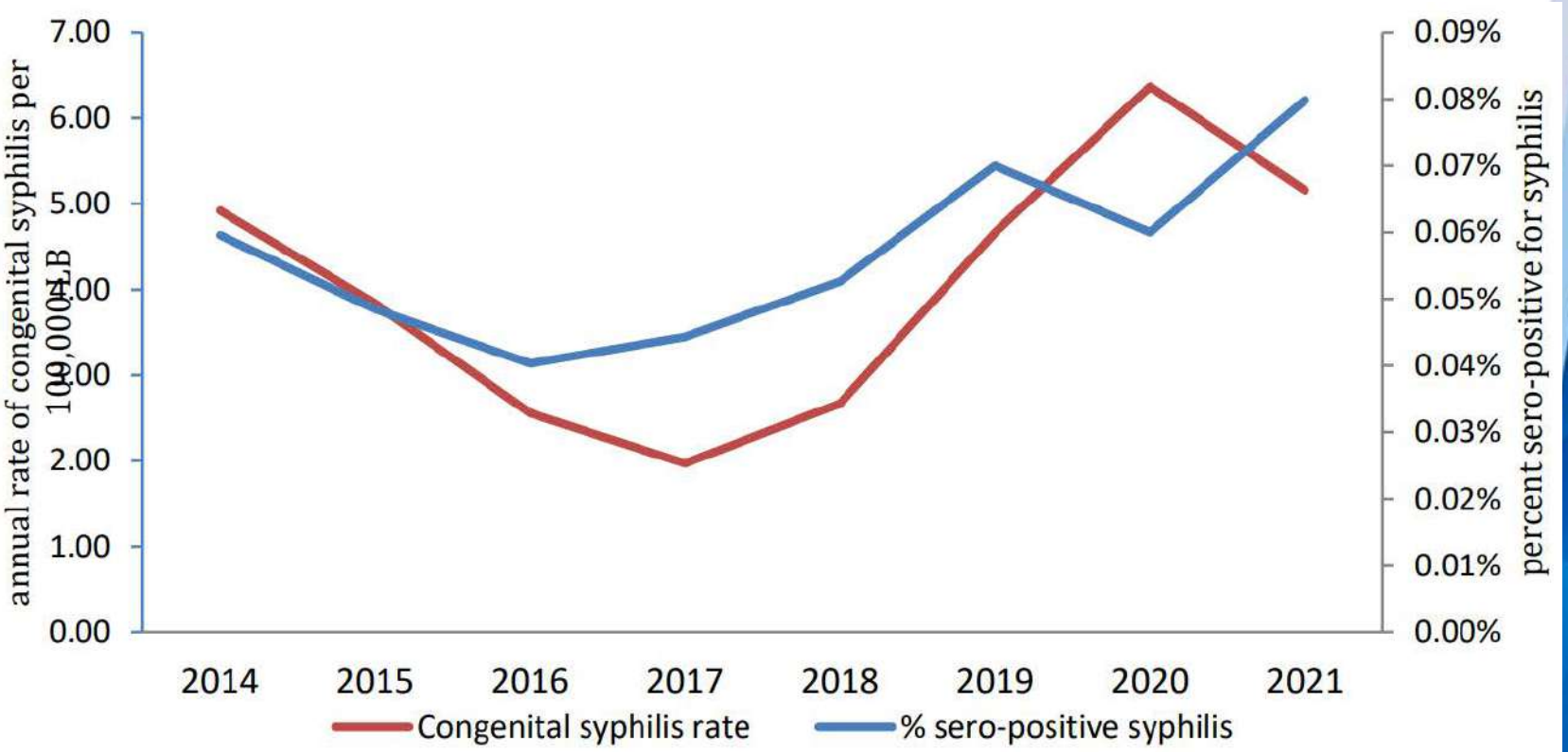


Treatable

Source:

1. Ministry of Heath. (2022). Health facts. From https://www.moh.gov.my/moh/resources/Penerbitan/Penerbitan%20Utama/HEALTH%20FACTS/Health_Facts_2022-updated.pdf
2. Ministry of Heath. (2021). Health facts. From https://www.moh.gov.my/moh/resources/Penerbitan/Penerbitan%20Utama/HEALTH%20FACTS/Health_Facts_2021.pdf

Syphilis Among Pregnant Women



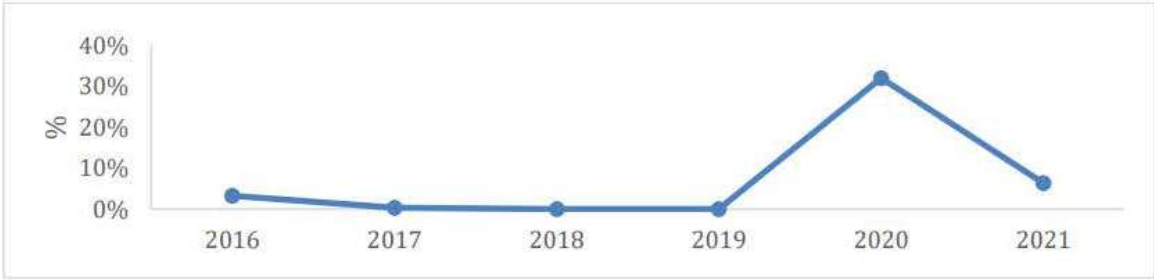
Below 10 cases (target ≤ 50) in 100,000 live birth

Source: https://www.moh.gov.my/moh/resources/Penerbitan/Laporan/Umum/MYS_country_report_2021.pdf

