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Wondfo Rapid One Step Test HIV1/2 (2 lines)

Presenter:
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Application Specialist



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



- 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





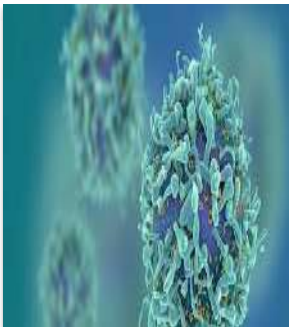
Infectious Diseases

- Respiratory infection
- Tropical fever
- Sexually Transmitted Infection



Toxicology

- Workplace
- Government
- Reference Lab



Family Health

- Women's Health
- Oncology



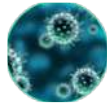
COVID-19 (Ag/Ab)



hCG Pregnancy (Strip/Cassette)



Flu A/B/RSV



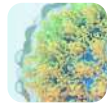
Rota/Adenovirus



Drug of Abuse



Syphilis



HbsAg



Mycoplasma pneumoniae



Dengue



Zika

Real-Time PCR

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

Viral Respiratory Panel

- FluA/H1N1/H3N2/FluB
- MERS-CoV
- Flu/MERS/SARS-CoV-2
- SARS-CoV-2

Bacterial Respiratory Panel

- *Bordetella pertussis*

Tropical Fever Panel

- Dengue 1-4
- Chikungunya
- Zika
- Dengue/Chikungunya/Zika
- Leptospirosis
- Malaria
- Malaria/Leptospirosis/Salmonella/B. *pseudomallei*

TB Panel

- MTBC/NTM

Endpoint

- *Vibrio Cholera*
- MTBC/NTM

1

Introduction of HIV

2

Principle of RTK

3

Specimen Collection

4

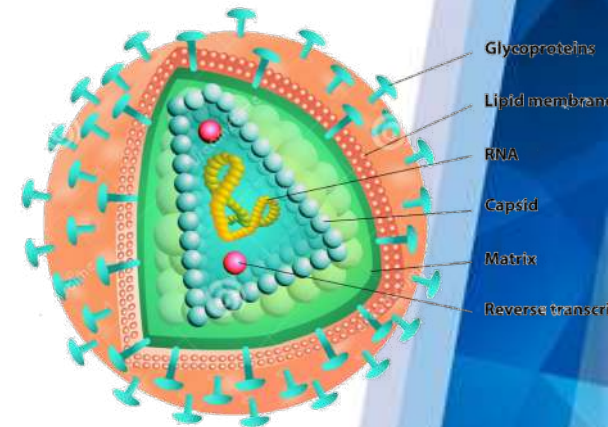
Test Procedure and Results Interpretation

5

IMR and WHO Report

Introduction to HIV

- HIV (human immunodeficiency virus) is a RNA virus that attacks the body's immune system.
- It is spread through a specific type of cell called CD4 cells, also known as T-cells. These special cells help the immune system fight off infections.
- If left untreated, HIV will reduce the number of CD4 cells (T-cells) in the body, damaging the immune system.
- Eventually, this will lead to AIDS (acquired immunodeficiency syndrome), which also makes it easier for infections or cancers to take advantage of a very weak immune system and cause death.



HIV Types

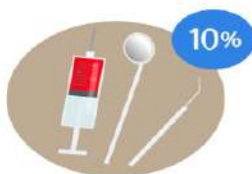
CHARACTERISTICS	HIV-1	HIV-2
<i>Infectivity</i>	High	Low
<i>Virulence</i>	High	Low
<i>Heterosexual Spread</i>	Higher	Lower
<i>Vertical Transmission</i>	20-25%	≤5%
<i>Genetic Diversity</i>	–	Lower
<i>Prevalence</i>	Global	West Africa
<i>Origin</i>	Common Chimpanzee	Sooty Mangabey
<i>Time to Aids</i>	≤10 Years	≥20 Years

