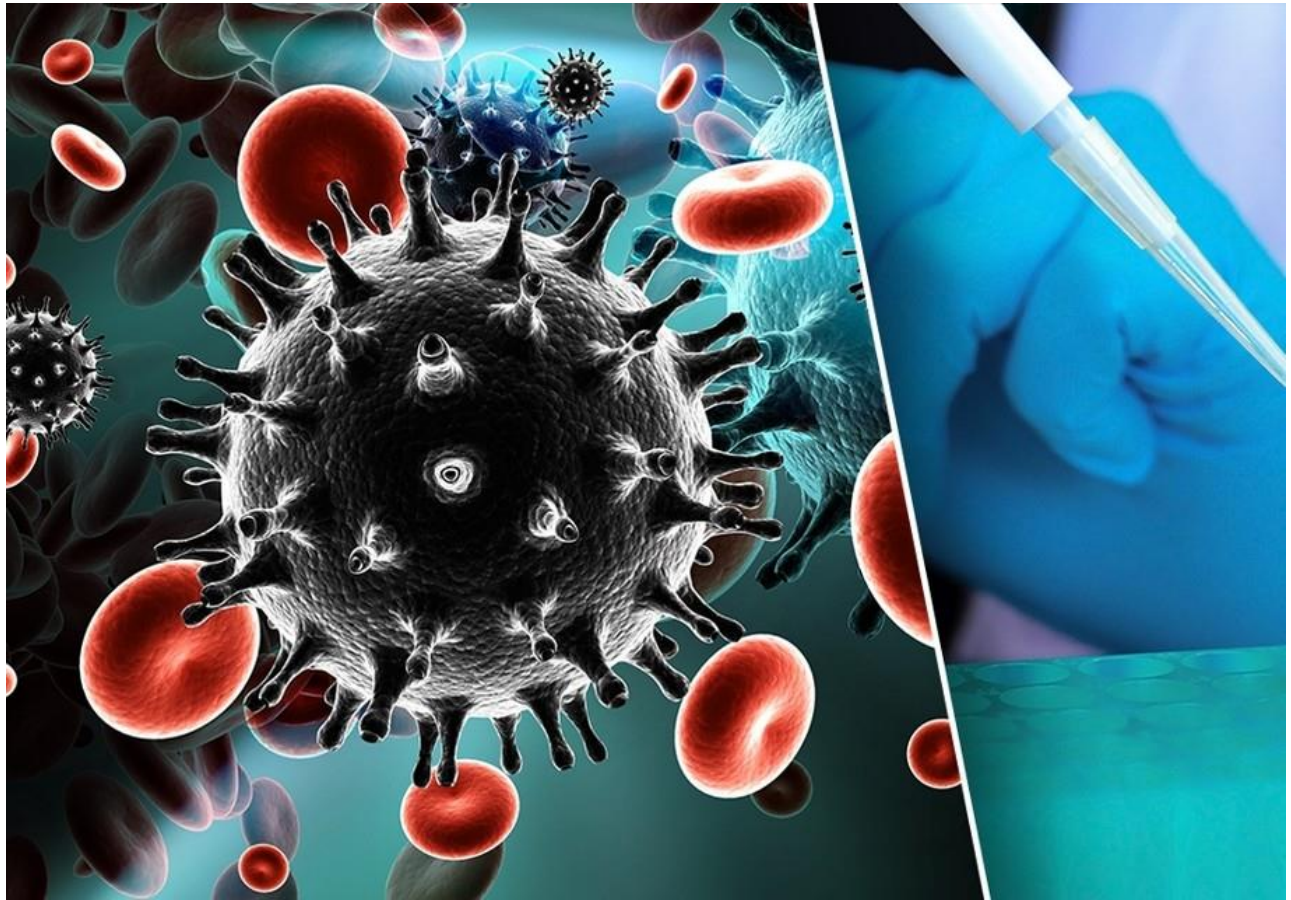
36ο ΠΑΝΕΛΛΗΝΙΟ ΣΥΝΕΔΡΙΟ AIDS

Ένας κόσμος χωρίς AIDS. **Θυμόμαστε και δεσμευόμαστε**

ΕΛΛΗΝΙΚΗ ΕΤΑΙΡΕΙΑ ΜΕΛΕΤΗΣ ΚΑΙ ΑΝΤΙΜΕΤΩΠΙΣΗΣ ΤΟΥ AIDS
HELLENIC SOCIETY FOR THE STUDY AND CONTROL OF AIDS

29/11-1/12 2024
Αθήνα, Ξενοδοχείο Royal Olympic



P O C T

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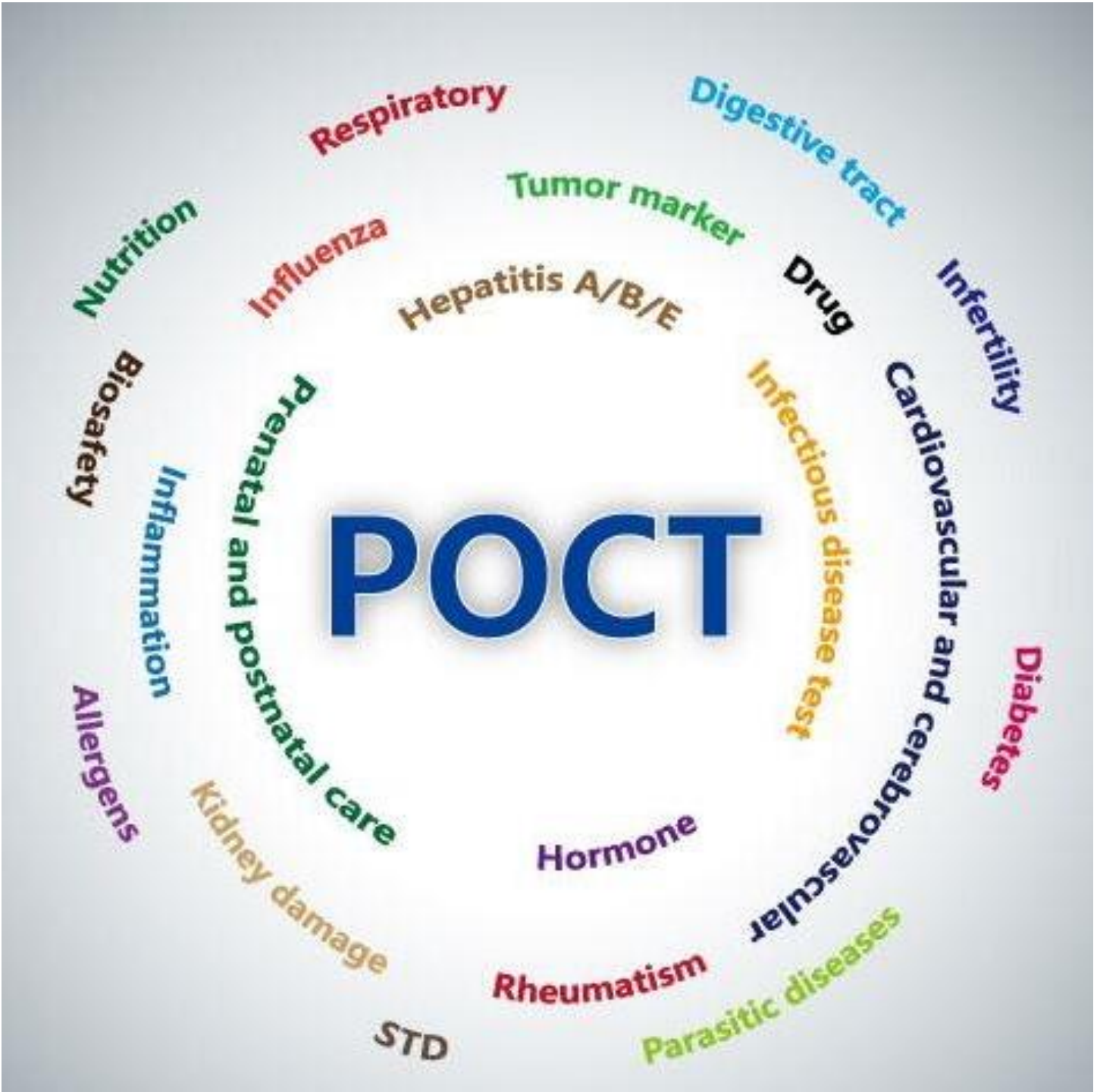
ΕΟΔΥ

ΕΘΝΙΚΟΣ ΟΡΓΑΝΙΣΜΟΣ ΔΗΜΟΣΙΑΣ ΥΓΕΙΑΣ



GLOBAL POINT-OF-CARE TESTING MARKET

DATA BRIDGE

DRIVERS ①
1.GROWING GERIATRIC POPULATION
2.ADVANCEMENT IN TECHNOLOGY
3.ECENTRALIZED LABORATORY TESTING
4.INCREASED INCIDENCE OF CHRONIC DISEAS

RESTRAINTS ②
1.UNFAVOURABLE REIMBURSEMENT SCENARIO
2.ECONOMIC COST

OPPORTUNITIES ③
1.EMERGING MICROFLUIDIC LAB-ON-A-CHIP TECHNOLOGY
2.EMERGING MARKETS
3.UNMET MEDICAL NEEDS

CHALLENGES ④
1.LACK OF ACCURACY AND EFFICIENCY
2.DATA MANAGEMENT AND LACK OF CONNECTIVITY
3.TESTING PERFORMED BY NON-LABORATORY PERSONNEL AND
4.LACK OF AWARENESS AMONG THE USERS

Global Point-of-Care Testing Market is expected to grow at a **CAGR of 8.4%** in the forecast period 2017-2024.

Point-of-Care Testing (POCT) helps in the rapid performance of diagnostic tests despite patient being at the point of care facility. This helps in obtaining the results immediately rather than waiting for hours or even days outside the laboratory.

Major Players

Some of the major players operating in this market are Abbott Laboratories, Inc. (U.S.), Alere Inc. (U.S.), Roche Diagnostics Limited (Switzerland), Siemens AG (Germany), Becton, Dickinson and Company (U.S.), Johnson & Johnson Services Inc. (U.S.), PTS Diagnostics (U.S.), Instrumentation Laboratory (U.S.), Nova Biomedical (U.S.), Beckman Coulter, Inc. (U.S.) and others.

DATA BRIDGE MARKET RESEARCH

EQUITY

Address social and structural barriers to HIV testing and treatment access.

12 populations being left behind

I am a person living with HIV.
Worldwide, 19 million of the 35 million people living with HIV today do not know that they have the virus.

I am a young woman.
76% of adolescent girls in sub-Saharan Africa do not have comprehensive and correct knowledge about HIV.

I am a prisoner.
HIV prevalence among prisoners in some settings is 50 times higher than among the general population.

I am a migrant.
Around the world, 39 countries have an HIV-related travel restriction.

I am an injecting drug user.
Only 55 of 192 countries offer a needle–syringe programme.

I am a sex worker.
HIV prevalence among sex workers is 12 times greater than among the general population.

I am a man who has sex with other men.
Same-sex sexual conduct is criminalized in 78 countries.

I am a transgender woman.
Transgender women are 49 times more likely to acquire HIV than all adults of reproductive age.

I am a pregnant woman.
Only 44% of pregnant women in low- and middle-income countries received HIV testing and counselling in 2013.

I am a child.
Of the 3.2 million children under the age of 15 living with HIV, 2.4 million are not accessing antiretroviral therapy.

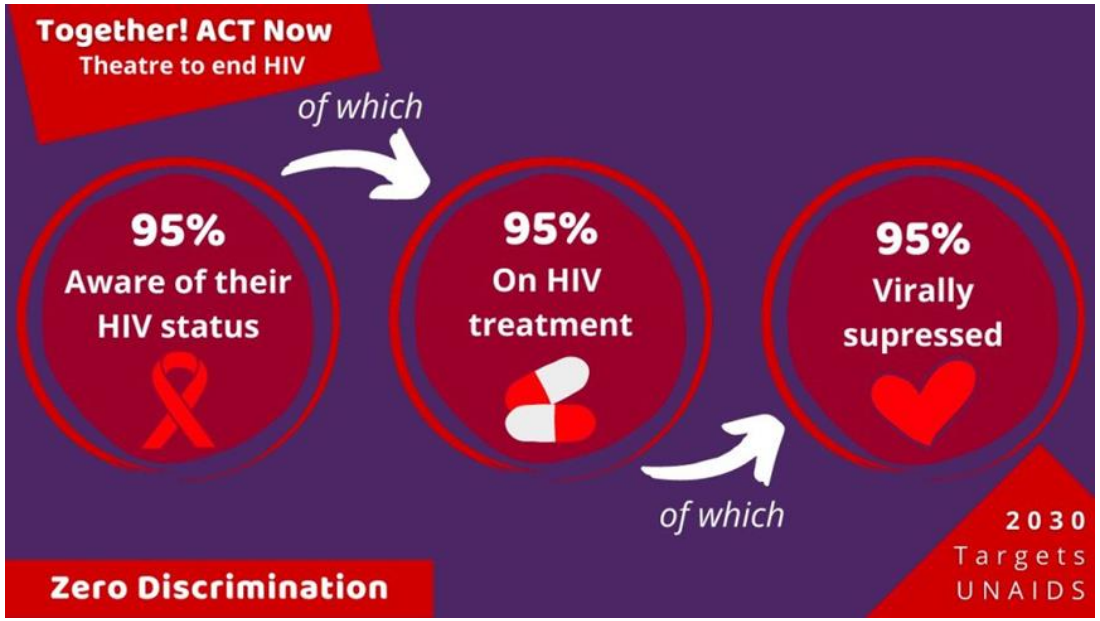
I am a displaced person.
At the end of 2013, there were 51.2 million people forcibly displaced worldwide.