Reports of Syphilis in Sex Activity

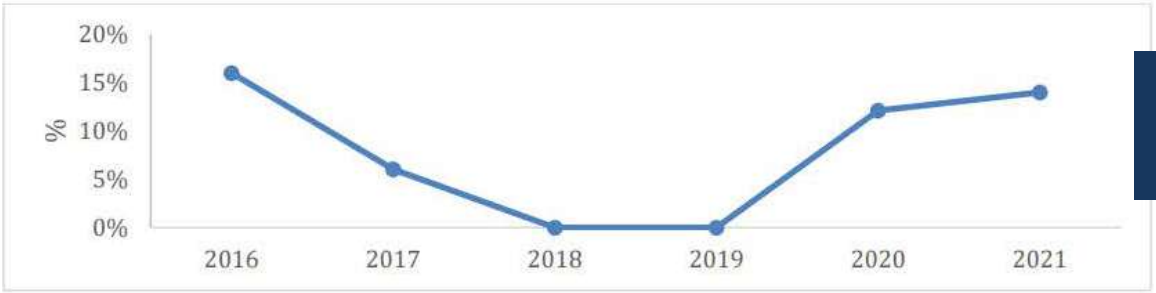
Active syphilis among sex workers, Malaysia (2016-2021)

Figure 28 Percentage of sex workers with active syphilis



Active syphilis among men who have sex with men, Malaysia (2016-2021)

Figure 29 Percentage of men who have sex with men with active syphilis



HIV cases also increases

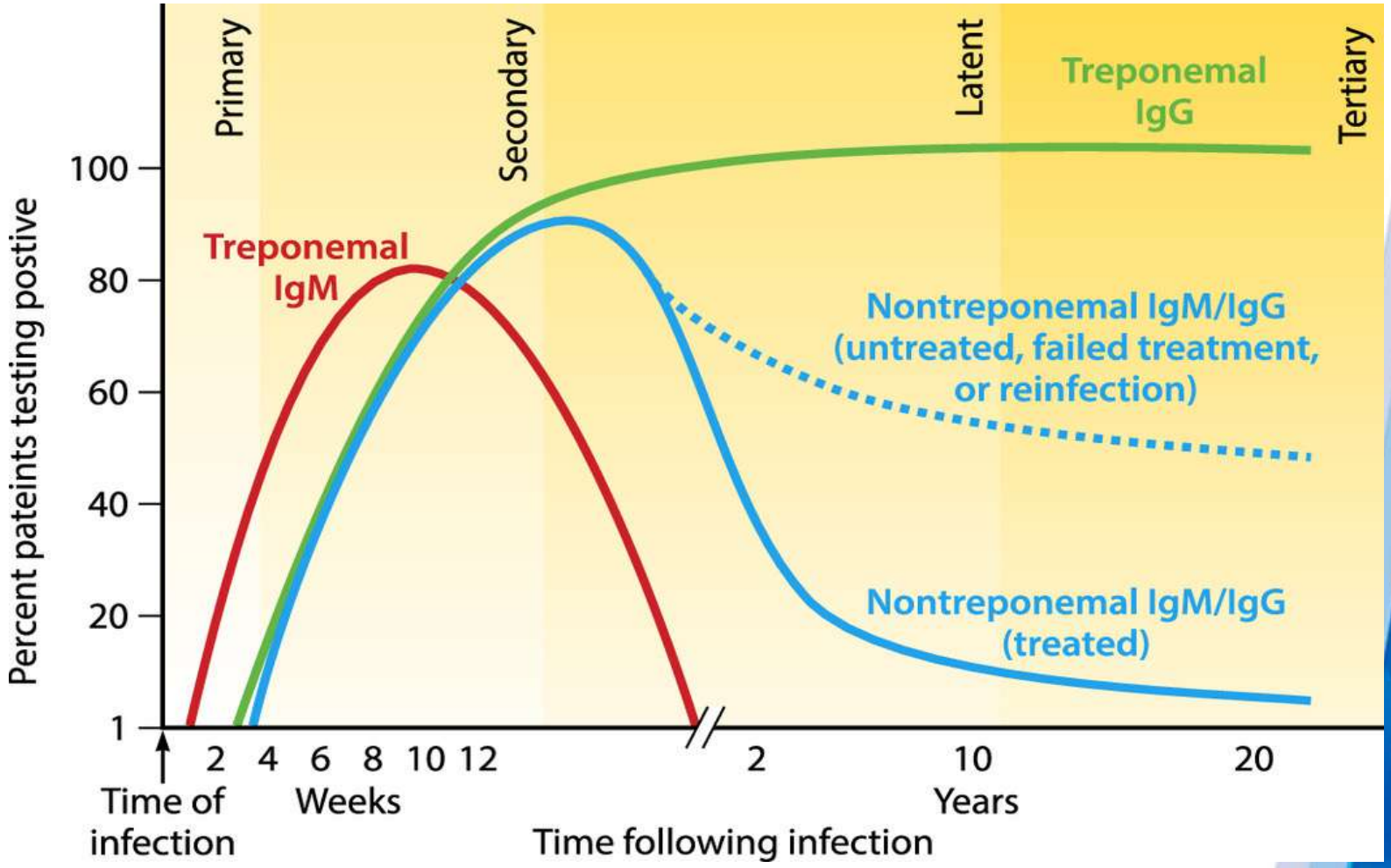
Source: https://www.moh.gov.my/moh/resources/Penerbitan/Laporan/Umum/MYS_country_report_2021.pdf