HIV Transmission



HIV/AIDS

HIV is transmitted



use of non-sterile syringes and tools



pregnancy
breastfeeding



blood transfusion



organ transplant



unprotected sex

HIV is not transmitted



food, drink,
utensils



insect bites



kiss, touch



clothes, towels

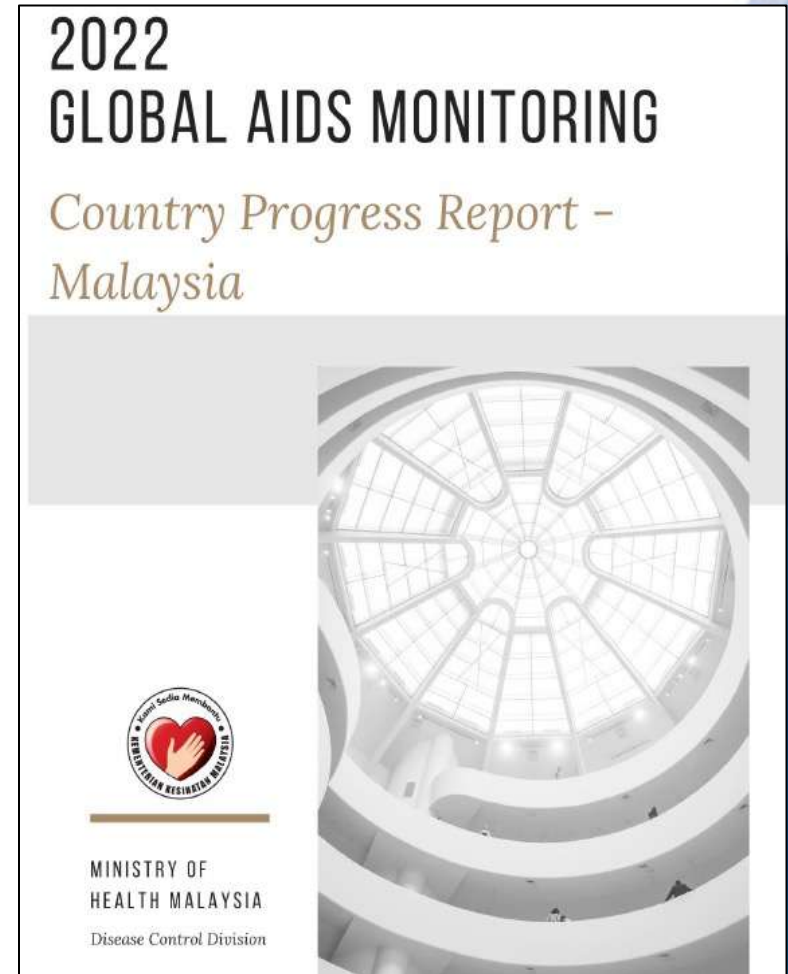


toilet, shower

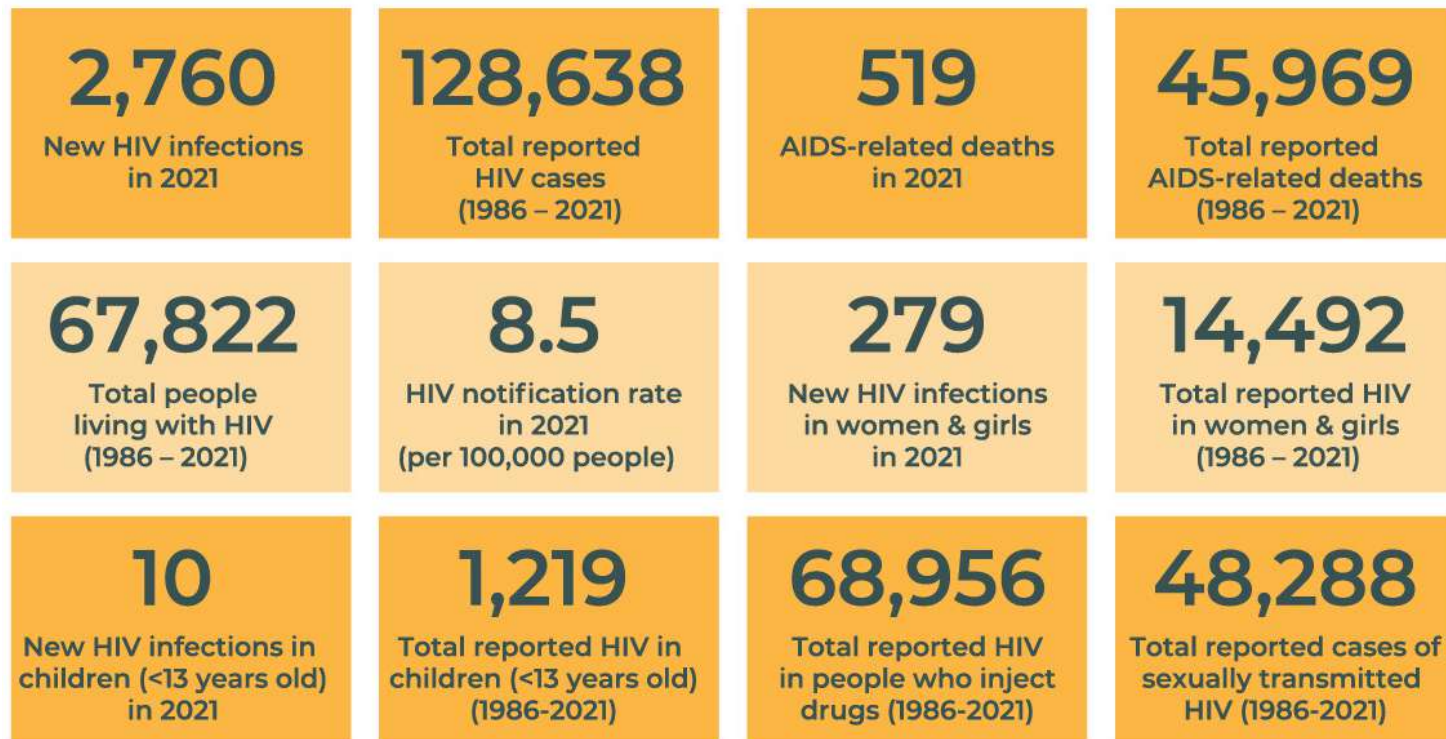
WHAT ARE THE STAGES OF HIV?

<p>1</p> <p>ACUTE HIV</p> <p>flu-like symptoms that occur days to weeks after contracting HIV</p>	<p>2</p> <p>CHRONIC HIV</p> <p>also known as the latent or asymptomatic stage; can last for several years</p>	<p>3</p> <p>AIDS</p> <p>occurs when CD4 cell count falls below 200 cells/mm³; makes a person vulnerable to opportunistic infections and AIDS-defining conditions</p>
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Statistic of HIV in Malaysia



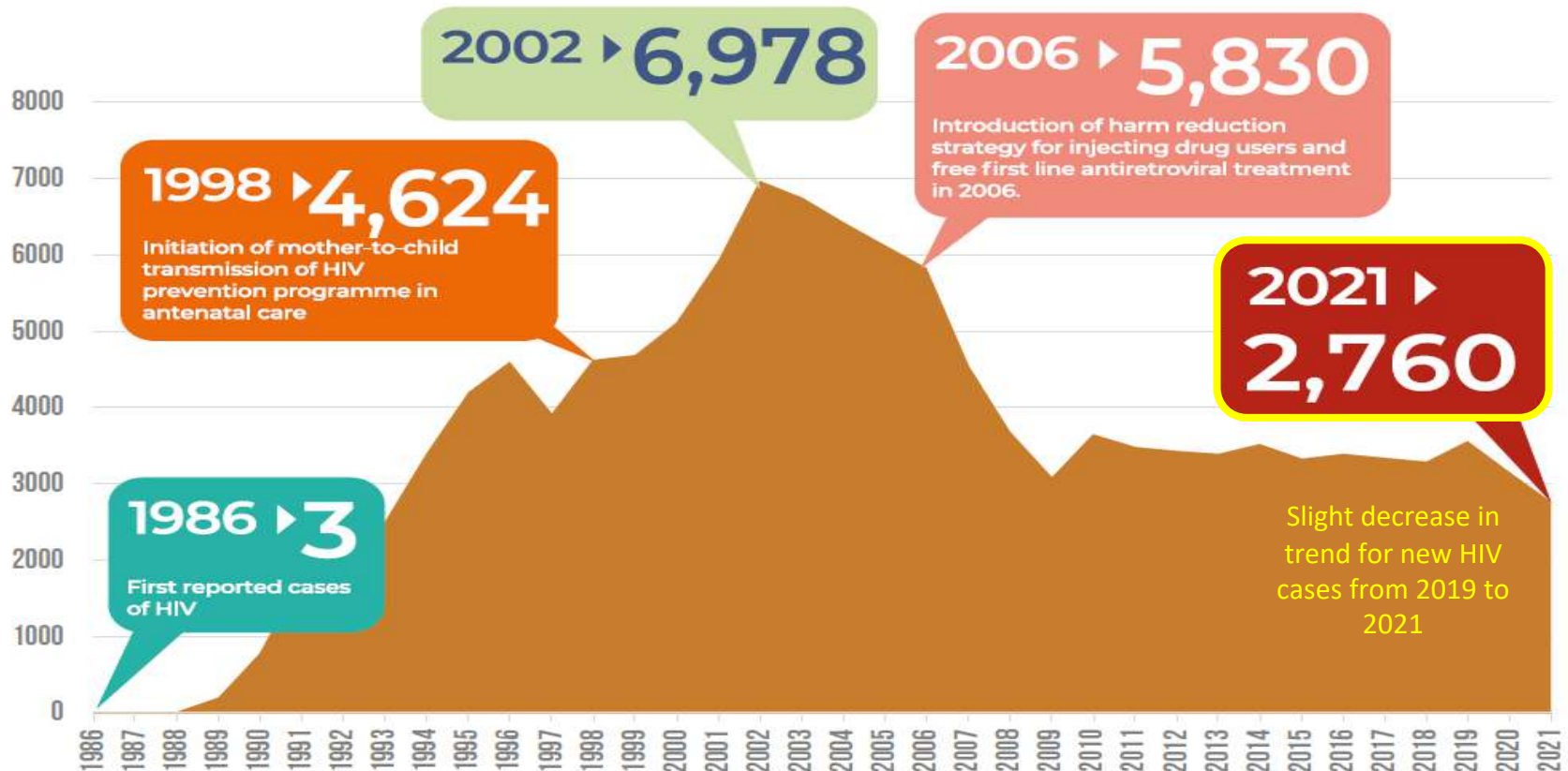
Overview of HIV & AIDS Epidemic in Malaysia (2021)