I am a person living with a disability.
23% of men with a disability do not return to seek health care because they were treated badly at a previous visit.

I am 50+.
The life expectancy of people aged 50 and older living with HIV and accessing treatment is the same as the life expectancy of others of the same age.

UNAIDS

Improving Disease Management



The UNAIDS Fast-track Targets

By 2030,

95 % of people living with HIV know their HIV status

95 % of people who know their status are receiving treatment

95 % of people receiving treatment are virally suppressed

UNAIDS

People living with HIV	**39.9 million** [36.1 million–44.6 million]
New HIV infections	**1.3 million** [1.0 million–1.7 million]
Deaths due to AIDS	**630 000** [500 000–820 000]

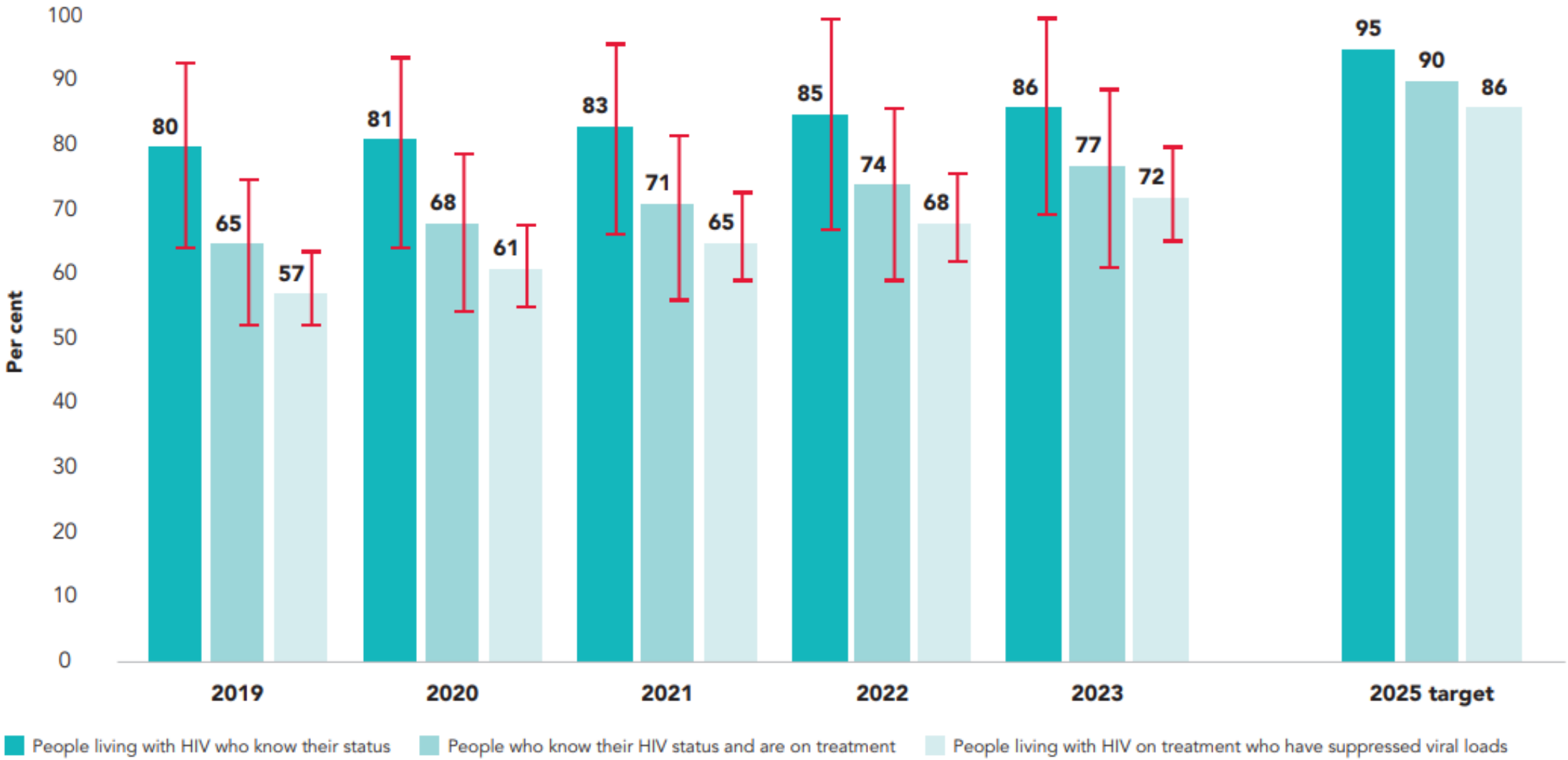
People living with HIV

- In 2023, there were 39.9 million [36.1 million–44.6 million] people living with HIV.
  - 38.6 million [34.9 million–43.1 million] adults (15 years or older).
  - 1.4 million [1.1 million–1.7 million] children (0–14 years).
  - 53% of all people living with HIV were women and girls.
- 86% [69–>98%] of all people living with HIV knew their HIV status in 2023.
- About 5.4 million people did not know that they were living with HIV in 2023.

About 3600 new HIV infections (adults and children) a day | **2023**

- **About 50% are in sub-Saharan Africa**
- **About 320 are among children under 15 years of age**
- **About 3200 are among adults aged 15 years and older, of whom:**
  - **almost 44% are among women**
  - **about 30% are among young people (15–24)**
  - **about 17% are among young women (15–24)**

Figure 3.1 Testing and treatment cascade among people living with HIV, global, 2019–2023

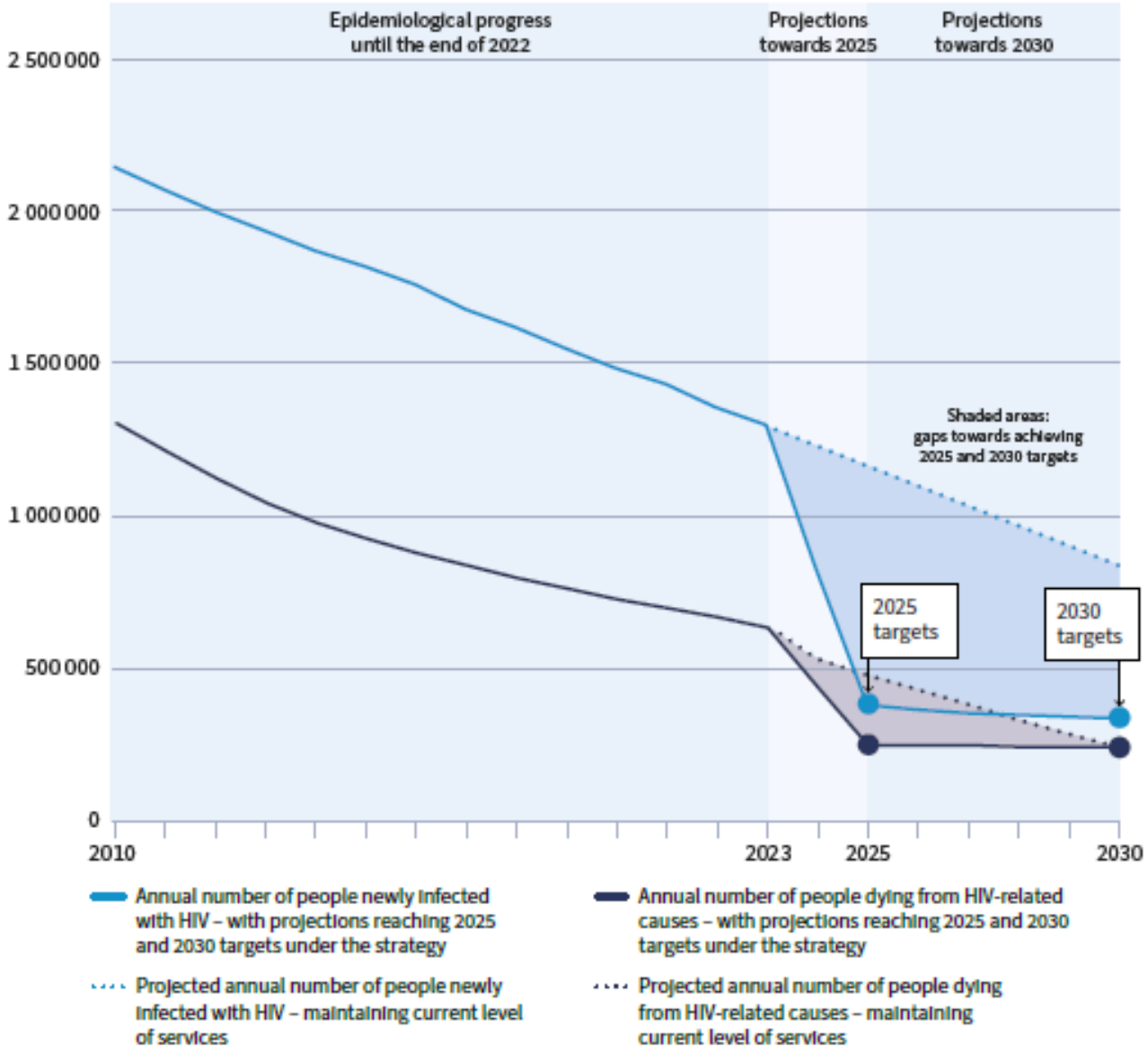


Source: Further analysis of UNAIDS epidemiological estimates, 2024.

Table 3.1 Overview of progress across priority elements of HIV treatment

95–95–95 FOR HIV TESTING AND TREATMENT	TARGET	2023 STATUS
Reduce number of annual AIDS-related deaths to fewer than 250 000	250 000	630 000
34 million people are on HIV treatment by 2025	34 million	30.7 million
95–95–95 testing, treatment and viral suppression targets	95–95–95	All ages: 86%–89%–93% Women (aged 15+ years): 91%–91%–94% Men (aged 15+ years): 83%–86%–94% Children: 66%–86%–84% Key populations: unknown
90% of people living with HIV receive preventive treatment for tuberculosis (TB) by 2025	90%	17 million people living with HIV initiative on TB preventive treatment between 2005 and 2022
Reduce numbers of TB-related deaths among people living with HIV by 80%	80%	71%

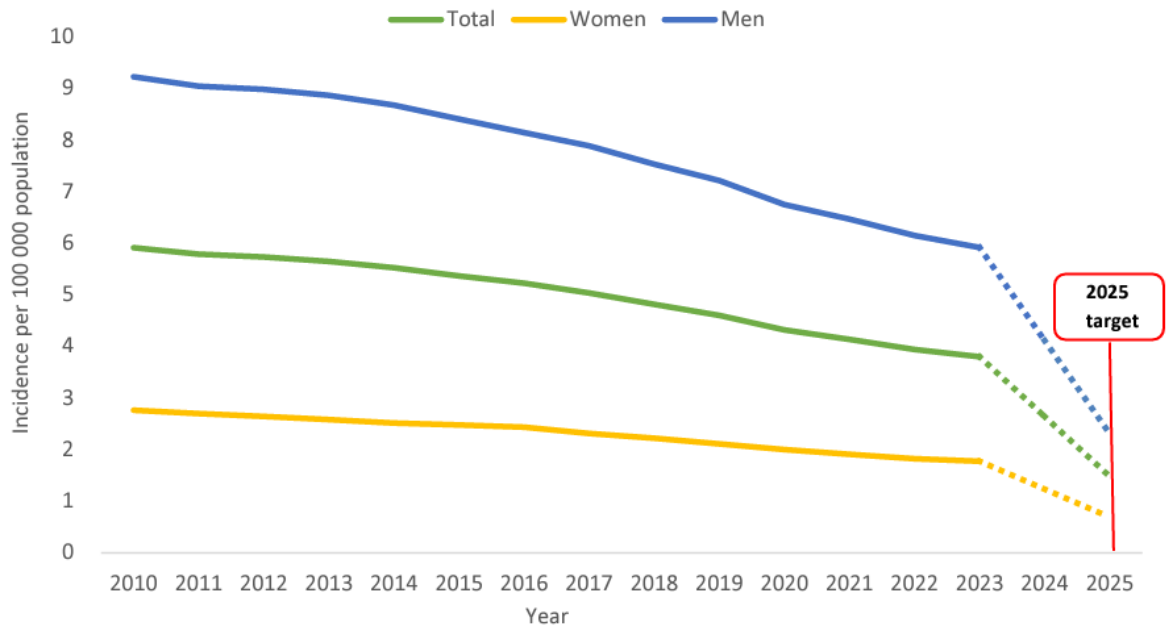
Fig 2. Global trends in people acquiring HIV and people dying from HIV-related causes, 2010–2023 and projections to 2030



Note: The United Nations global targets for 2025 are twinfold: reducing the number of people acquiring HIV to less than 370 000 and reducing the number of HIV-related deaths to less than 250 000. To end AIDS as a public health threat by 2030, the targets are a 90% reduction of the number of people acquiring HIV and dying from HIV using 2010 as the baseline.