Laboratory Diagnosis of Syphilis

Table 3. Common Diagnostic Tests for Syphilis

Test	*Explanation*	*Advantages*	*Limitations*
Dark-field microscopy	Direct visualization of spirochetes in ulcer exudate fluid	Immediate diagnosis Allows for faster partner notification	Not useful for oral lesions (nonvenereal treponemes inhabit the mouth) Dark-field microscope required Requires experienced technician
Nontreponemal serology (Venereal Disease Research Laboratory test, rapid plasma reagin test)	Detects antibodies to cardiolipin in blood	Inexpensive Titers correlate with treatment success/failure	Lack reactivity in early primary syphilis High titer levels may be read as false negative (prozone phenomenon) 1 to 2 percent false-positive rate in pregnant women and in persons with autoimmune disorders, lymphoma, malaria, cirrhosis
Treponemal serology (fluorescent treponemal antibody absorption assay, *Treponema pallidum* particle agglutination test)	Detects antibodies to *T. pallidum* in blood	Confirmatory test with high specificity and low false-positive rate Becomes reactive earlier in primary syphilis than nontreponemal tests	Relatively expensive Lack reactivity in early primary syphilis

Syphilis Serology



Source: Satyaputra F, Hendry S, Braddick M, Sivabalan P, Norton R. 2021. The laboratory diagnosis of syphilis. J Clin Microbiol 59: e0010

Serological Test for Syphilis

Non Treponemal test (Screening)

1. Venereal disease research laboratory **(VDRL)**
2. Rapid plasma reagin **(RPR)**

Treponemal Tests (Confirmatory)

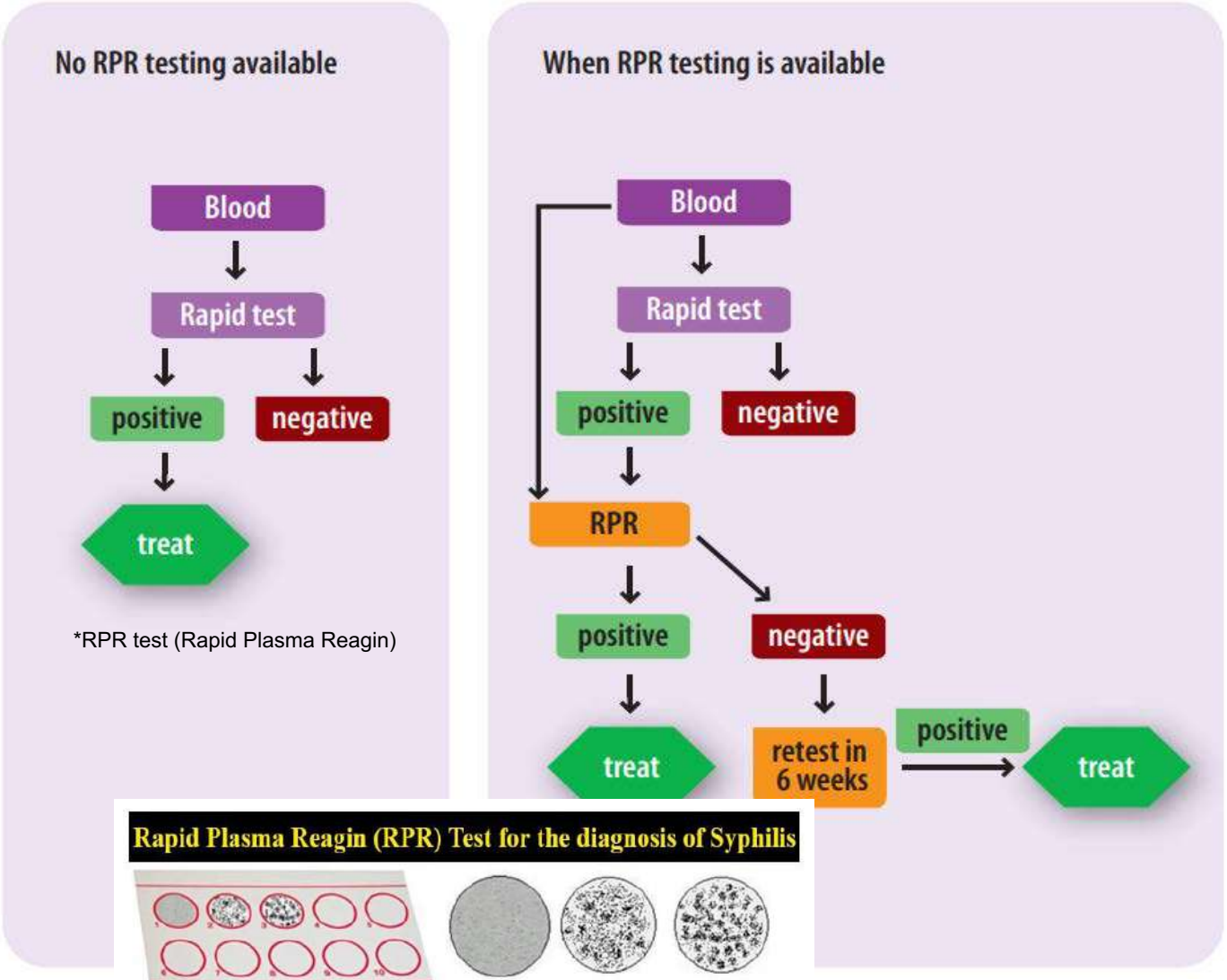
1. *T.pallidum* hemagglutination assay **(TPHA)**
2. Enzyme Immunoassay **(EIA)**
3. Fluorescent treponemal antibody absorption **(FTA-ABS)**.