Source: HIV/STI Sector, Division of Disease Control, Ministry of Health Malaysia

Current HIV Trend in Malaysia

NEW HIV CASES (1986-2021)

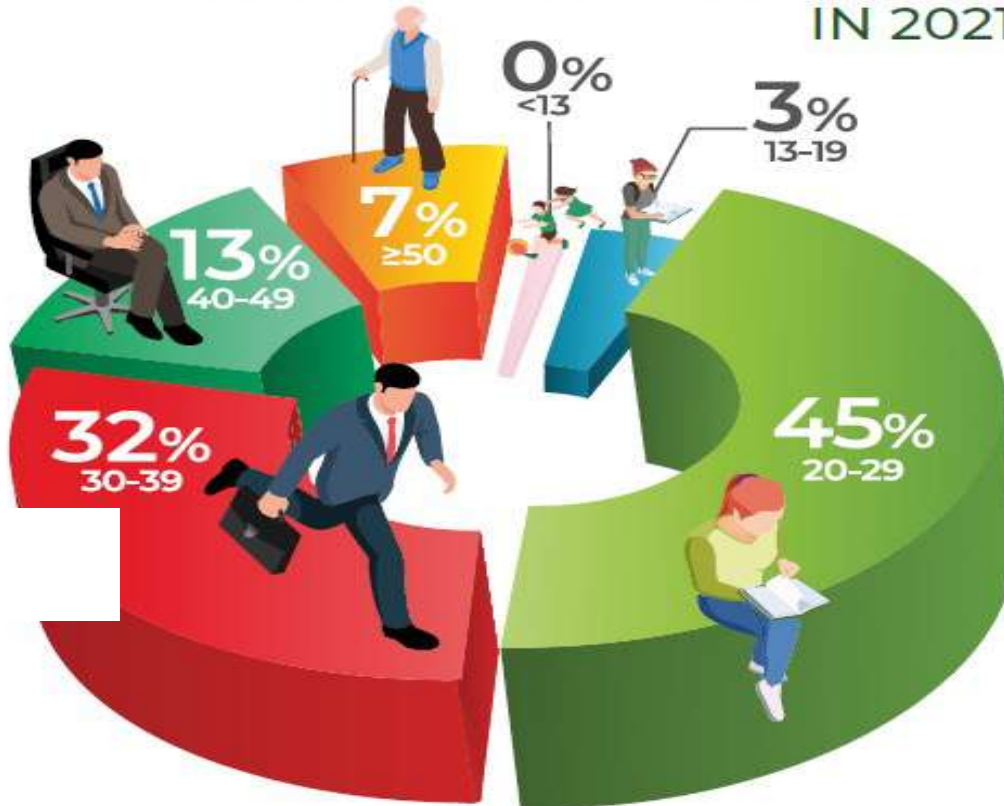


Impact of COVID-19 pandemic on HIV management in Malaysia

- In 2021, Malaysia **did not** meet the fast-track targets for Ending AIDS, despite previous successes.
- COVID-19 pandemic **disrupted** community-based **HIV screening** and **prevention activities**.
- COVID-19 pandemic also **affected** the **distribution of health workers** in places they are needed the most.
- Prolonged **movement control orders** and various non-pharmacological prevention strategies such as **physical distancing**, limitations in **face-to-face consultations restricted** PLHIVs' access to health care and other social support.

Statistic of HIV in Malaysia

HIV TRANSMISSION BY AGE IN 2021



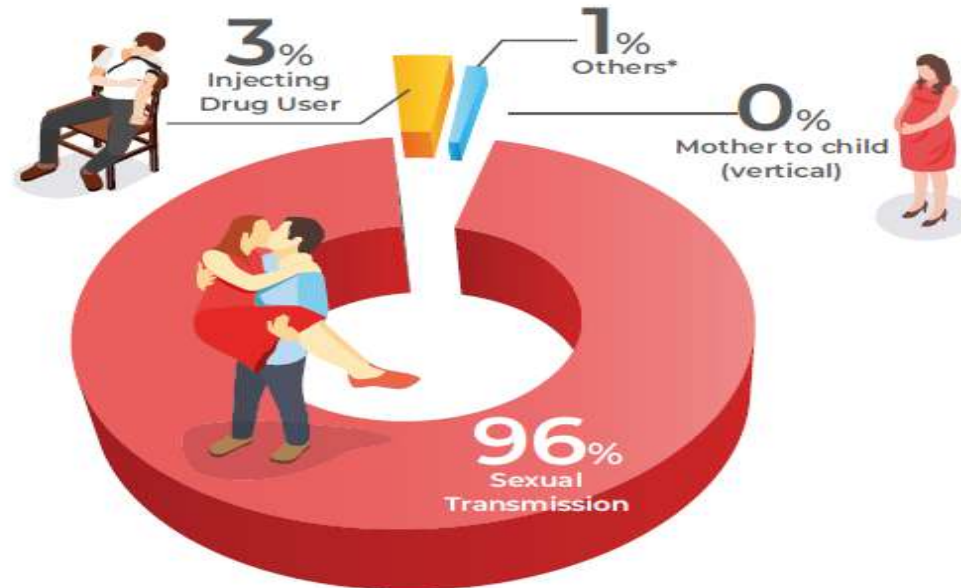
(% of 2,760 new infections)

New HIV infections are mainly contributed by patients in the age group of 20-29 and 30-39.

Statistic of HIV in Malaysia

HIV TRANSMISSION BY RISK FACTOR IN 2021

Most common mode of HIV transmission in Malaysia in 2021 is sexual transmission.