Sources: Avenir Health using 2025 targets and UNAIDS/WHO epidemiological estimates, 2024.

Figure 3. **HIV incidence per 100 000 population, EU/EEA, 2010–2023**



Dotted lines indicate progress needed to reach the 2025 targets. Source: UNAIDS estimates, 2024.

HIV/AIDS Report card

Sustainable Development Goal (SDG) 3.3 aims to end the AIDS epidemic by 2030.
How is the EU/EEA progressing?

ecdc

Cases declined in 2023, but not quickly enough to reach the 2030 SDG targets, from the 2010 baseline.

24,731

HIV diagnoses were reported in 2023 in the EU/ EEA at an average age of 39.

The increases we see are likely due to two main factors:

ongoing transmission among key populations

increased testing efforts to reduce late diagnoses

75%

reduction in case numbers is our target. To achieve this, we will need to work harder on **prevention, testing and treatment, and stigma.**

72%

of people diagnosed were men.

1 Prevention

53%

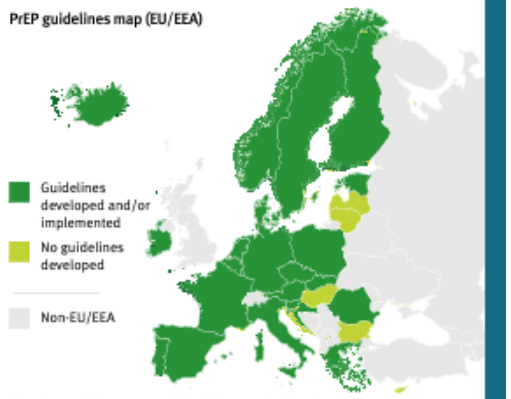
Of reported cases are classified as late diagnoses. This remains a significant issue despite efforts to improve testing in the EU/EEA.

48%

Of reported cases are among migrant populations, Prevention and testing strategies need to be improved for this key group.

5 Number of EU/EEA countries which have not implemented any PrEP guidelines. PrEP is a medicine that stops HIV from entering cells.

PrEP guidelines map (EU/EEA)



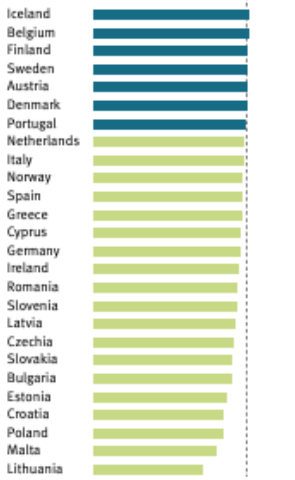
*Countries not visible: Luxembourg Malta, Liechtenstein (guidelines developed and/or implemented), Cyprus (no guidelines developed).

2 Testing and treatment

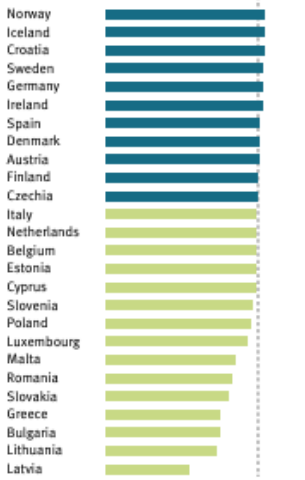
We are making good progress against the UNAIDS 95:95:95 targets.

However, many countries are well below the **95%** in all three areas.

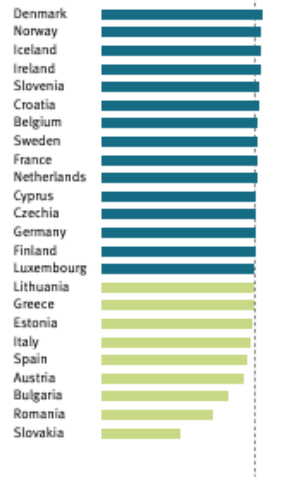
Target 1: Diagnosis — Only six out of 26 countries are on target. Testing services need to be scaled up in most countries



Target 2: Treatment — Only 11 out of 26 countries are meeting the target and six are below 80%



Target 3: Viral suppression — Most countries have reached the 95% target. But 23% of people living with HIV are not virally surpressed



Note: Data missing for some EU/EEA countries for some targets and therefore these countries are not shown on the bar charts above.

3 Stigma

Stigma often involves negative judgements, discrimination, and misconceptions about HIV. The UN's target is for less than 10% of people living with HIV to experience stigma.

19% had not told a single family member they had HIV

24% had been rejected by friends

17% threatened, verbally harrassed or physically harmed by a sexual partner

36% avoided healthcare services because expected to be treated differently

23% had refused or delayed healthcare

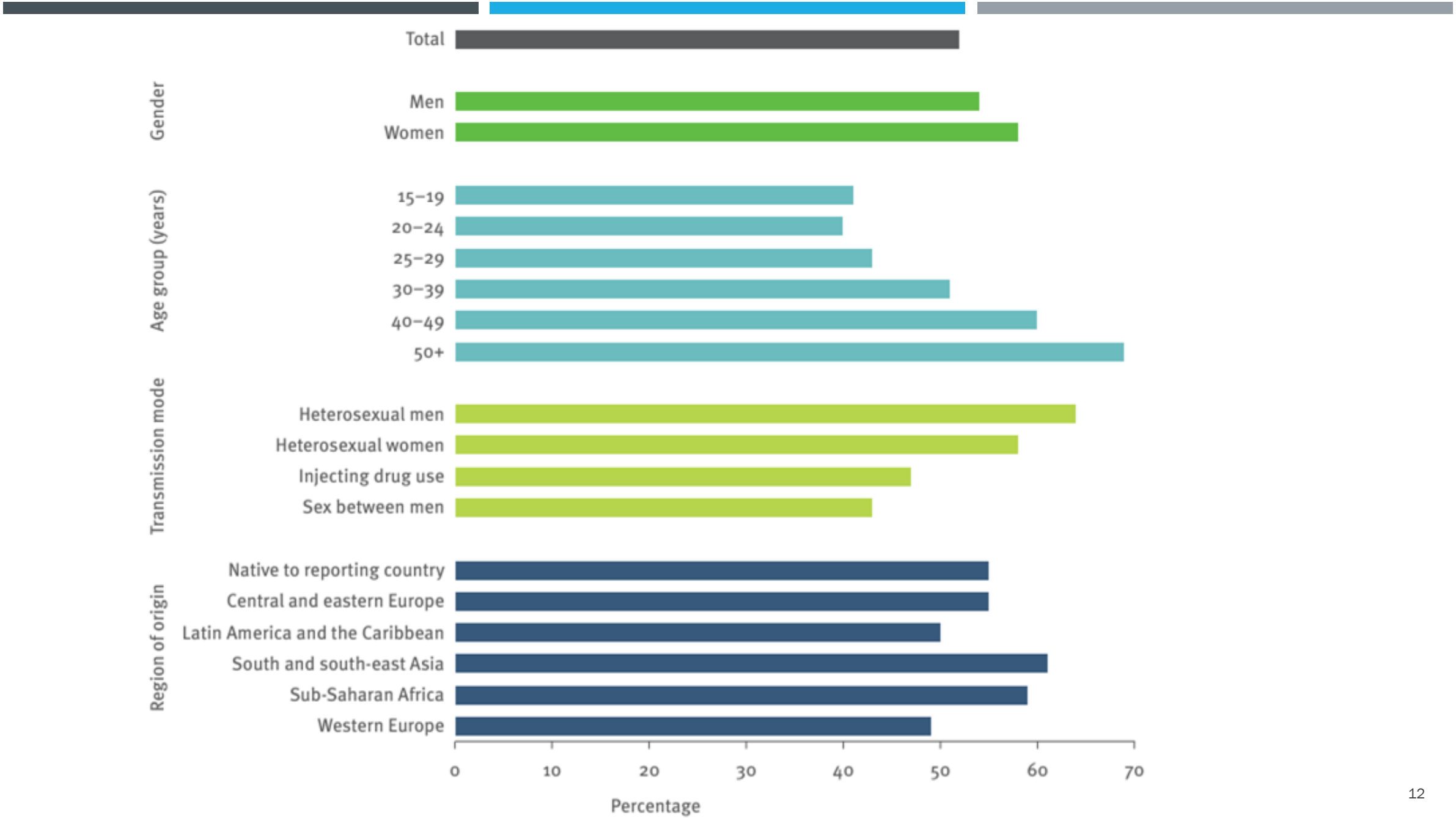
Reducing stigma requires greater public education, promoting empathy and dismantling misconceptions about HIV transmission, treatment and those living with the virus.

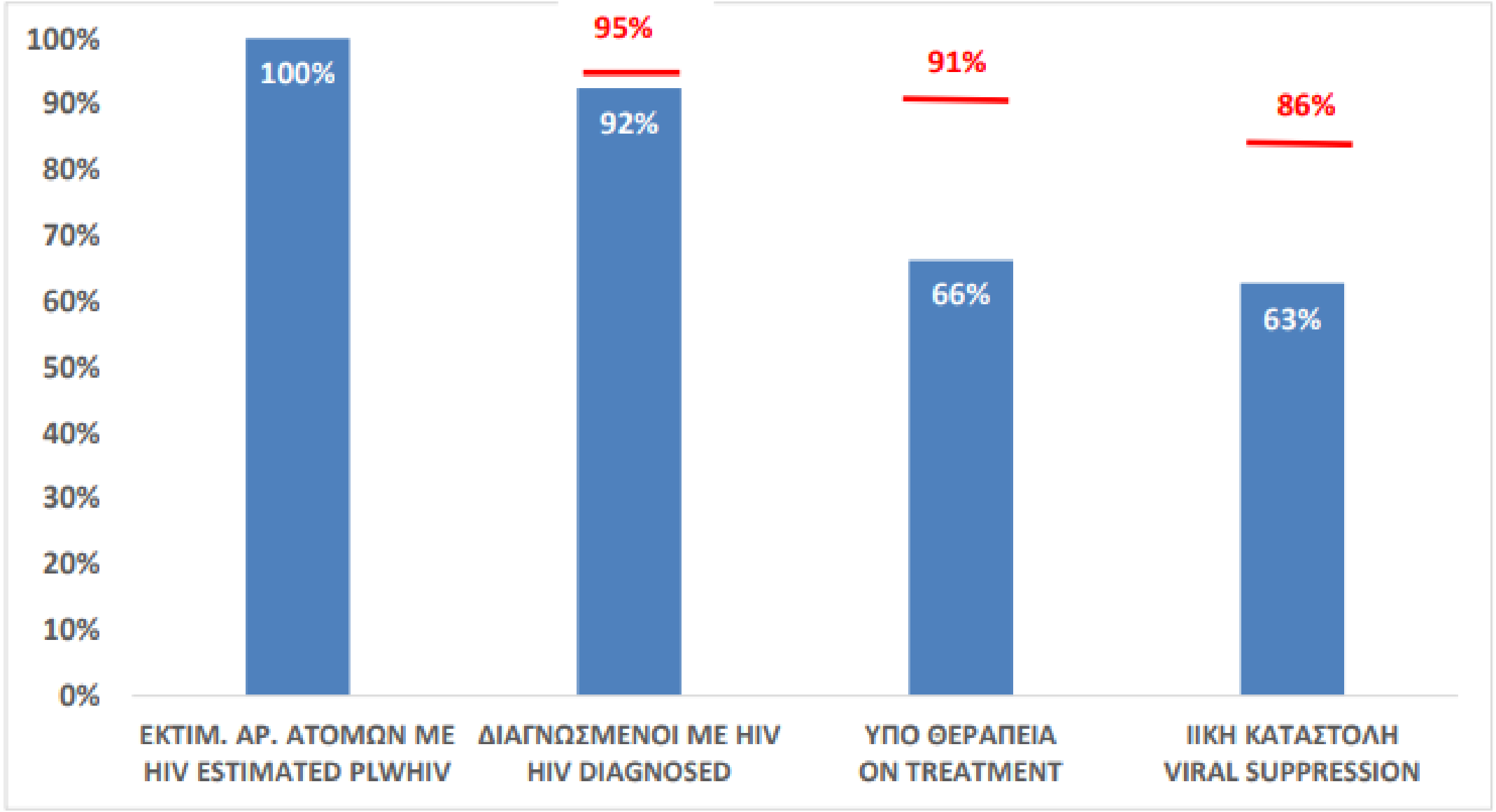
Priority areas for action

- Increase testing and target affected groups to improve rates of diagnosis
- Greater access to PrEP and sharing best practice on prevention among member states
- Improve treatment to maximize the number of people with viral suppression
- End stigma so that those living with HIV can live full lives
- Effective monitoring of of key indicators for prevention and treatment

For more information, visit https://www.ecdc.europa.eu/en/hiv-infection-and-aids

Fig. 1.8. Percentage of people diagnosed late (CD_4 cell count < 350 per mm^3) by demographic, EU/EEA, 2023 (n=11 961)





Καταρράκτης των σταδίων φροντίδας για το σύνολο των ατόμων που ζουν με HIV, βάσει των στόχων 95-91-86.