Rapid Syphilis Test

Comparison of non-treponemal vs rapid treponemal tests

	Advantages	Disadvantages
Non-treponemal tests: RPR or VDRL	- simple to perform - can distinguish between active and past treated infection (antibodies wane after effective treatment except for a small number of serofast individuals)	- require electricity for refrigerator to store reagent, and for a rotator and centrifuge - cannot be used with whole blood - false negative results can occur with excess antibody (prozone effect)
Rapid treponemal tests	- simple to perform -can be used with whole blood, serum or plasma - can be transported and stored at temperatures below 30°C - no prozone effect	- cannot distinguish between active and past treated infection (antibodies to treponemal antigens are retained for years)

WHO's Testing Algorithms



Source: http://apps.who.int/iris/bitstream/handle/10665/43590/TDR_SDI_06.1_eng.pdf;jsessionid=DEDA1A534F24A24E4F64ACE823BFE8F7?sequence=1

When is a Rapid Syphilis Test Useful?

Targeted screening of syphilis for at risk individuals

- Pregnant women (to prevent congenital syphilis)
- Individuals with or at risk of STIs
- Sex workers
- Clients of sex workers
- Men who have sex with men
- Injection drug users

ProDetect® Syphilis Rapid Test

PR-SYP

Kit's Content

20 Individual sealed pouches, each containing:

- Test device
- Disposable pipette
- Desiccant pouch
- Sample Buffer
- Alcohol pad
- Sterile Lancet
- One leaflet with instruction for use

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ProDetect® Syphilis Rapid Test

Product Name	**ProDetect® Syphilis Rapid Test**
Product Code	PR-SYP
Technology	Immunochromatographic assay / lateral flow assay
Packing	20 test/box, individually packed
Target	***T. Pallidum* antibody**
Sample	Whole blood / Serum / Plasma
Incubation Time	5 mins*
Result	Qualitative: Positive/Negative
Sensitivity	> 99.9%
Specificity	99.7%

*Confirm negative results in 10-20 minutes.

Kit Storage

1. When stored in sealed pouch at 2-30°C and protected from direct sunlight, moisture and heat, the test device is stable until the indicated expiry date.

2. Keep away from direct sunlight, moisture, and heat.

3. DO NOT FREEZE.

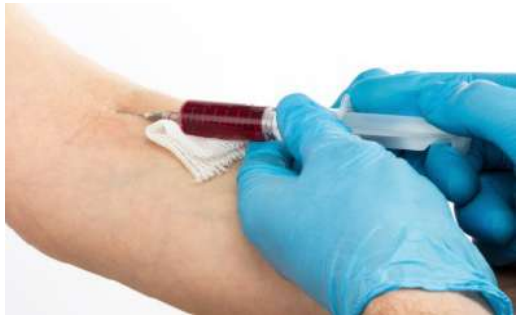
4. Preferably open the pouch shortly before the test.

Specimen Preparation

Fingerprick: Whole blood

- Use after taking 80 µL of blood using sampler

Venipuncture: whole blood, serum or plasma



- Serum: Collect blood in a tube without anticoagulant and allow it to clot. ***Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed samples.**
- Plasma: Collect blood in a tube containing anticoagulant.
- Whole blood: Collect blood in a tube containing anticoagulant and should be tested immediately after sample collection.

-May be stored at **2-8°C for up to 3 days**

*Blood samples should be allowed to **attain room temperature prior to use**

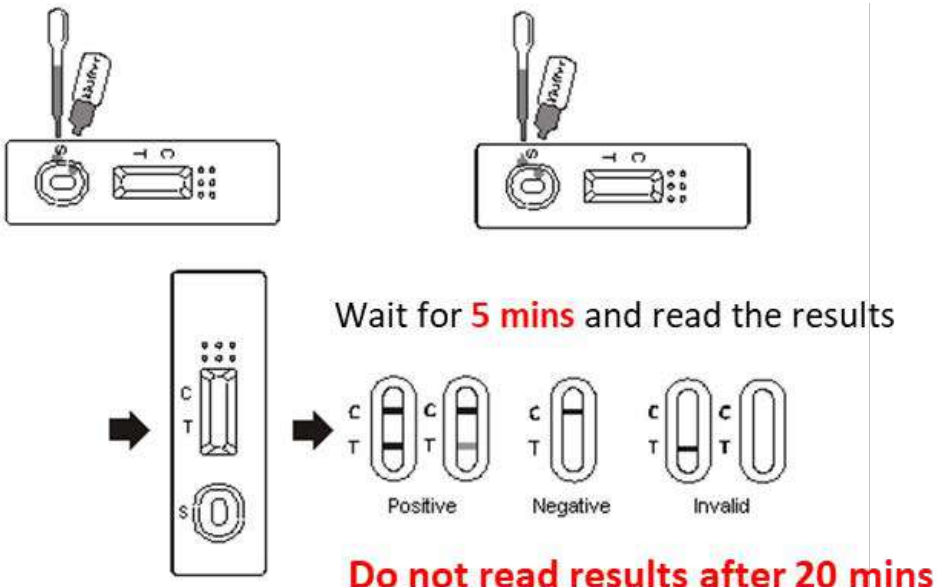
Test Procedure and Results Interpretation

Whole Blood Sample

1. Add **2 drops (~80 µL)** of sample
2. Add **1 full drop (40µL)** of buffer

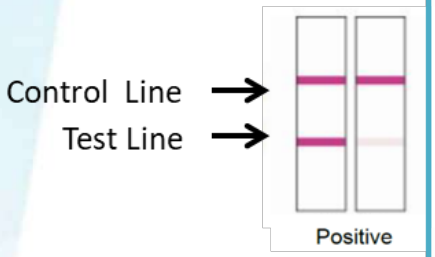
Serum/plasma Sample

1. Add **1 drop (40 µL)** of sample
2. Add **1 full drop (40µL)** of buffer



Note: Specimens with high concentrations of *T. pallidum* antibodies may produce positive results in as soon as 1 minute. **Confirm negatives in 10-20 minutes.**