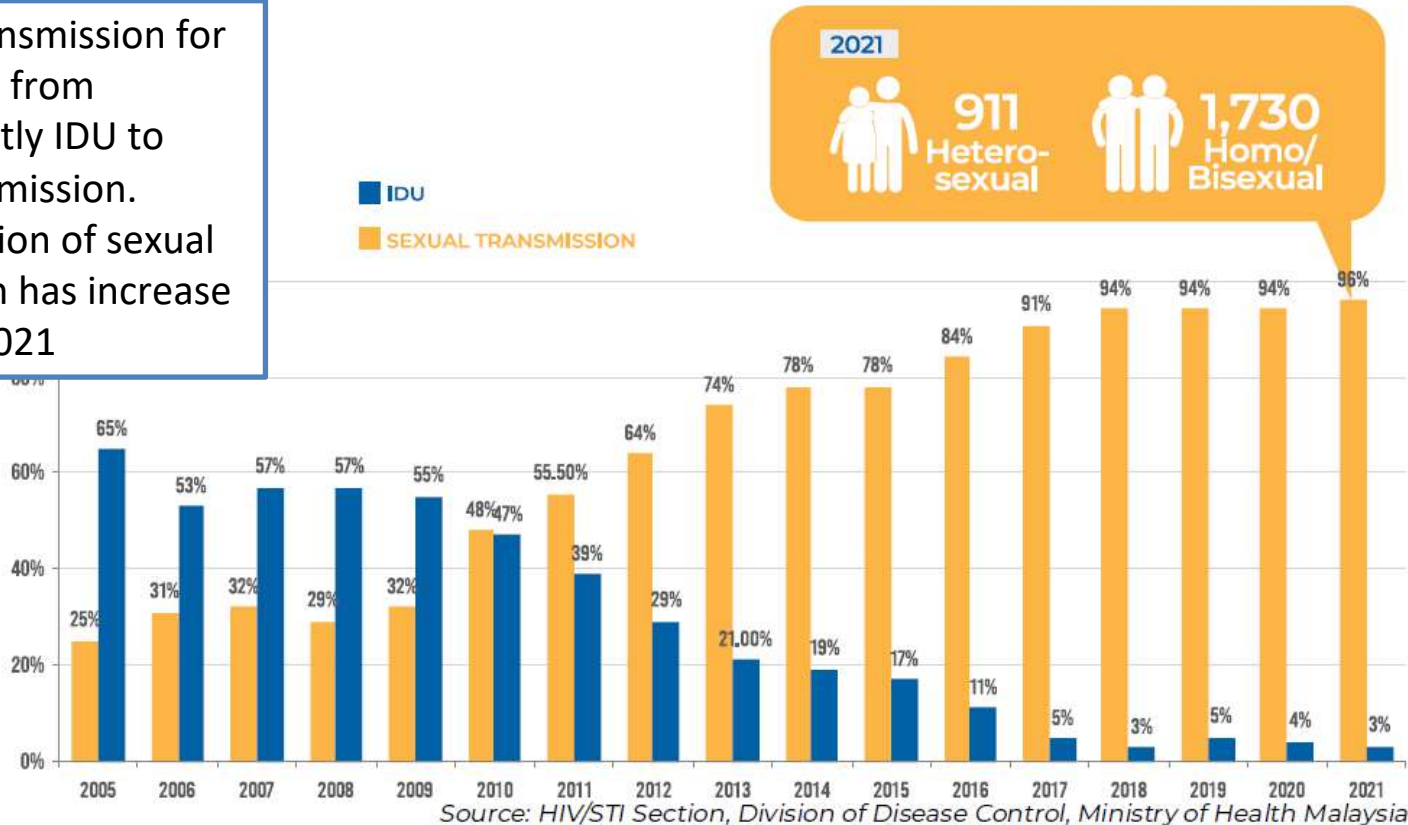
*Include blood transfusions, organ transplantations, needle stick injuries and no information.

(% of 2,760 new infections)

Changes in mode of transmission over the last 2 decades

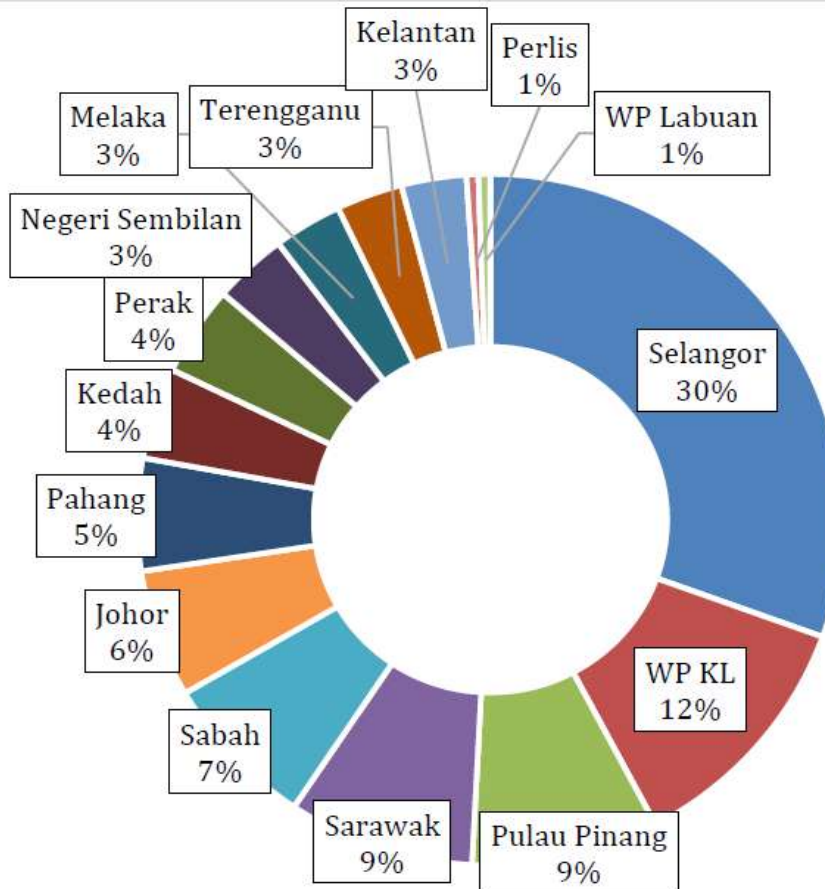
COMPARISON OF NEW HIV INFECTIONS BETWEEN INJECTING DRUG USERS (IDU) & SEXUAL TRANSMISSION (2005-2021)

- Mode of transmission for HIV changes from predominantly IDU to sexual transmission.
- The proportion of sexual transmission has increase to 96% in 2021



HIV Cases in Malaysian States

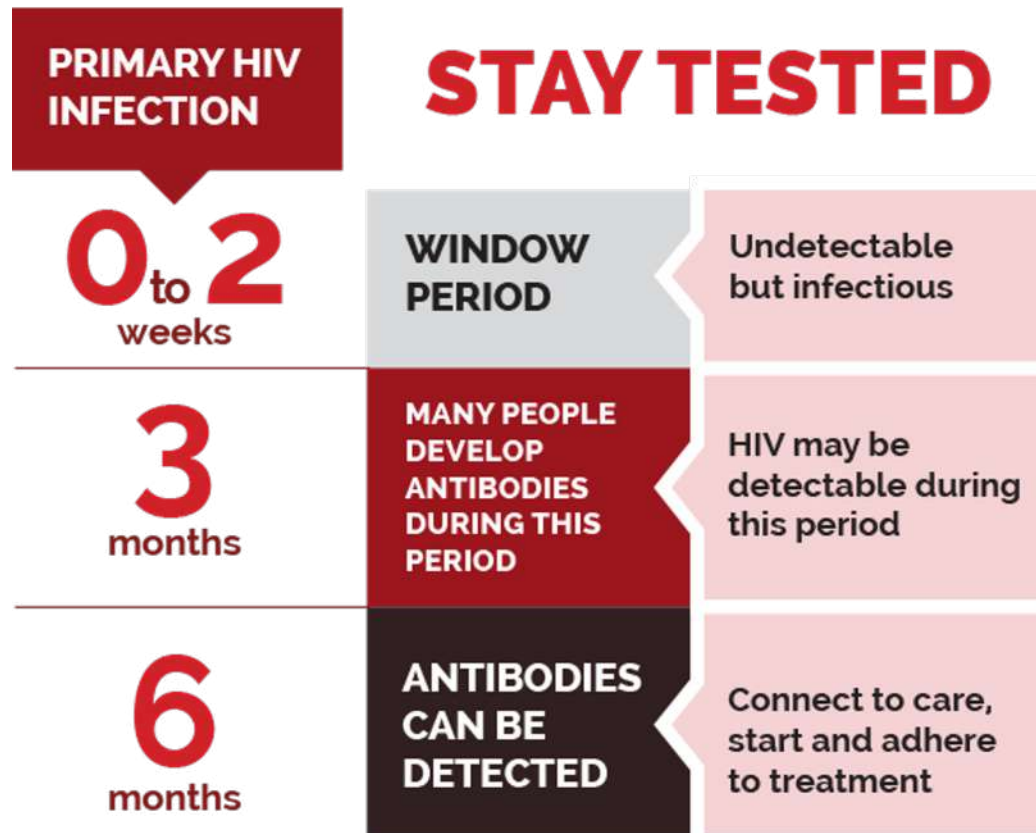
Figure 4: People living in HIV in Malaysia by state, 2021