Νέες διαγνώσεις HIV λοίμωξης* κατά κατηγορία μετάδοσης και κατά φύλο στην Ελλάδα (1/1/2023 - 31/12/2023) New HIV diagnoses* by transmission mode and sex in Greece (1/1/2023 - 31/12/2023)							
Κατηγορία μετάδοσης	Άνδρες** Males**		Γυναίκες Females		Σύνολο Total		Transmission mode
	N	(%)	N	(%)	N	(%)	
Σεξουαλική επαφή μεταξύ ανδρών	240	(47,4)	0	(0,0)	240	(36,5)	Sex between men
Ετεροφυλοφιλική σεξουαλική επαφή	37	(7,3)	69	(45,7)	106	(16,1)	Heterosexual contact
Ενέσιμη χρήση εξαρτησιογόνων ουσιών	63	(12,5)	21	(13,9)	84	(12,8)	Injecting drug use
Κάθετη μετάδοση	0	(0,0)	1	(0,7)	1	(0,2)	Mother to child transmission
Ακαθόριστη	166	(32,8)	60	(39,7)	226	(34,4)	Undetermined
Σύνολο	506	100	151	100	657	100	Total

** Συμπεριλαμβανομένων των περιστατικών που όταν διαγνώσθηκαν είχαν ήδη αναπτύξει AIDS*

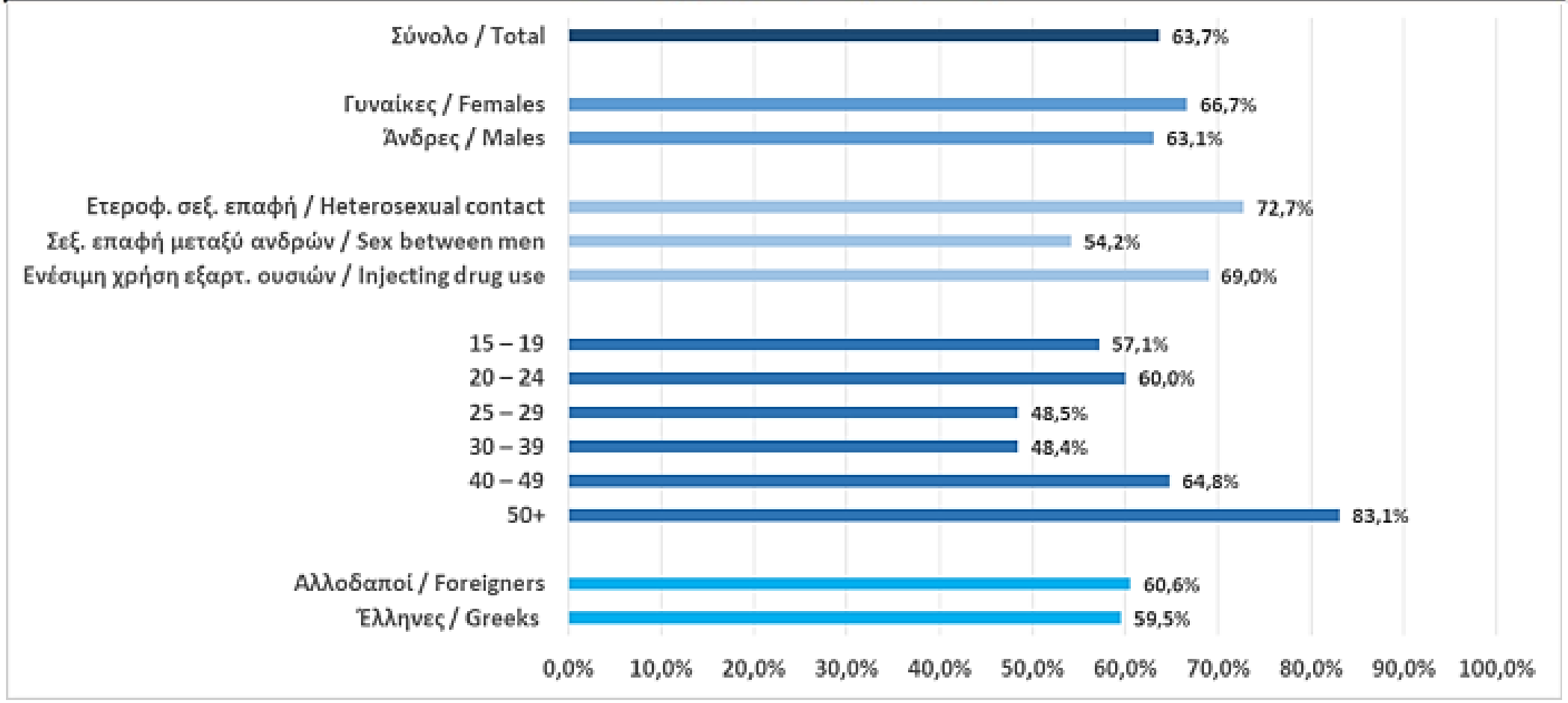
** Including cases presenting with AIDS when first diagnosed with HIV*

*** Περιλαμβάνεται 1 διεμφυλική γυναίκα (γυναίκα της οποίας το φύλο κατά τη γέννηση ήταν άρρεν)*

*** Including 1 transgender woman (woman who assigned male at birth)*

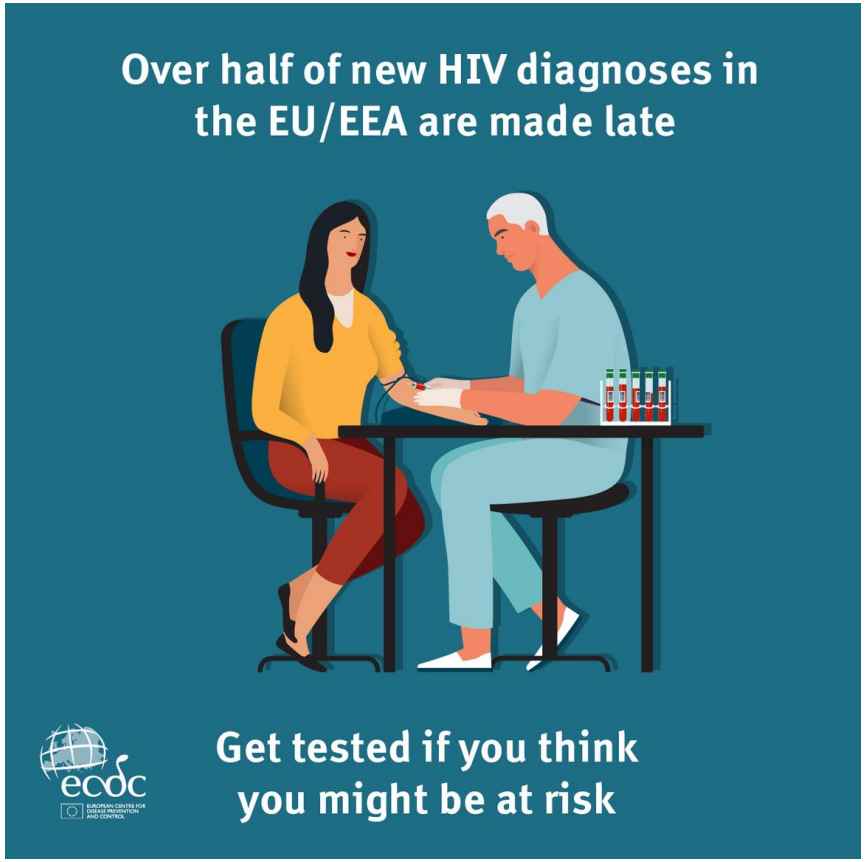
Ποσοστό περιστατικών HIV* που διαγνώστηκαν καθυστερημένα το 2023 (CD4<350 κύτταρα/mm³), ανά φύλο, κατηγορία μετάδοσης, ηλικιακή ομάδα και εθνικότητα (1/1/2023 - 31/12/2023)

Proportion of HIV cases* diagnosed late in 2023 (CD4<350 cells/mm³), by sex, transmission group, age group and ethnicity (1/1/2023 - 31/12/2023)



* *Συμπεριλαμβανομένων των περιστατικών που όταν διαγνώσθηκαν είχαν ήδη αναπτύξει AIDS*

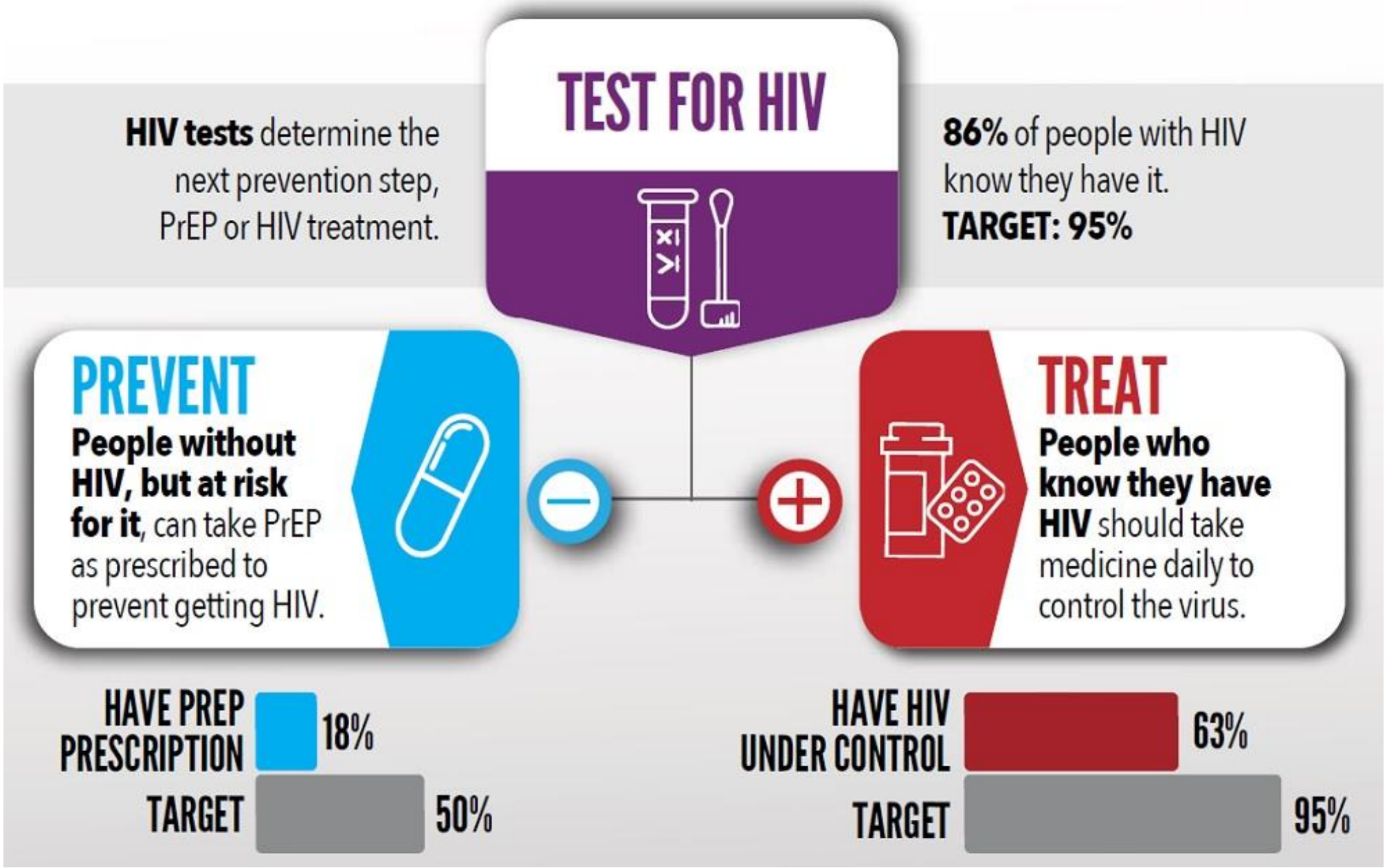
* *Including cases presenting with AIDS when first diagnosed with HIV*


Over half of new HIV diagnoses in the EU/EEA are made late
Get tested if you think you might be at risk
ecdc