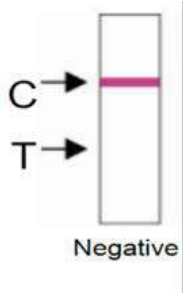
Results Interpretation



Positive (+) / Reactive

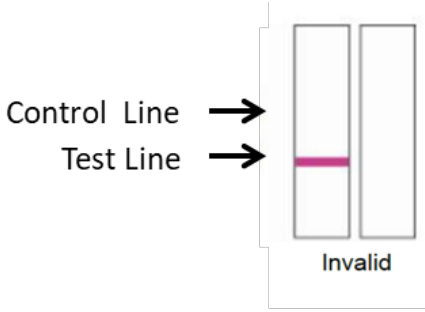
- Two lines appear. One coloured line should be in the control line region (C) and another apparent coloured line should be in the test line region (T).

**Note: The intensity of the color in the test line region (T) will vary depending on the concentration of TP antibodies present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.



Negative (-) / Non-Reactive

- One colored line appears in the control line region (C).
- No line appears in the test line region (T).



Invalid

- Control line fails to appear. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately.

**Note: Insufficient sample volume, incorrect procedure or expired test device are the most common reasons of invalid results.

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Limitations

1. This product is an *in vitro* diagnostic test designed for **professional use** only.
2. The test should be used for **qualitative detection** of TP antibodies in **whole blood, serum or plasma specimens only**.
3. **Humidity** and **temperature** can adversely affect the results.
4. The **instructions for use of the test should be followed** when performing the test procedures.
5. There is always a possibility that **false results** will occur due to the presence of **interfering substances** in the sample or factors beyond the control of the manufacturer, such as technical or procedural errors associated with the testing.
6. A definitive clinical diagnosis **should not** be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
7. If the test result is **negative** and **clinical symptoms persist, additional testing** using other clinical methods is **recommended**.
8. A negative result does not at any time preclude the possibility of TP infection.
9. The **hematocrit** of the whole blood should be between **25%** and **65%.**

Performance Characteristics

Diagnostic Performance

The accuracy of ProDetect® Syphilis Rapid Test had been evaluated by a comparison study with a currently marketed *T. pallidum* test device and the study was conducted at external clinical sites. 540 clinic samples were studied. The relative sensitivity is >99.9% while the relative specificity is 99.7%.

Comparison Data of ProDetect® Syphilis Rapid Test:

		Results of commercial kit		Subtotal
		Positive	Negative	
Result of ProDetect® Syphilis Rapid Test (Whole Blood, Plasma and Serum)	Positive	210	1	211
	Negative	0	329	329
Subtotal		210	330	540

Relative Sensitivity: >99.9% (95%CI*: 99.4%-100%)

Relative Specificity: 99.7% (95%CI*: 98.3%-100%)

Accuracy: 99.8% (95%CI*: 98.9%-100%)

*Confidence Interval

Performance Characteristics

Cross-reactivity

ProDetect® Syphilis Rapid Test has been tested by HAMA, RF, HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, HCV, HIV, H. Pylori, MONO, CMV, Rubella and TOXO positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following potentially interfering substances were added to Syphilis negative and positive specimens.

Acetaminophen: 20 mg/dL	Caffeine: 20 mg/dL
Acetylsalicylic Acid: 20 mg/dL	Gentisic Acid: 20 mg/dL
Ascorbic Acid: 2g/dL	Albumin: 2 g/dL
Creatin: 200 mg/dL	Hemoglobin 1.1 mg/dL
Bilirubin: 1g/dL	Oxalic Acid: 600mg/dL

None of the substances at the concentration tested interfered in the assay.

MKAK Evaluation Report

ProDetect® Syphilis Rapid Test	Confirmed TPPA		Total
	Positive	Negative	
Positive	27	0	27
Negative	1	32	33
Total	28	32	60

- 60 individuals: 28 known syphilis positive; 32 known syphilis negative
- **Sensitivity 96.43%, specificity 100%**
- The results obtained also indicated that the estimated PPV was 100% of positive TP and estimated NPV was found to be 96.97%

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MDA Certified

No. Siri:
Serial No.: 026484

LAMPIRAN 1
Attachment 1

ASAL
ORIGINAL

PIHAK BERKUASA
PERANTI PERUBATAN

MEDICAL DEVICE AUTHORITY

PIHAK BERKUASA PERANTI PERUBATAN
MEDICAL DEVICE AUTHORITY
AKTA PERANTI PERUBATAN 2012 (AKTA 737)
MEDICAL DEVICE ACT 2012 (ACT 737)
SIJIL PENDAFTARAN PERANTI PERUBATAN
MEDICAL DEVICE REGISTRATION CERTIFICATE
Seksyen 5(1) Akta 737
Section 5(1) of Act 737

No. Pendaftaran: **IVDC54657378919**
Registration No.:

Tarikh Sah Laku Pendaftaran: **09/01/2019 - 08/01/2024**
Registration Validity Date:

Sijil ini adalah dengan ini dikeluarkan kepada:
This Certificate is hereby issued to:

MEDICAL INNOVATION VENTURES SDN BHD

yang beralamat di:
of:

LEVEL 4, BIOPHARMACEUTICAL BLOCK, MALAYSIAN INSTITUTE OF PHARMACEUTICALS AN
NATIONAL INSTITUTES OF BIOTECHNOLOGY MALAYSIA, MINISTRY OF SCIENCE,
TECHNOLOGY AND INNOVATION, BLOCK 5-A, HALAMAN BUKIT GAMBIR, 11700 GELUGOR, PENA
11700 PULAU PINANG