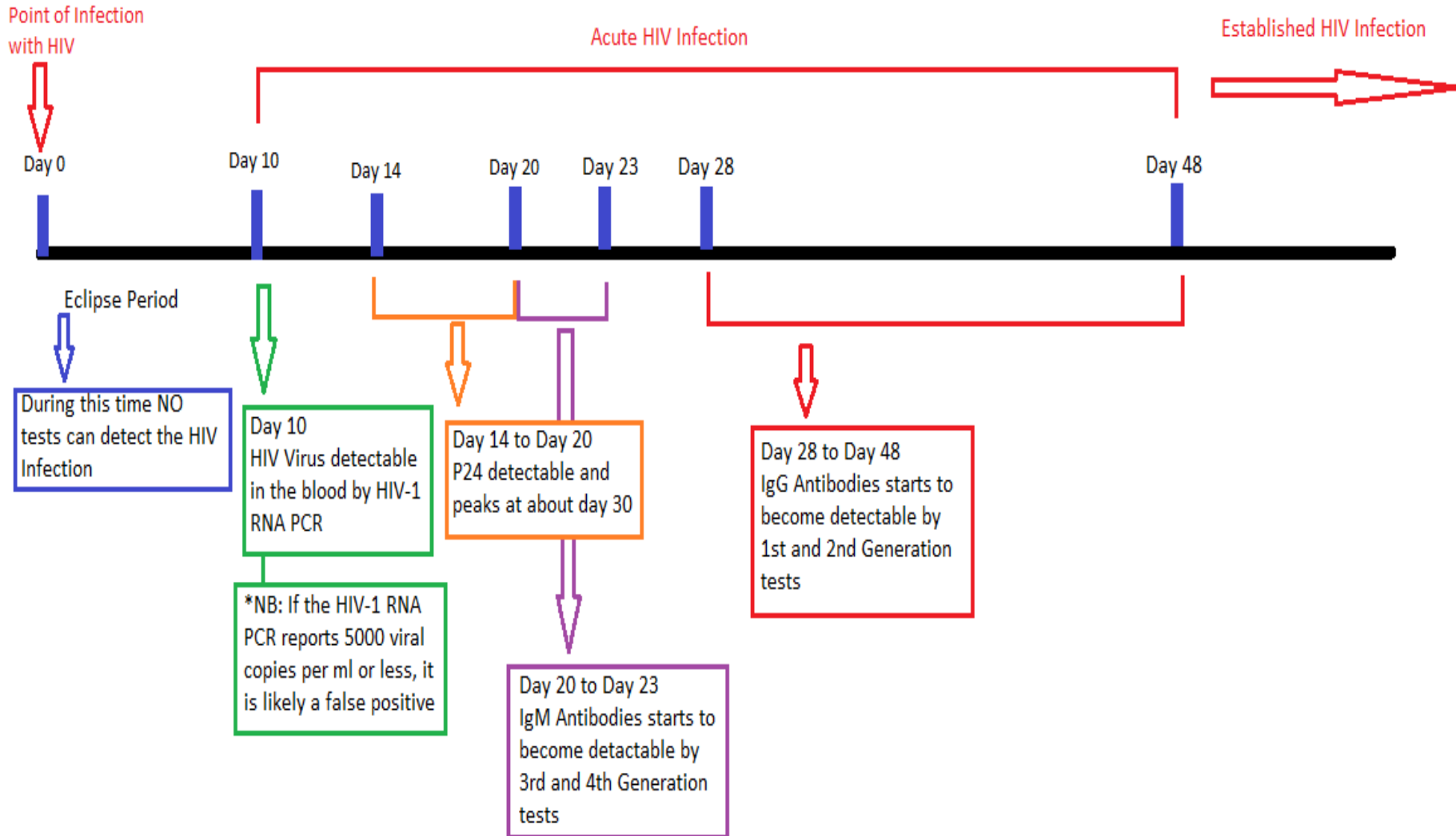
More than half of new HIV cases were notified from populous states such as Selangor, Federal Territory of Kuala Lumpur and Penang