WORLD AIDS DAY REPORT 2024
TAKE THE RIGHTS PATH
TO END AIDS
UNAIDS

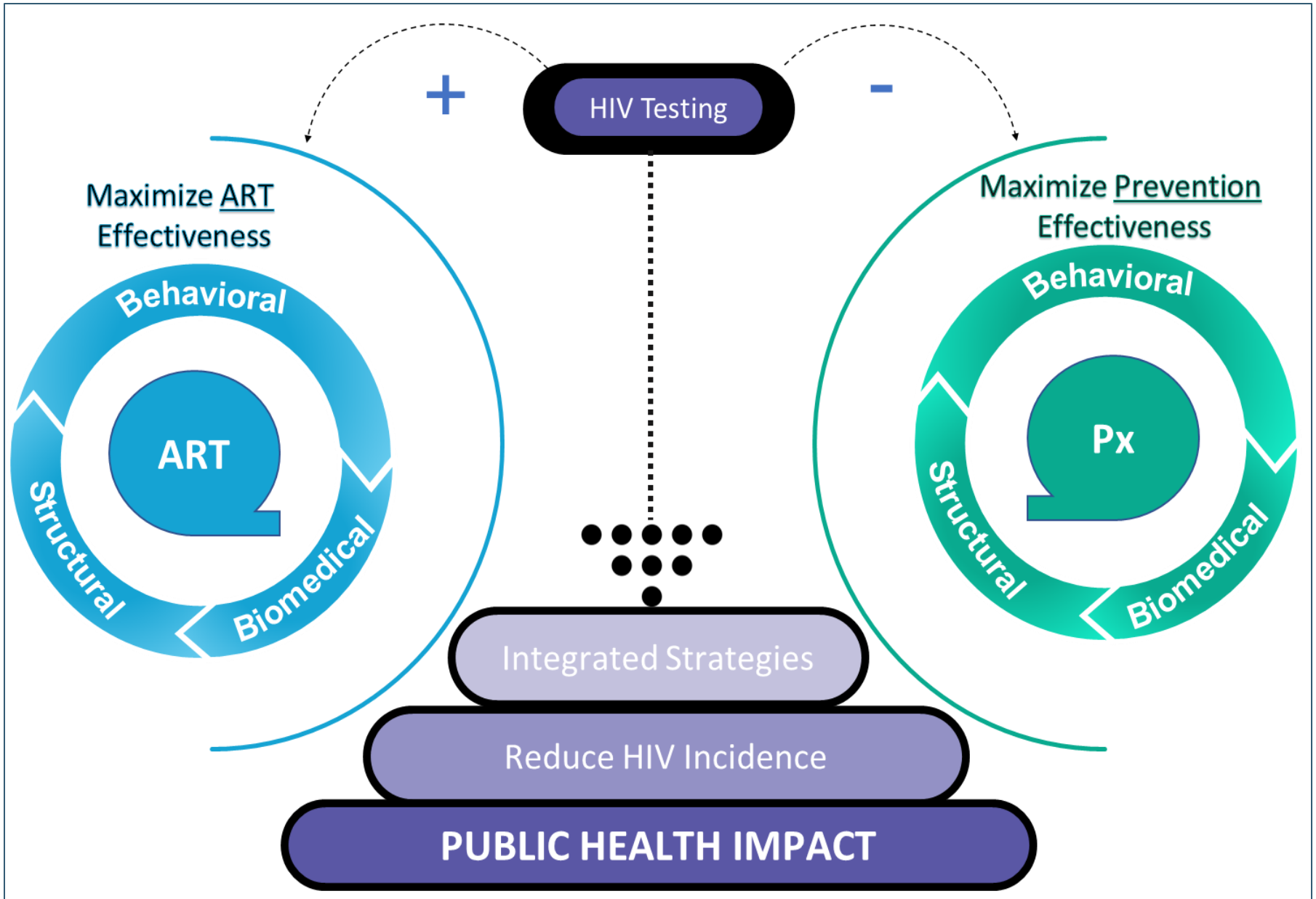

Promoting Public Health

Importance of Early Diagnosis of HIV/AIDS


TEST FOR HIV
HIV tests determine the next prevention step, PrEP or HIV treatment.
86% of people with HIV know they have it.
TARGET: 95%
PREVENT
People without HIV, but at risk for it, can take PrEP as prescribed to prevent getting HIV.
TREAT
People who know they have HIV should take medicine daily to control the virus.
HAVE PREP PRESCRIPTION
18%
TARGET
50%
HAVE HIV UNDER CONTROL
63%
TARGET
95%

UNIVERSAL TEST AND CONNECT/ ONE DOOR

Testing is pivotal to identifying & referring people for services and support–for treatment & prevention



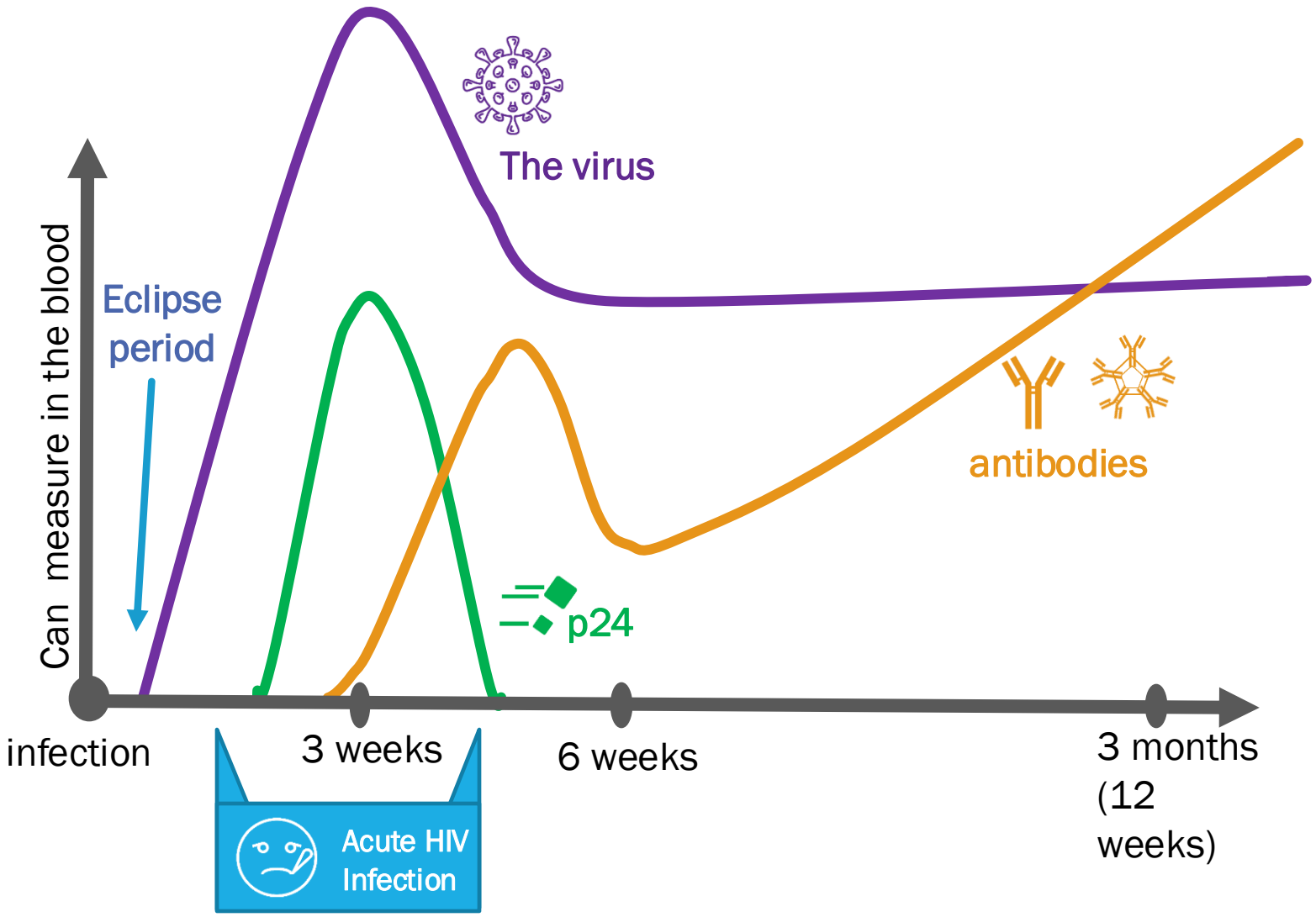

WHAT'S
INVOLVED
IN TESTING
FOR HIV
?

HIV INFECTION TIMELINE

New infection may cause flu-like symptoms and/or rash known as **acute HIV infection**; usually 2-4 weeks after infection for 1-2 weeks

Frequent symptoms

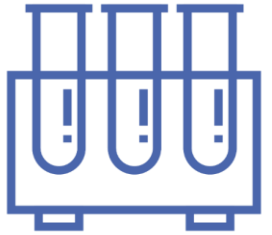
- fever
- muscle pain
- swollen lymph nodes
- sore throat
- rash
- GI (nausea, diarrhea, etc.)
- headache and fatigue



HIV TESTING

There are three ways that people can be tested for :

- **Standard HIV testing** Blood must be collected in a tube for testing and sent to the lab. More than one test is done on any reactive result, which makes this testing diagnostic.



- **Rapid point-of-care testing** can be done quickly and easily, collecting blood with a finger prick and providing results all in the same appointment. This is a screening test, used to screen the populations most at risk of HIV infection.

- **Self/home-based testing** can be done quickly and easily, collecting blood with a finger prick and providing results in a few minutes. This is a screening test, and would require lab-based confirmatory testing.

SUMMARY OF HIV TEST TYPES AND CHARACTERISTICS

Four main types of HIV tests are produced, sold and distributed under different brands and packaging

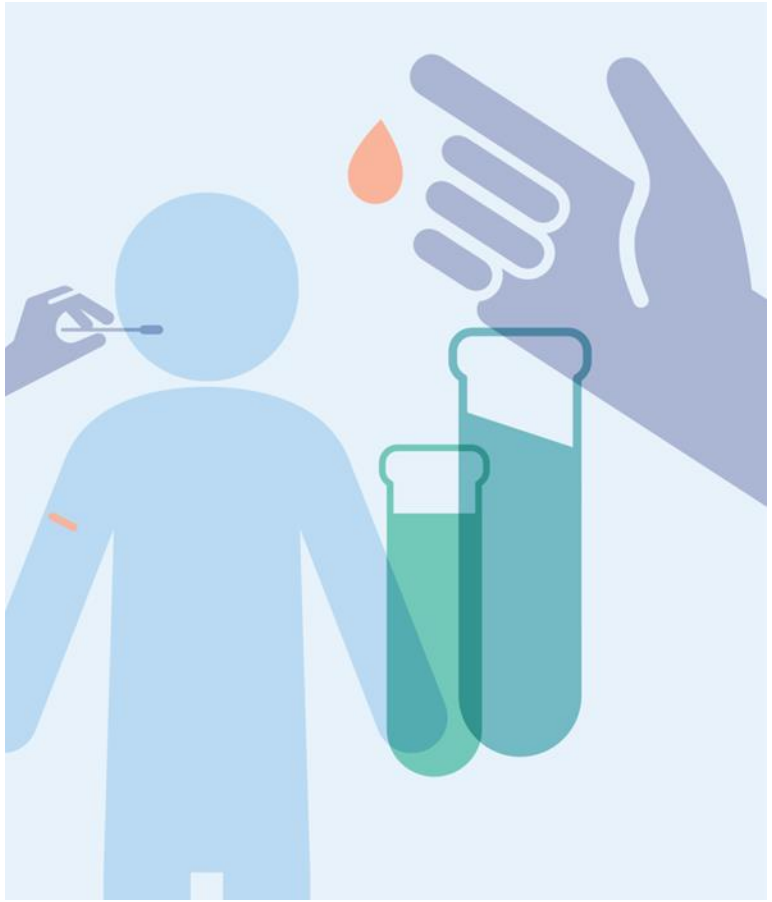
Different types of tests are used for different diagnostic and programmatic purposes

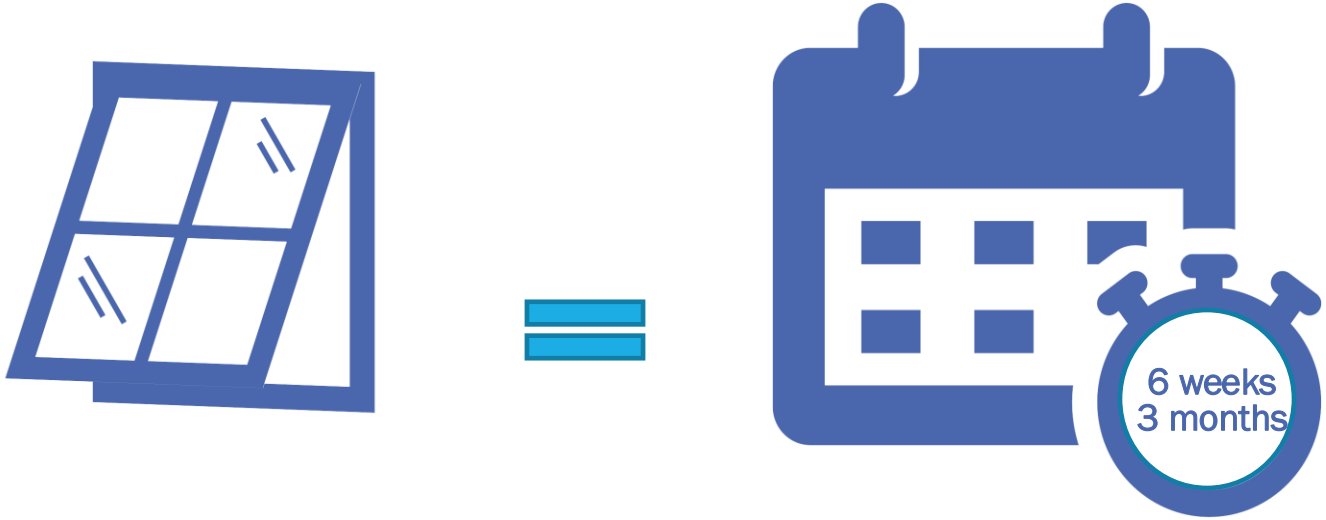
Programs have worked to expand use of rapid tests and self-testing to increase access to testing and to meet program goals