No. Pendaftaran: **IVDC54657378919**
Registration No.:

Butir butir peranti perubatan yang didaftarkan
Particulars of the registered medical device

Nama Peranti Perubatan *Medical Device Name*	**PRODETECT SYPHILIS RAPID TEST**		
Kelas *Class*	**CLASS C**	Brand *Brand*	**PRODETECT**
Kelompok *Group*	**IVD TEST KIT**		
Displin *Discipline*	**IMMUNOLOGY**	Kategori *Category*	**BACTERIAL INFECTION - IMMUNOLOGY**
Nama dan alamat pembuat: *Name and address of manufacturer*	**MEDICAL INNOVATION VENTURES SDN. BHD. LEVEL 4, BIOPHARMACEUTICAL BLOCK, IPHARM,NIBM,MOSTI,BLOCK 5-A, HALAMAN BUKIT GAMBIR, GELUGOR, PENANG**		

APPENDIX

No.	NAME AS PER DEVICE LABEL	IDENTIFIER	INTENDED PURPOSE
1.	ProDetect Syphilis Rapid Test	PR-SYP	ProDetect Syphilis Rapid Test is a rapid and convenient immunochromatographic assay used for the qualitative detection of antibodies against Treponema pallidum in whole blood, serum or plasma samples. It is intended for professional use as an aid in diagnosis of Syphilis. This assay provides only a preliminary result. Clinical expertise and professional judgment should be sought to further evaluate the result of the test. For in vitro and professional use only.
2.	ProDetect Syphilis Rapid Test Buffer Solution	PR-SYP	ProDetect Syphilis Rapid Test is a rapid and convenient immunochromatographic assay used for the qualitative detection of antibodies against Treponema pallidum in whole blood, serum or plasma samples. It is intended for professional use as an aid in diagnosis of Syphilis. This assay provides only a preliminary result. Clinical expertise and professional judgment should be sought to further evaluate the result of the test. For in vitro and professional use only.
3.	Disposable pipette	PR-SYP	ProDetect Syphilis Rapid Test is a rapid and convenient immunochromatographic assay used for the qualitative detection of antibodies against Treponema pallidum in whole blood, serum or plasma samples. It is intended for professional use as an aid in diagnosis of Syphilis. This assay provides only a preliminary result. Clinical expertise and professional judgment should be sought to further evaluate the result of the test. For in vitro and professional use only.