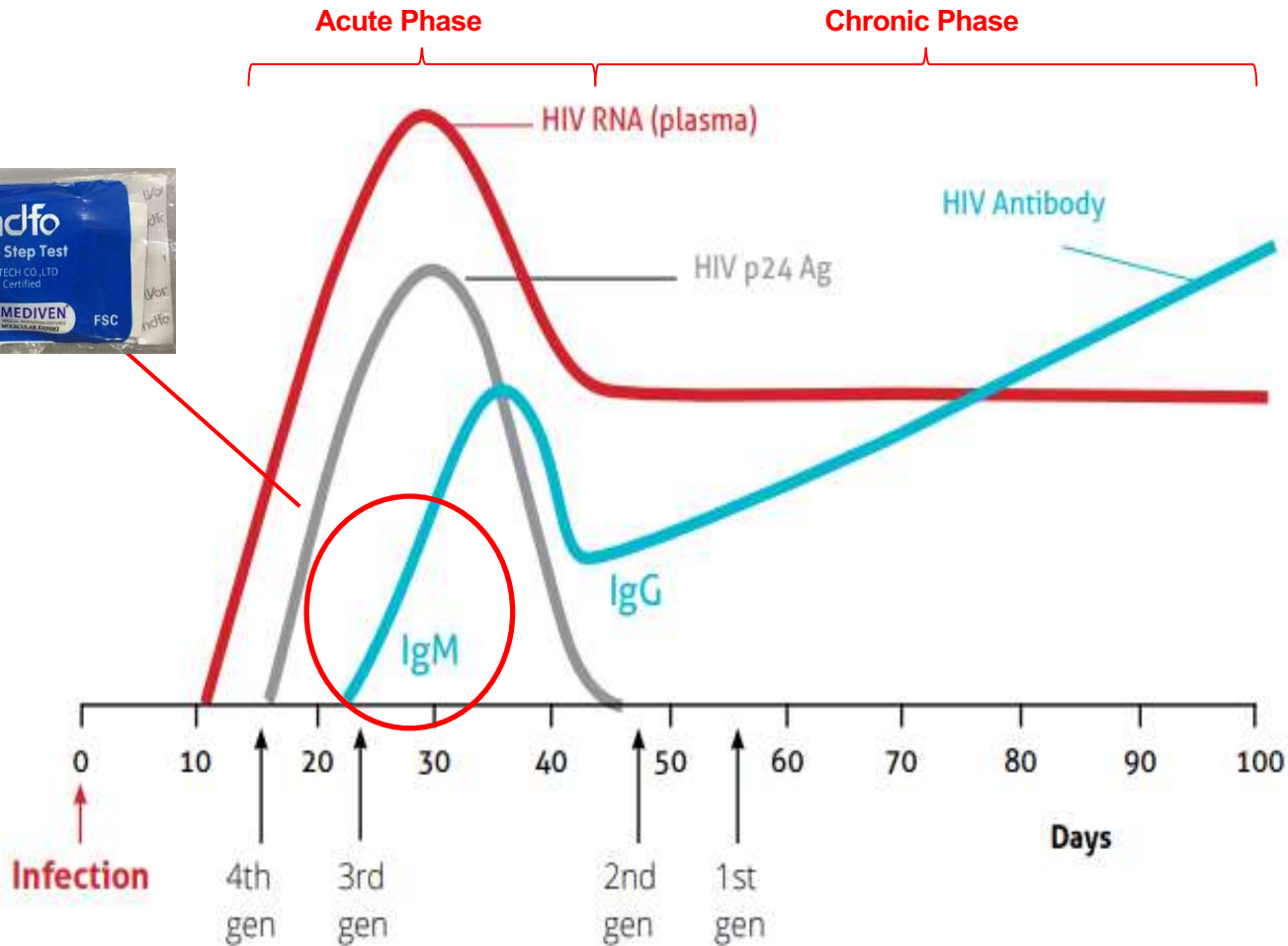
Window Period of HIV/AIDS

- After exposure to HIV, there will be biomarkers in the blood of the patients such as HIV RNA, HIV antibody, HIV antigen p24.
- From the day of exposure to the day where these biomarkers are detectable, it is called window period.



Window Period of HIV/AIDS





HIV Detection Methods

Nucleic Acid Test (NAT)*
window period

10-33 days



Antigen/Antibody Lab Test*
window period

18-45 days

Rapid Antigen/Antibody Test†
window period

18-90 days



Antibody Test‡
window period

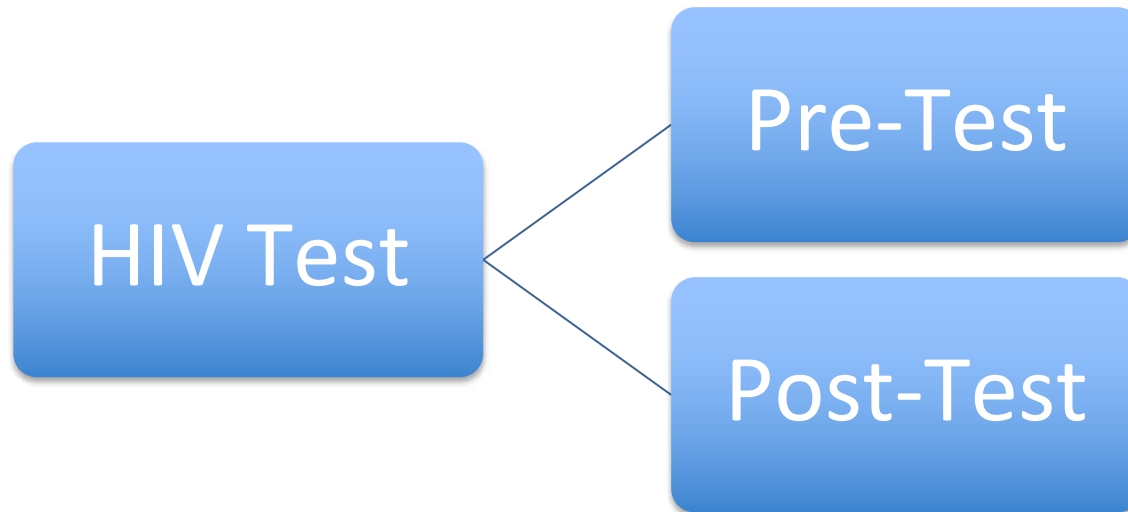
23-90 days



* Performed by a lab on blood from a vein.

† Done with blood from a finger stick.

‡ Most rapid tests and self-tests are antibody tests.



Risk assessment

Assessment of
behavioral risk

Five P's approach

- Partner
- Practice
- Protection
- Past history
- Pregnancy

Assessment of
biologic risk

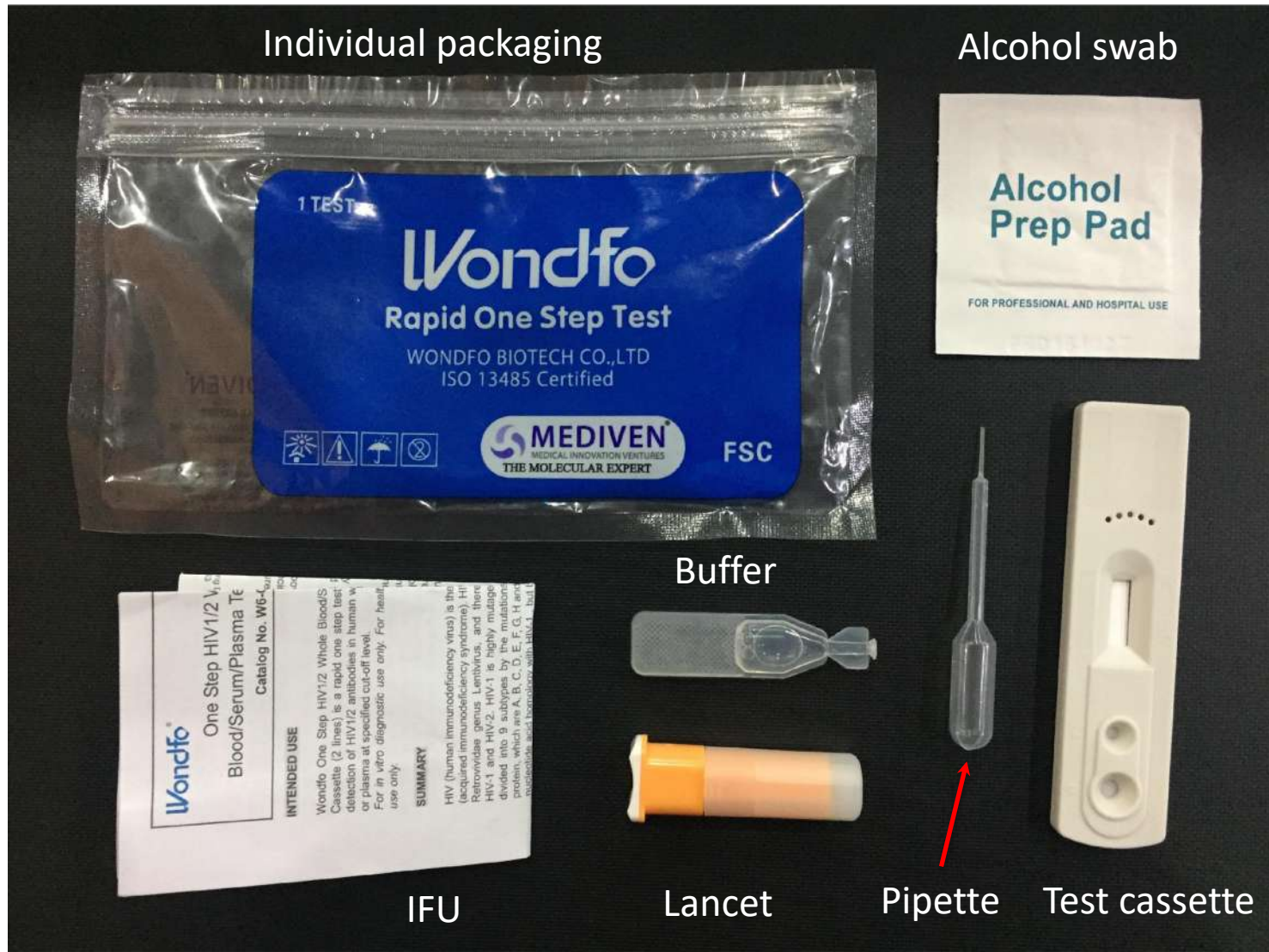
Test for the presence of
anti-HIV antibody