Nucleic Acid Testing (NAT) is not widely available for screening

Test Type	Sample/ Measures	How Soon to Detection	How Long to Result	Key Considerations
Nucleic Acid Test (NAT) (also called RNA or Viral Load)	Blood from vein HIV RNA	10 days after exposure	Days to weeks	• Not in routine use for screening • Sometimes used to monitor VL in PLWHIV taking ART • Requires laboratory capacity and skilled technicians • Expensive to perform and maintain • WHO recommends use to diagnose children $\leq$ 18 months of age
Enzyme Immunoassay Test (EIA)	Blood from vein or finger prick Antibodies and Antigens	14 days - 1 month after exposure	2.5 hours – days	• 4th generation RDT; quick and easy to use • Measures antibodies AND p24 viral proteins (antigens) that are present earlier than antibodies • More costly than 3rd generation • Not widely available in LMIC
Rapid Diagnostic Test (RDT)	Blood from vein, finger prick; oral sample with swab Antibodies	4 weeks - 3 months after exposure	Within 20 minutes	• Quick and easy to use • HIV- result considered definitive; HIV+ result needs confirmation. WHO recommends 2 confirmatory tests • Included in national HIV testing algorithms; WHO recommends for HIV diagnosis
Self- Test	Blood from finger prick or oral sample with swab Antibodies	3 months after exposure	Within 20 minutes	• Quick and easy to use; helps expand access and privacy • HIV+ result needs confirmation; WHO recommends 2 confirmatory tests • Use has expanded during COVID • WHO guidance evolving to expand access; some countries still slow to adopt

WHAT IS THE WINDOW PERIOD?





Date of possible exposure

6 weeks
99% of infections detected with lab-based testing – definitive results

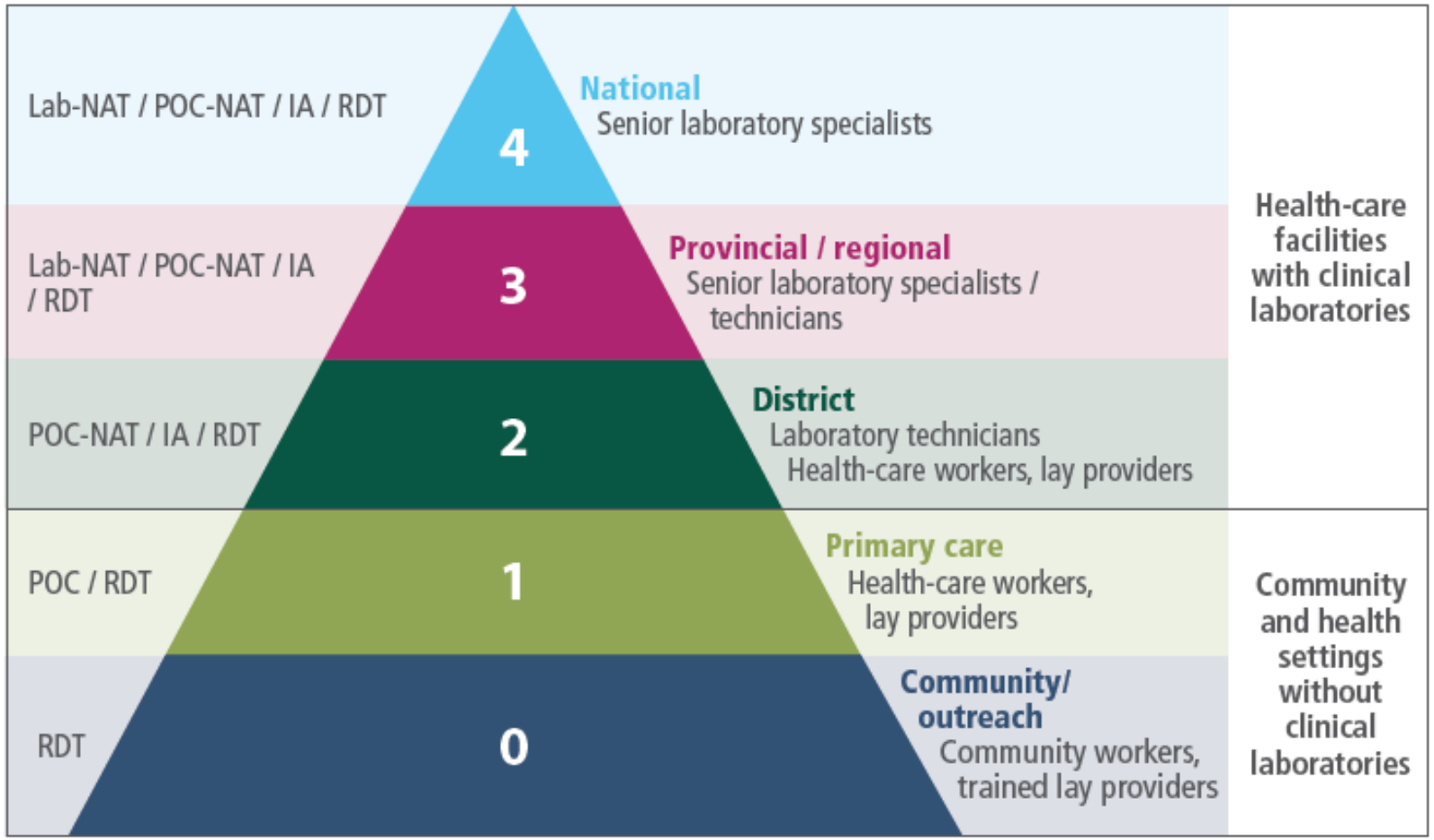
3 months
Over 99.6% of people with HIV test positive with rapid testing.

WHAT IS POINT-OF-CARE TESTING (POCT)?

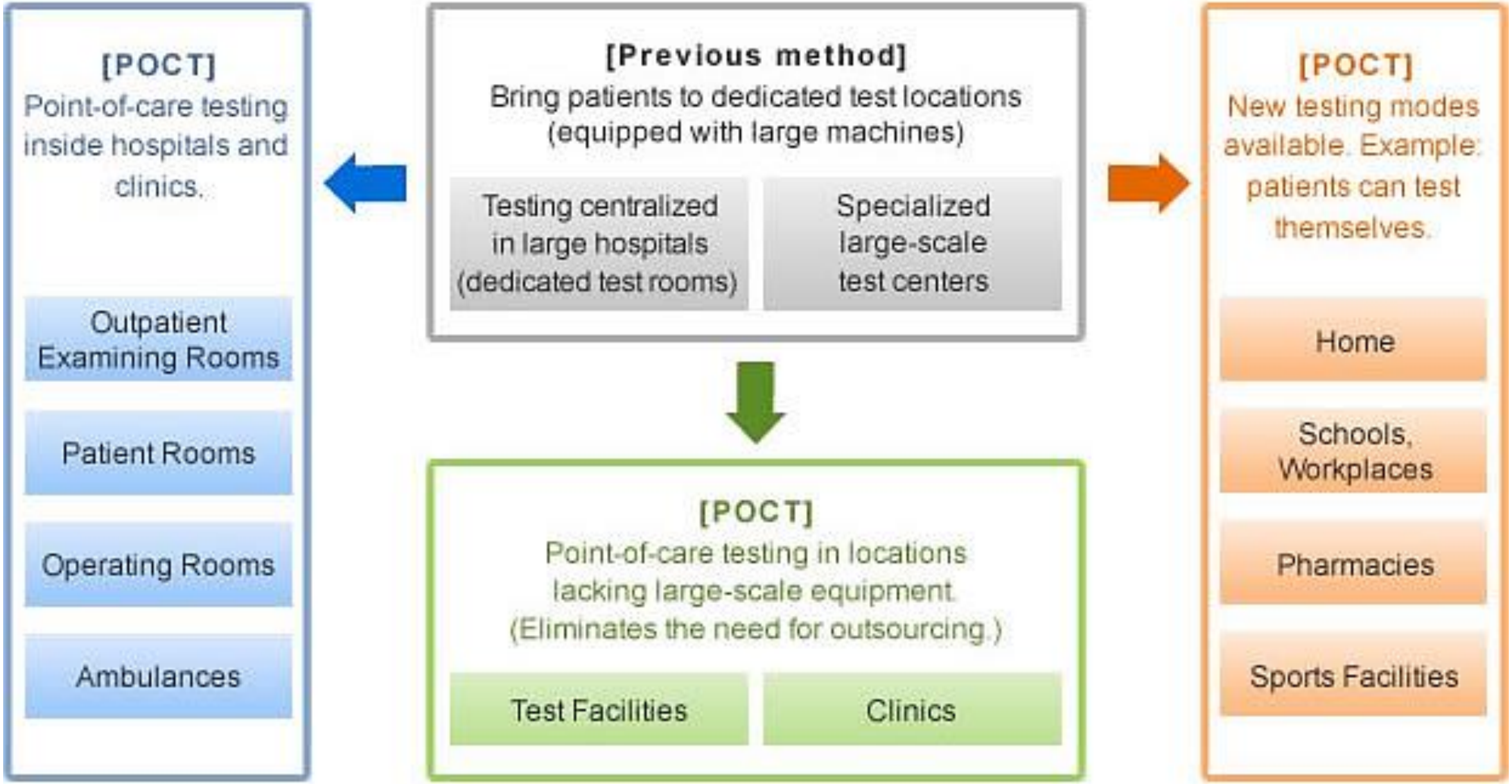
Point-of-care testing (POCT) has revolutionized the diagnosis of infectious diseases by providing rapid and accurate results at the patient's bedside.

Point-of-care testing of HIV refers to the practice undertaken **by healthcare professionals at the time of testing outside of a designated laboratory**. The standard methods of HIV testing, enzyme linked immunosorbent assay (ELISA) or Western blot with confirmatory testing, can take several days for result availability. A significant proportion of individuals who agree to undergo HIV serologic testing do not return to the HIV testing site to receive their test results**. POC testing of HIV attempts to address delay in detection of HIV status** by providing preliminary antibody results.

Point-of-care testing has been shown to reduce patient loss to follow-up and increase access to antiretroviral therapy.



IA: enzyme immunoassay; Lab-NAT: laboratory-based nucleic acid testing; POC-NAT: nucleic acid testing at point-of-care; RDT: rapid diagnostic test, including HIV self-testing.


[POCT]
Point-of-care testing inside hospitals and clinics.
Outpatient Examining Rooms
Patient Rooms
Operating Rooms
Ambulances
[Previous method]
Bring patients to dedicated test locations (equipped with large machines)
Testing centralized in large hospitals (dedicated test rooms)
Specialized large-scale test centers
[POCT]
Point-of-care testing in locations lacking large-scale equipment. (Eliminates the need for outsourcing.)
Test Facilities
Clinics
[POCT]
New testing modes available. Example: patients can test themselves.
Home
Schools, Workplaces
Pharmacies
Sports Facilities

Πίνακας 1: Ορισμοί παθήσεων ενδεικτικών λοίμωξης και συστάσεις για εξέταση HIV

1. Παθήσεις οι οποίες ορίζουν τη νόσο AIDS μεταξύ των ατόμων που ζουν με τη λοίμωξη HIV (PLHIV)*

Η εξέταση συνιστάται ιδιαίτερα:

Νεοπλάσματα:
- Καρκίνος του τραχήλου της μήτρας
- Λέμφωμα Non-Hodgkin
- Σάρκωμα Kaposi

Βακτηριακές λοιμώξεις
- Μυκοβακτήριο φυματίωσης, με πνευμονική ή εξωπνευμονική εντόπιση
- *Mycobacterium avium* σύμπλοκο (MAC) ή *Mycobacterium kansasii*, διάχυτο ή με εξωπνευμονική εντόπιση
- *Mycobacterium, άλλα είδη ή μη ταυτοποιημένα είδη, διάχυτα ή με εξωπνευμονική εντόπιση*
- Πνευμονία, υποτροπιάζουσα (2 ή περισσότερα επεισόδια σε 12 μήνες)
- Σηψαιμία από σαλμονέλλα, υποτροπιάζουσα

Ιογενείς λοιμώξεις
- Αμφιβληστροειδοπάθεια από μεγαλοκυτταροϊό
- Μεγαλοκυτταροϊός, άλλες εντοπίσεις (εκτός από ήπαρ, σπλήνα, αδένες)
- Απλός έρπης, έλκος(η) >1 μήνα/βρογχίτιδα/πνευμονίτιδα
- Προϊούσα πολυεστιακή λευκοεγκεφαλοπάθεια