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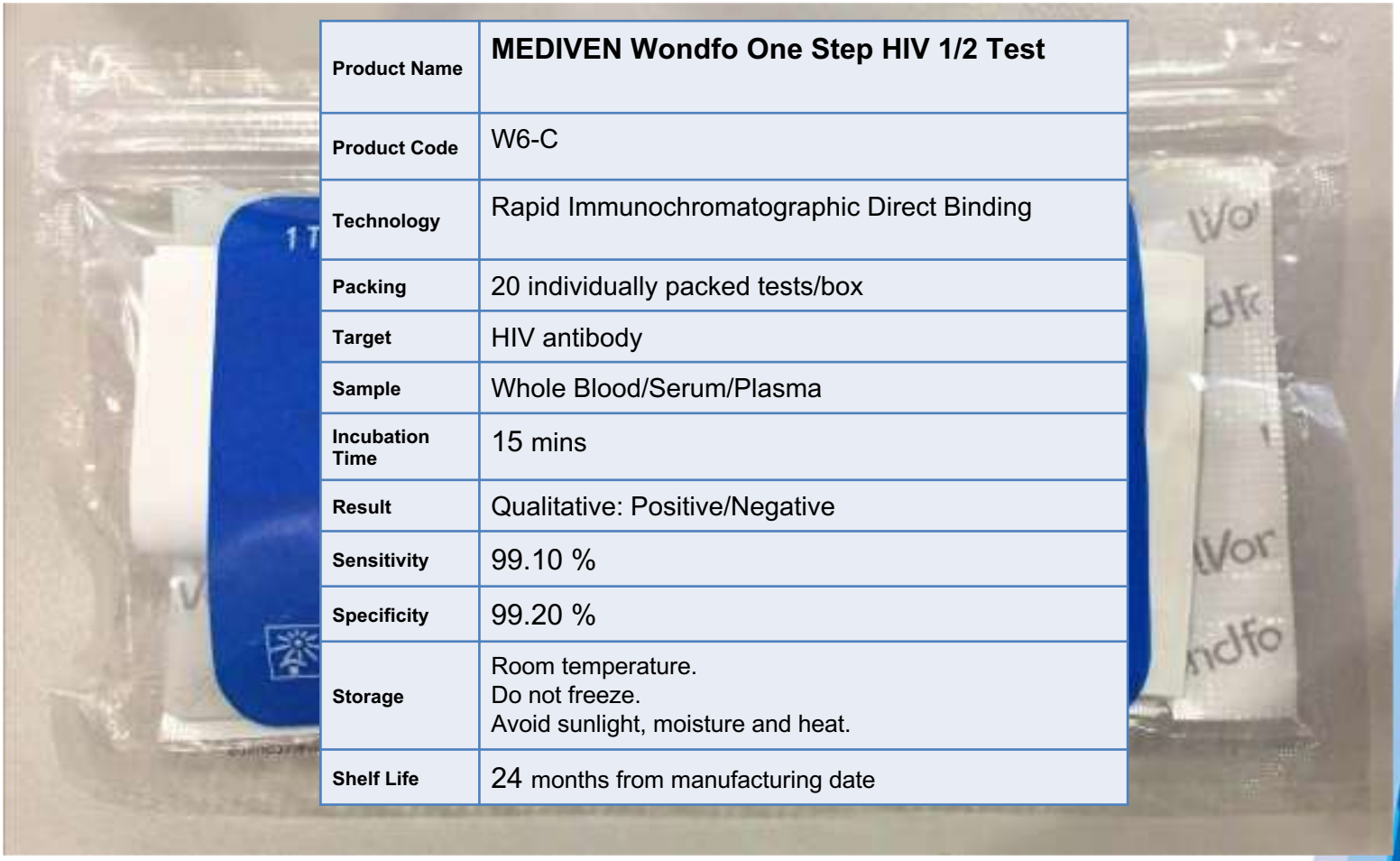
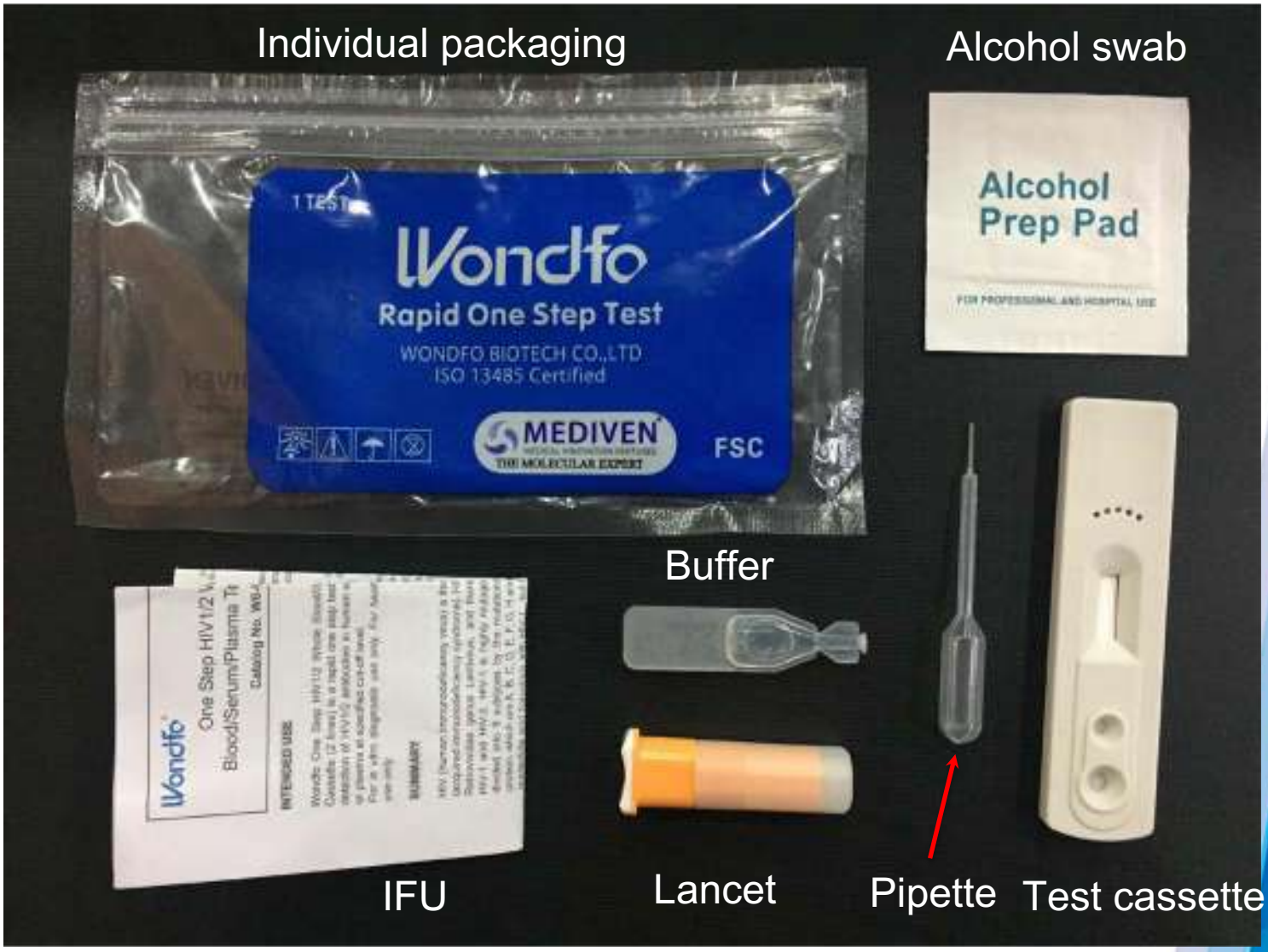
HIV: Hands-On

Product Specification



Product Name	**MEDIVEN Wondfo One Step HIV 1/2 Test**
Product Code	W6-C
Technology	Rapid Immunochromatographic Direct Binding
Packing	20 individually packed tests/box
Target	HIV antibody
Sample	Whole Blood/Serum/Plasma
Incubation Time	15 mins
Result	Qualitative: Positive/Negative
Sensitivity	99.10 %
Specificity	99.20 %
Storage	Room temperature. Do not freeze. Avoid sunlight, moisture and heat.
Shelf Life	24 months from manufacturing date