Product Specification



Product Name	Mediven Wondfo One Step HIV1/2 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



Individual packaging

Alcohol swab

Buffer

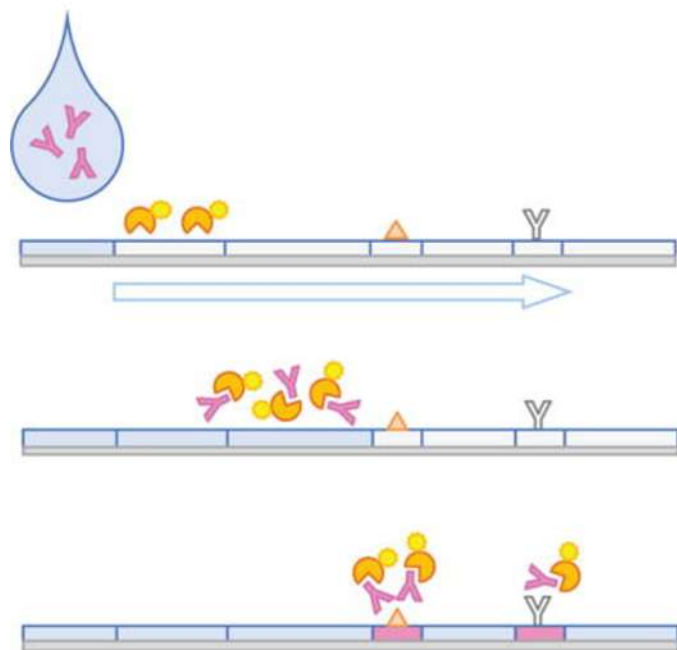
IFU

Lancet

Pipette

Test cassette

Lateral flow



Process:

1. The test strip contains **antigen conjugated to colloidal gold**, **synthetic HIV antigens** and **immobilized anti-human antibody**.
2. When sample containing HIV antibody is drop onto the test strip, it binds to **antigen conjugated with colloidal gold** forming **antigen-HIV antibody complex**.
3. The flow continues, **antigen-HIV antibody complex** will bind to the **synthetic HIV antigens**.
4. The flow continues, **immobilized anti-human antibody** will capture the **non specific human antibody**.
5. Accumulation of **colloidal gold** at the control and test lines creates a **reddish-purple stripe**.



Synthetic HIV antigen



HIV antibody
(from specimen)



Immobilized anti-
human antibody



Antigen conjugated to
colloidal gold

Specimen Collection

Whole blood



Heparin tube
EDTA tube
Sodium citrate tube

Serum & Plasma



- Recommended: specimen should be used immediately after collection
- If not tested immediately: May be stored at **2-8°C** for not more than **7 days**

- Separate the serum/plasma from blood as soon as possible to avoid hemolysis
- Recommended: specimen should be used immediately after collection
- If not tested immediately: May be stored at **2-8°C** up to **3 days**
- Long term storage:
- Below **-20°C**

Bring specimens to room temperature before testing

Fingerstick

- Select the **finger** for puncture
- Clean the **area** to be lanced with an **alcohol pad** and allow finger to dry.
- Using a **sterile lancet**, **puncture skin** just off centre of finger
- Apply gentle **pressure** to finger
- **Wipe away 1st drop of blood**
- Allow a **new drop of blood** to form
- Take the **dropper** provided, while gently **squeezing** the **tube**, immerse the open end in the blood drop and gently release the pressure.
- Whole blood samples collected by fingerstick should be **used immediately**



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.



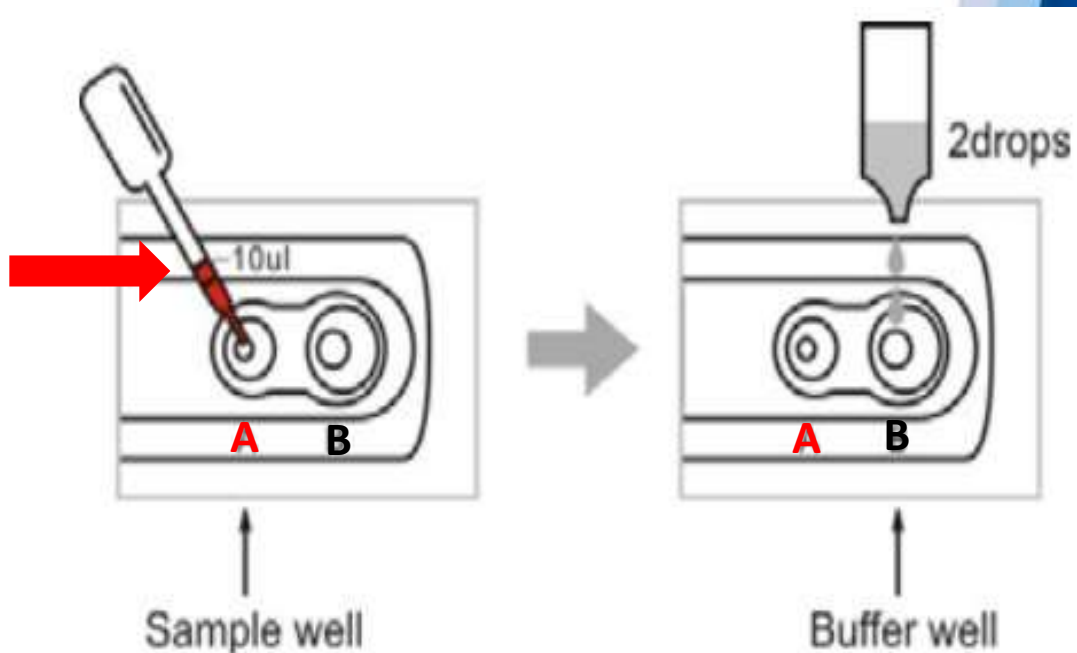
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3. Slowly release the pressure on the pipette and draw the blood slowly into the pipette until it reaches the **second mark line**.

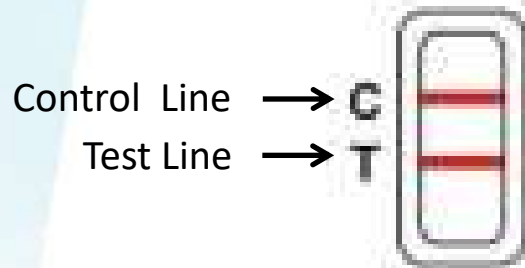
4. Slowly add **10 μ l** of specimen to the **sample well (A)** and then add **2 drops** of **dilution buffer** to the **buffer well (B)**.