Παρασιτικές λοιμώξεις
- Εγκεφαλική τοξοπλάσμωση
- Διάρροια από κρυπτοσπορίδίωση > 1 μήνα
- Ισοσπορίαση > 1 μήνα
- Άτυπη διάχυτη λεϊσμανίαση
- Επανενεργοποίηση Αμερικανικής τρυπανοσωμίασης (μηνιγγοεγκεφαλίτιδα ή μυοκαρδίτιδα)

Μυκητιασικές λοιμώξεις
- Πνευμονία από Πνευμονοκύστη carinii
- Καντιντίαση, οισοφαγική
- Καντιντίαση, βρογχική/τραχειακή/στους πνεύμονες
- Κρυπτοκόκκωση, εξωπνευμονική
- Ιστοπλάσμωση, διάχυτη/εξωπνευμονική
- Κοκκιδιομύκωση, διάχυτη/εξωπνευμονική
- Πενικιλλίωση, διάχυτη

* Βάσει του συστήματος ταξινόμησης του CDC και του ΠΟΥ

2α. Παθήσεις που σχετίζονται με επιπολασμό μη διαγνωσθείσας λοίμωξης HIV ≥0,1%

Η εξέταση συνιστάται ιδιαίτερα:
- Σεξουαλικώς μεταδιδόμενες λοιμώξεις
- Κακόηθες λέμφωμα
- Καρκίνος/δυσπλασία πρωκτού
- Δυσπλασία τραχήλου της μήτρας
- Έρπης ζωστήρας
- Ηπατίτιδα Β ή C (οξεία ή χρόνια)
- Ανεξήγητη λεμφαδενοπάθεια
- Νόσος τύπου μονοπυρήνωσης
- Πνευμονία της κοινότητας
- Ανεξήγητη λευκοπενία/θρομβοπενία που διαρκεί > 4 εβδομάδες
- Σμηγματορροϊκή δερματίτιδα/εξάνθημα
- Διηθητική πνευμονοκοκκική νόσος
- Ανεξήγητος πυρετός
- Καντινταιμία
- Σπλαγχνική λεϊσμανίαση
- Εγκυμοσύνη (συνέπειες για το έμβρυο)

2β. Άλλες παθήσεις που θεωρείται ότι είναι πιθανό να έχουν επιπολασμό μη διαγνωσθείσας λοίμωξης HIV > 0,1%

Πρόταση για εξέταση:
- Πρωτοπαθής καρκίνος του πνεύμονα
- Λεμφοκυτταρική μηνιγγίτιδα
- Τριχωτή λευκοπλακία στόματος
- Σοβαρού βαθμού ή άτυπη ψωρίαση
- Σύνδρομο Guillain–Barré
- Μονονευρίτιδα
- Υποφλοιώδης άνοια
- Νόσος τύπου πολλαπλής σκλήρυνσης
- Περιφερική νευροπάθεια
- Ανεξήγητη απώλεια βάρους
- Ανεξήγητη καντιντίαση στόματος
- Ανεξήγητη χρόνια διάρροια
- Ανεξήγητη χρόνια νεφρική ανεπάρκεια
- Ηπατίτιδα Α
- Καντιντίαση

3. Παθήσεις στις οποίες η μη αναγνώριση της παρουσίας της λοίμωξης HIV ενδέχεται να δημιουργήσει σημαντικές ανεπιθύμητες συνέπειες για την κλινική αντιμετώπιση του ατόμου.

Πρόταση για εξέταση:
- Παθήσεις στις οποίες απαιτείται επιθετική ανοσοκατασταλτική θεραπεία:
  - Καρκίνος
  - Μεταμόσχευση
  - Αυτοάνοση πάθηση που αντιμετωπίζεται με ανοσοκατασταλτική θεραπεία
- Πρωτοπαθής χωροκατακτητική βλάβη του εγκεφάλου.
- Ιδιοπαθής/Θρομβωτική θρομβοπενική πορφύρα

"I did not think HIV was a risk for me ... nor did my GP. So HIV testing was never really thought about until I was ill and in hospital."

Ben Cromarty

Stigma Considerations

- Misconceptions that HIV only affects some groups means that some people don't think they are at risk of HIV and so don't test.
- Healthcare staff sometimes don't think of HIV when patients present indicator conditions because of misconceptions about who is at risk of HIV.

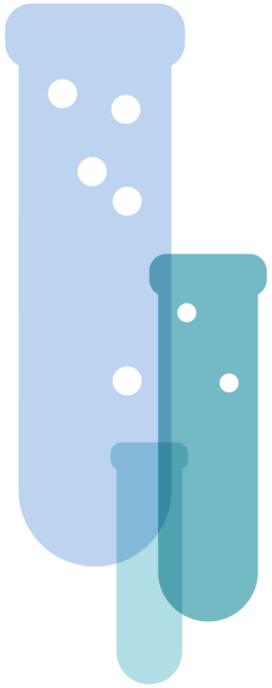
ACTION 4

Opt-out rather than opt-in HIV testing must become routine across healthcare settings, starting with areas of high prevalence.

Regular health checks allow you to be sure that you are in good health.

A health check can include testing to see if you have HIV.

When you attend a clinic or hospital **for any reason**, the doctor may offer you an HIV test.



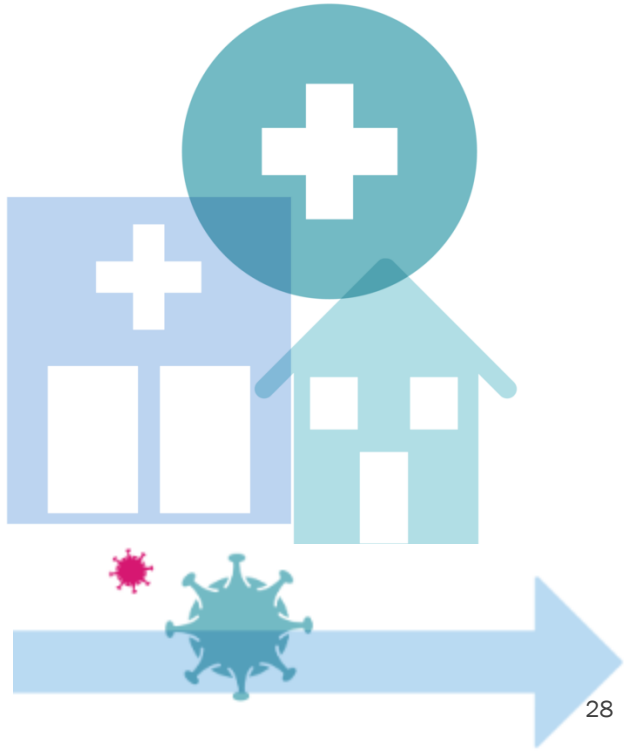
There are lots of places you can test for HIV:

At home, using a self-test

Sexual health clinics

GP surgeries

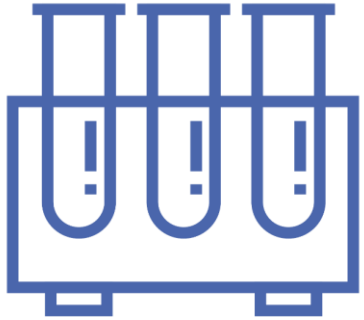
Community testing projects



CAN THE TEST BE WRONG (FALSE POSITIVE/REACTIVE)?

A single rapid test

The manufacturer suggests it could be falsely reactive 4 times in every 1000 tests



Standard Public Health Lab Testing

Public Health uses several tests to confirm every positive test. Evaluation suggests it could be falsely positive/reactive less than 3 times in every 10,000 tests

Test	Detects	Sensitivity	Specificity
OraQuick HIV-1/2 Rapid HIV-1/2 (OraSure)	IgG	99.1%	100%
HIV 1/2 STAT-PAK (Chembio)	IgG	99.5%	100%
Determine HIV Early Detect (Abbott)	IgG + IgM + p24	100%	99.4%
Determine HIV-1/2 (Abbott)	IgG + IgM + p24	100%	98.9%
Uni-Gold HIV (Trinity)	IgG + IgM	99.8%	99.9%
INSTI HIV-1/HIV-2 Antibody Test (bioLytical)	IgG + IgM	100%	99.7%
SD BIOLINE HIV-1/2 3.0 (Standard Diagnostics)	IgG + IgM	99.8%	99.8%
DPP® HIV 1/2 Assay (Chembio)	IgG	99.9%	99.9%

https://www.aidsmap.com/about-hiv/how-accurate-are-rapid-point-care-tests-hiv

CHARACTERISTICS OF AN IDEAL POINT-OF-CARE (POC) TEST

A consensus definition proposed for a provider-based POC test is a "test to support clinical decision making, which is performed: (i) by qualified staff nearby the patient; (ii) during or very close to the time of consultation; (iii) to help the patient and clinician to decide upon the most appropriate approach; and (iv) for which results should be known at the time of clinical decision making".

In order to meet this definition, regardless of its format, a POC test should have certain characteristics. In 2003, the acronym, "**ASSURED**", was coined to describe the ideal criteria for a POC test to be used at all levels of a health-care system.

In recent years, two additional criteria for an ideal POC test have been proposed: real-time connectivity (R) and ease of specimen collection (E). This has led to the definition of a new acronym, the "**REASSURED**" criteria.

Box 3.1: The REASSURED criteria for the ideal point-of-care (POC) diagnostic test

R = Real-time connectivity
E = Ease of specimen collection
A = Affordable
S = Sensitive
S = Specific
U = User-friendly (simple to perform in a few steps with minimal training)
R = Robust and rapid (can be stored at room temperature and results available in < 30 minutes)
E = Equipment-free or minimal equipment that can be solar- or battery-powered
D = Deliverable to those who need them

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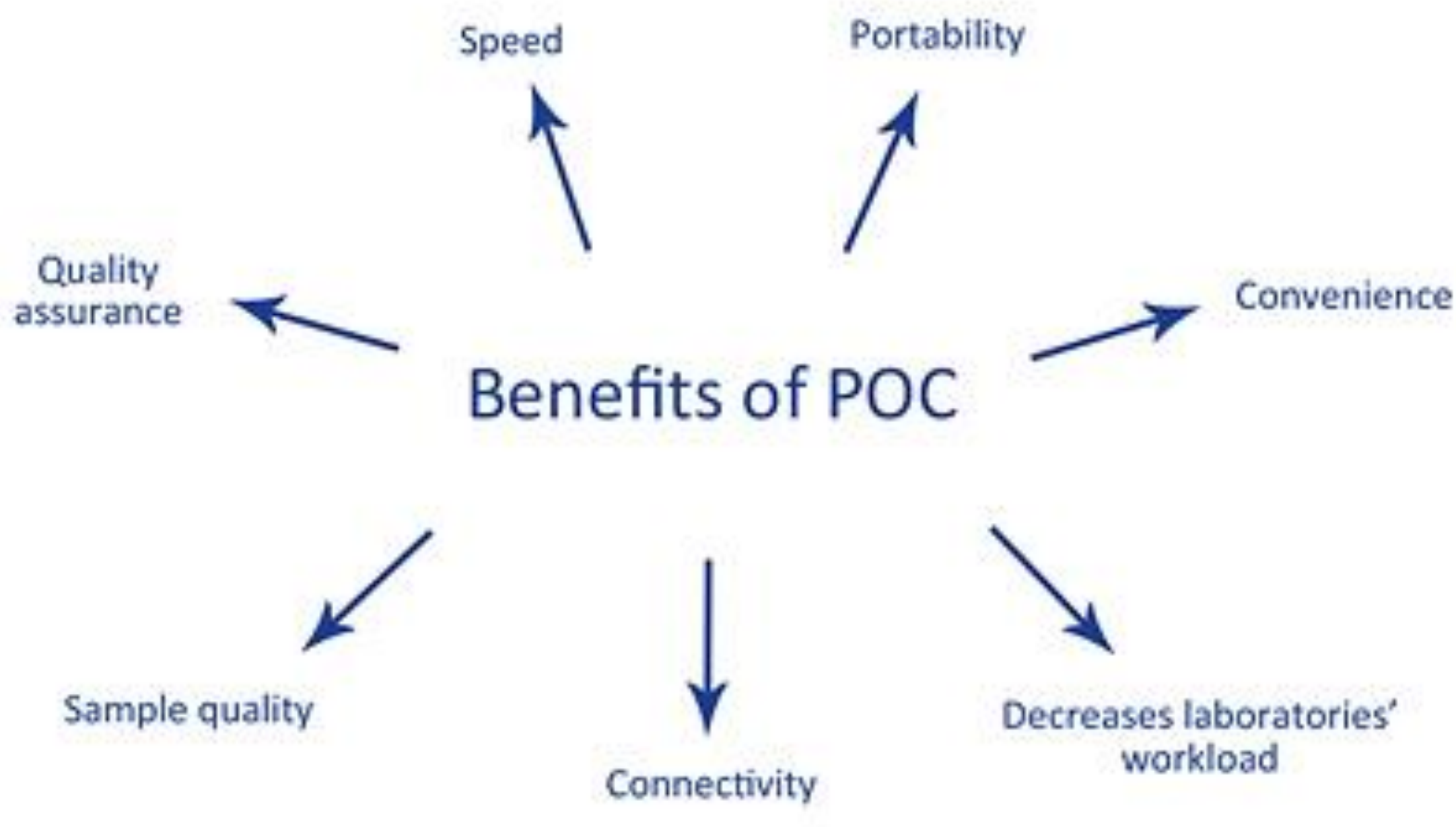
Speed
Portability
Quality assurance
Convenience
Benefits of POC
Sample quality
Connectivity
Decreases laboratories' workload

ADVANTAGES OF POCT IN INFECTIOUS DISEASE DIAGNOSIS

POCT devices are portable, user-friendly, and often handheld, making them suitable for use in various healthcare settings, including hospitals, clinics, physician offices, and even at home. These devices are designed to be operated by non-laboratory personnel, such as nurses or physicians, without the need for specialized training.