Wondfo HIV1/2 Rapid Test



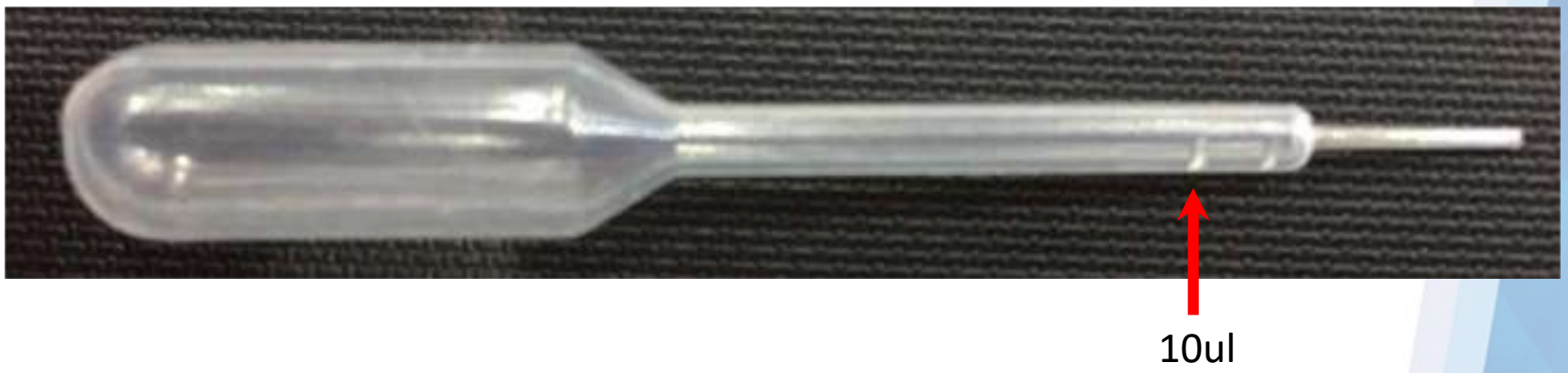
Specimen Collection

1. Select the finger for puncture.

Fingerstick

Test Procedure

1. Remove a test cassette from the foil pouch by tearing at the notch and place it on a level surface.
2. Squeeze the pipette gently before placing the tip of pipette to the blood drop.

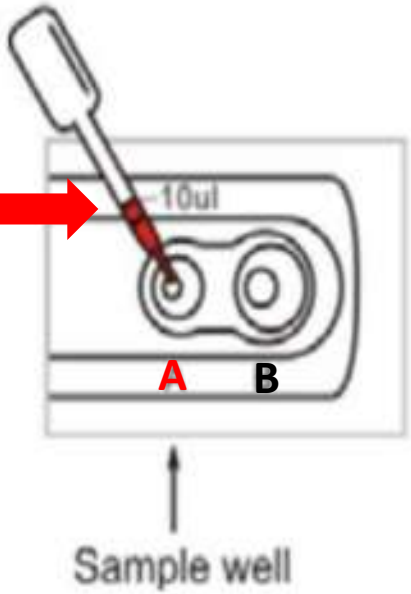


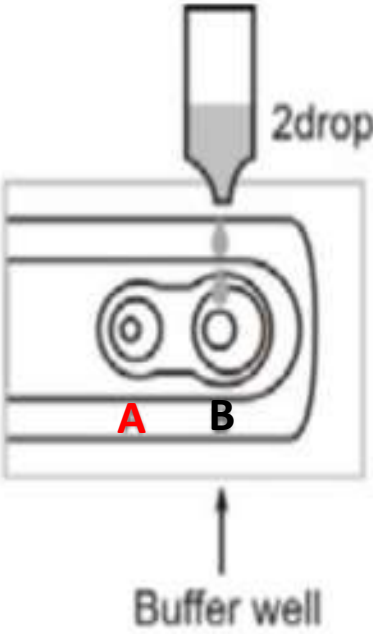
3. Slowly release the pressure on the pipette and draw the blood slowly into the pipette until it reaches the second mark line.

Test Procedure

4. Slowly add 10 µL of specimen to the sample well (A) and then add 2 drops of dilution buffer to the buffer well (B).

2nd Tick Mark Line





4. Wait for 15 mins and read the results.

5. Discard the results after **30 mins**.

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THANK YOU

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For those who needs E-certificate

MyDocLab

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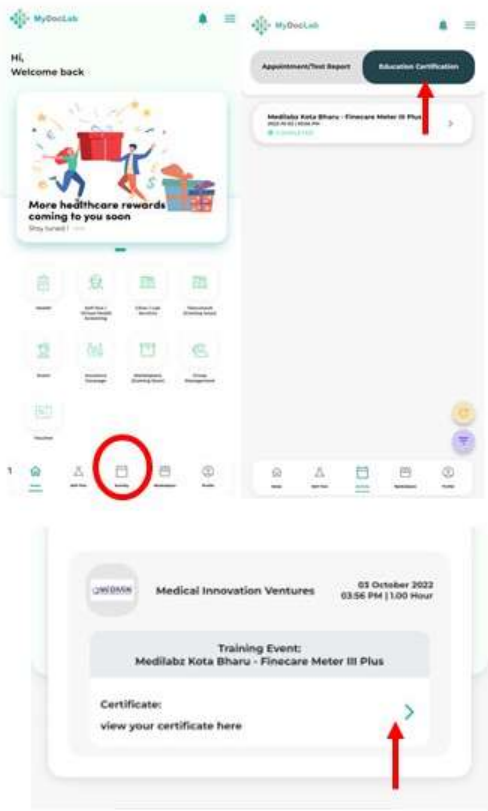
MyDocLab **Step 1:** Download MyDocLab (for those attendees that do not have the apps)

Open the app, click **SIGN UP**

Fill in **Phone No.**, click **Send Code**,
Enter the **sms code**,
Create **password**

Click **Complete your profile** to complete the details

Complete the details and input **IC No.** that you have filled in the Google Form



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Step 2: Where to view your E-certificate ?