**2nd Tick
Mark Line**

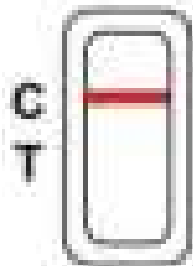


5. Wait for 15 mins and read the results.
6. **Discard the results after 30 mins.**



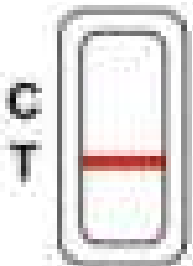
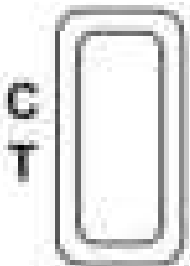
Positive (+) / Reactive

- Rose-pink bands are visible in both the C and T regions.
- Indicates presence of HIV1/2 is equal to/ higher than the detection limit of the test



Negative (-) / Non-Reactive

- Rose-pink band is visible in C region.
- No colour band appears in T region.
- Indicates that concentration of HIV1/2 Ab is zero/below the detection limit of the test.



Invalid

- No visible band at all, or there is a visible band only in the T region (not in C region)
- Repeat with a new test device.
- If test still fails, please contact the distributor/store with the lot number

Negative



- High risk patient
- Retest after eclipse period/window period

Positive



- Proceed with validation/confirmation test
- ELISA, Western blot or PCR

		True HIV status of panel sera		Total
		HIV-1 Positive	HIV-1 Negative	
Wondfo One Step HIV 1/2	Positive	100	0	100
	Negative	0	100	100
	Total	100	100	200

- The evaluation was performed on 200 well characterized samples; 100 positive known HIV individuals and 100 HIV negative individuals.
- Test kit has correctly identified **all** the 100 HIV-1 Ab positive sera and 100 HIV-1 Ab negative sera.
- **Sensitivity 100.0%, specificity 100.0%**
- Results obtained also indicate that the kit produces an estimated value of **100.0% for PPV** (probability that the serum does contain HIV Ab when test is positive) and **100.0% NPV** (probability that the serum does not contain HIV Ab when the test is negative).

Assay (manufacturer)	Report No ^a	Sensitivity (%) ^{b,c}	Specificity (%) ^{c,d}	Inter-reader variability %
Retrocheck HIV WB / Core HIV 1&2 (Qualpro Diagnostics / Core Diagnostics)	16	100 (98.8–100)	99.1 (97.8–99.8)	0.4
Alere Determine™ HIV-1/2 (Alere Medical Co. Ltd)	17	100 (99.1–100)	98.9 (97.8–99.6)	1.4
HIV 1/2 STAT-PAK® (Chembio Diagnostic Systems, Inc.)	17	99.5 (98.3–99.9)	100 (99.4–100)	0.2
HIV 1/2 STAT-PAK® Dipstick (Chembio Diagnostic Systems, Inc.)	17	100 (99.1–100)	99.7 (98.9–99.9)	0.1
One Step HIV 1/2 Whole Blood/Serum/ Plasma Test (Guangzhou Wondfo Biotech Co., Ltd)	17	100 (99.1–100)	99.9 (99.2–100)	0.2
Uni-Gold™ HIV (Trinity Biotech Manufacturing Ltd)	17	99.8 (98.7–100)	99.9 (99.2–100)	0.1
Anti-human immunodeficiency virus (HIV) antibody diagnostic kit (colloidal gold) (Beijing Wantai Biological Pharmacy Enterprise Co., Ltd)	17	100 (99.1–100)	98.5 (97.2–99.3)	0.1
INSTI HIV-1/HIV-2 Antibody Test (bioLytical Laboratories)	17	100 (99.1–100)	99.7 (98.9–100)	0.0
Reveal Rapid HIV Antibody Test (MedMira Laboratories Inc)	17	99.8 (98.6–100)	99.9 (99.2–100)	1.6

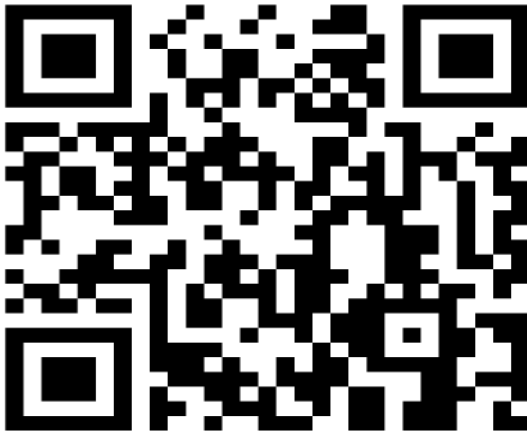


THANK YOU

Technical Supports

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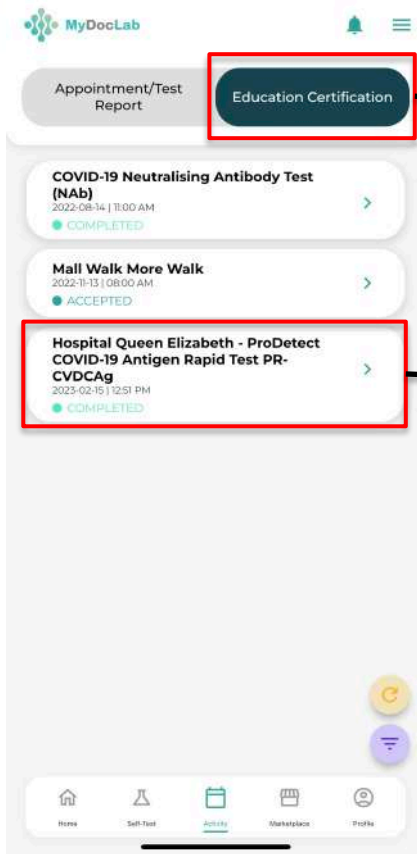
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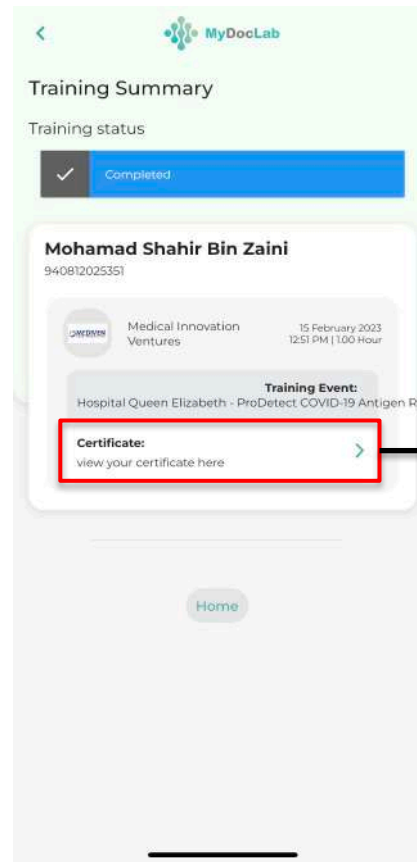
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