Key features of POCT include:

1. **Speed**: POCT provides rapid results, typically within minutes, allowing for immediate decision-making and timely intervention.
2. **Convenience**: POCT can be performed at the point of care, eliminating the need for sample transportation and reducing the time patients have to wait for results.
3. **Accuracy**: POCT devices are designed to deliver accurate and reliable results, ensuring the quality of patient care.
4. **Portability**: POCT devices are compact and portable, allowing for easy transport and use in various healthcare settings.

Benefits of POCT include:

1. **Improved patient outcomes**: Rapid diagnosis and immediate treatment decisions based on POCT results can lead to improved patient outcomes and better disease management.
2. **Enhanced patient satisfaction**: POCT reduces waiting time and provides patients with faster results, leading to increased satisfaction and convenience.
3. **Cost-effectiveness**: POCT can help reduce healthcare costs by minimizing the need for additional tests, hospital admissions, and unnecessary treatments.
4. **Point-of-care monitoring**: POCT enables frequent monitoring of patients' conditions, allowing for timely adjustments in treatment plans.

In summary, POCT is a valuable diagnostic tool that brings testing closer to the patient, providing rapid results, convenience, and improved patient outcomes. Its key features and benefits make it an **essential component of modern healthcare delivery AND a valuable tool in the fight against infectious diseases**.

Where POC tests that meet the ASSURED criteria have been implemented, they have demonstrably improved patient management and public health. The individual criteria are of varying importance, depending on the context of implementation. These benefits include:

- **reduced time to notification of results**: POC test enables patients to receive test results faster, including during the initial clinical visit;1
- **faster (and appropriate) treatment delivery**: receiving test results in an initial clinical visit means patients can be treated immediately, thus reducing loss to follow-up; asymptomatic infections can be treated; and presumptive treatment can be avoided with detected specific causative organism treated, thus reducing overtreatment with antibiotics;
- **the opportunity for immediate patient counselling to be initiated**: individuals with positive test results can receive appropriate counselling that is tailored to the specific infection and the patient's situation;
- **improved partner treatment/tracing and reduction of transmission**; having a specific diagnosis at the time of the initial visit can facilitate partner notification discussions, leading to improved partner treatment;
- **reduced onward transmission and progression of disease**; faster and appropriate treatment can help break the chain of transmission between partners and prevent disease progression;
- **improved patient acceptability**: patients and health workers find POC testing clinical pathways acceptable, and the ability to know the test result at the initial clinic visit desirable; and
- **cost-effectiveness**; the ability to diagnose and treat the patient in the same clinic visit avoids the need for a second visit for treatment and partner notification discussions, saving both the patient and the health worker time and money; and reducing transmission, which in turn reduces the number of individuals needing of diagnosis and treatment, and successful treatment of infections saves the costs associated with managing the reproductive health sequelae to which the infection would have progressed.

The increased focus of manufacturers on developing STI POC tests in recent years has resulted in a reasonably strong pipeline for platforms that are suitable, as evidenced by the current landscape of STI POC diagnostics. However, continued support for pipeline technologies is required. This includes technical guidance, financial support, ongoing advocacy and political will.

Box 3.2: WHO prequalified (PQ) HIV rapid diagnostic tests (RDTs)

PQ for professional use only (to be performed by health workers):

ABON HIV 1/2/O Tri-Line HIV Rapid Test (ABON Biopharm [Hangzhou] Co. Ltd, China)
Bioline HIV-1/2 3.0 (Abbott Diagnostics, USA)
Determine HIV Early Detect (Abbott Diagnostics, USA)
Determine HIV-1/2 (Abbott Diagnostics, USA)
Diagnostic kit for HIV (1+2) antibody (colloidal gold) v2 (Shanghai Kehua Bio-Engineering, China)
DPP HIV-1/2 Assay (Chembio Diagnostic Systems, USA)
First Response HIV 1-2-O Card Test v2.0 (Premier Medical, India)
Geenius HIV 1/2 Confirmatory Assay (Bio-Rad Laboratories, France)
Genie Fast HIV 1/2 (Bio-Rad Laboratories, France)
HIV 1/2 STAT-PAK (Chembio Diagnostics, USA)
HIV 1/2 STAT-PAK Dipstick (Chembio Diagnostics, USA)
INSTI HIV-1/HIV-2 Antibody Test (bioLytical Laboratories, Canada)
MERISCREEN HIV 1-2 WB (Meril Diagnostics Pvt. Ltd., India)
ONE STEP Anti-HIV (1&2) Test (INTEC Products, Inc., China)
One Step HIV 1/2 Whole Blood/Serum/Plasma Test (Guangzhou Wondfo Biotech Co., China)
OraQuick HIV 1/2 Rapid Antibody Test (OraSure Technologies, Inc., USA)
Rapid Test for Antibody to HIV (Colloidal Gold Device) (Beijing Wantai Biological Pharmacy Enterprise Co. Ltd, China)
STANDARD Q HIV 1/2 Ab 3-Line Test (SD Biosensor, Inc., Republic of Korea)
SURE CHECK HIV 1/2 Assay (Chembio Diagnostics, USA)
TrinScreen HIV (Trinity Biotech Manufacturing, Ireland)
Uni-Gold HIV Test (Trinity Biotech Manufacturing, Ireland)

PQ for self-testing (using a self-collected specimen):

Check-NOW HIV (Abbott Diagnostics, USA)
INSTI HIV Self Test (bioLytical Laboratories, Canada)
Mylan HIV Self Test (Atomo Diagnostics Pvt. Ltd, Australia)
OraQuick HIV Self Test (OraSure Technologies, Inc., USA)
SURE CHECK (Chembio Diagnostics, USA)
Wondfo HIV Self-Test (Guangzhou Wondfo Biotech Co., China)

In the last 15 years, HIV diagnosis has moved increasingly from laboratory to non-laboratory settings as a result of availability of dozens of HIV rapid tests. Worldwide, **more than 100 million people were tested with HIV rapid tests in 2020 alone.**

C. Geenius HIV-1/2 rapid supplementary test that include various HIV-1 or HIV-2 recombinant or peptide antigens to detect specific antibodies

Source: Bharat Parekh, Larry Westerman, Lara Vojnov and Chunfu Yang.

Table 3.3: Performance of four commercially available combined HIV/syphilis tests

RDT (manufacturer)	Sample	Parameters	Performance (95% CI) HIV antibody	Performance (95% CI) TP antibody
DPP HIV-Syphilis Assay (Chembio Diagnostics Systems, Inc.)	Serum/plasma	Sensitivity	98.9% (93.6–99.9%)	95.3% (87.9–98.5%)
			99.6% (98.8–99.9%)	97.0% (95.5–98.0%)
			100% (98.2–100%)	86.5% (81–90.9%)
		Specificity	98.1% (88.6–99.9%)	100% (92.9–100%)
			97.9% (96.7–98.7%)	99.6% (98.9–99.9%)
			97.5% (94.3–99.2%)	100% (98.2–100%)
INSTI Multiplex HIV-1/ HIV-2/Syphilis Antibody Test (bioLytical Laboratories, Inc.)	Serum/plasma	Sensitivity	NA	NA
			NA	NA
			99.5% (97.2–100%)	81.0% (74.9–86.2%)
		Specificity	NA	NA
			NA	NA
			93.5% (89.1–96.5%)	99.0% (96.4–99.9%)
Multiplo Rapid TP/HIV Antibody Test (MedMira, Inc.)	Serum/plasma	Sensitivity	97.9% (92.0–99.6%)	94.1% (86.3–97.8%)
			99.5% (99.4–99.8%)	94.2% (92.3–95.7%)
			99.5% (97.2–100%)	73.5% (66.8–79.5%)
		Specificity	94.2% (83.1–98.5%)	96.9% (88.2–99.5%)
			98.3% (97.2–99.0%)	99.1% (98.2–99.6%)
			99.5% (97.2–100%)	99.5% (97.2–100%)
SD Bioline HIV/Syphilis Duo Rapid Test (Standard Diagnostics/ Abbott)	Serum/plasma	Sensitivity	97.9% (92.0–99.6%)	93.0% (84.8–97.1%)
			99.0% (98.8–99.9%)	99.6% (95.0–97.7%)
			100% (98.2–100%)	87.0% (81.5–91.3%)
		Specificity	100% (91.5–100%)	100% (92.9–100%)
			99.0% (98.0–99.5%)	99.1% (98.2–99.6%)
			99.5% (97.2–100%)	99.5% (97.2–100%)

CI: confidence interval; NA: not available; RDT: rapid diagnostic test; TP: treponemal.

There is a significant need for combination tests to screen for syphilis and HIV for certain target populations, including men who have sex with men (MSM), sex workers and pregnant women. Perhaps the most urgent need is for a dual test to help eliminate mother-to-child transmission (MTCT) of HIV and syphilis, which is a significant cause of death in infants and young children globally each year.

WHO recommends the use of dual HIV/syphilis RDTs at the POC as the first test to screen pregnant women as part of antenatal care .

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FUTURE USE OF POINT-OF-CARE (POC) TESTING IN CLINICAL CARE

There are now at least 10 commercially available integrated NAAT-based platforms for near-patient testing for C. trachomatis and N. gonorrhoeae (separately or combined), as well as T. vaginalis, M. genitalium, HSV-1 and -2 and HIV. A good number of these are FDA and/or CE-IVD marked. More such tests for use at POC are in the pipeline. Collectively, these platforms have the potential to improve STI testing, thereby enhancing the public health response to the STI global epidemic.

Table 3.6: Commercially available point-of-care (POC) or near-POC platforms for STIs

Platform (manufacturer)	System type; setting	Sample preparation; TAT	Amplification technology	Detection technology	Fluidic handling	Available assays regulatory status	Pipeline assays
ARIES and ARIES M1 (Luminex)	Multiplex; Level 2	Integrated intest cassette; 2 hours	Real-time PCR	Real-time fluorescence	Rotary valves	HSV 1&2 (CE-IVD/FDA)	NA
EasyNAT (Ustar Biotechnologies)	Multiplex; Level 2	Integrated; ~50 minutes	iNAAT – CPA	Visual read out in device integrated lateral flow strip	Pressure-driven microfluidics	CT/NG; NG; TV; MG; HPV; HSV 1&2 (all CE-IVD)	NA
GeneXpert (Cepheid)	Multiplex; Level 2	Integrated in cartridge; 60–90 minutes depending on assay	Real time PCR	Real-time fluorescence	Pressure-driven microfluidics (rotary valves)	CT/NG and TV (CE-IVD/FDA); HIV and HIV VL (CE-IVD)	NA
HGSwift (Hibergene Diagnostics)	Multiplex; Level 2	Not integrated; less than 60minutes	Isothermal LAMP	Fluorometric	None	CT/NG; MG; HSV 1&2 (All CE-IVD)	NA
m-PIMA (Abbott)	Multiplex; Level 2	Integrated in cartridge; 60–70 minutes	Real-time PCR	Real-time fluorescence based on competitive reporter probe hybridization integrated microarray	Pressure-driven microfluidics	HIV VL (CE-IVD)	NA
SAMBA II (Diagnostics for the Real World)	Multiplex; Level 2	Integrated in assay module; ~2 hours	iNAAT – NASBA	Fluorescence	NA	HIV VL (CE-IVD)	CT/NG

Table 3.6 (continued): Commercially available point-of-care (POC) or near-POC platforms for STIs

Platform (manufacturer)	System type; setting	Sample preparation; TAT	Amplification technology	Detection technology	Fluidic handling	Available assays regulatory status	Pipeline assays
Solana (QuidelOrtho)	Multiplex; Level 2	Not integrated; 35–70 minutes depending on assay	iNAAT – HDA	Fluorescence; probe-based	None	TV and HSV 1&2 (CE-IVD/FDA)	NA
Truelab RT micro PCR (Molbio)	Multiplex; Level 2	Not integrated; 35–45 minutes, depending on assay	Real time PCR	Real-time fluorescence	Pressure-driven macrofluidics	CT; NG; CT/NG; TV; HPV; HIV VL (all CE-IVD)	NA
io Diagnostic System (binx health, inc.)	Multiplex; Level 1, possible	Integrated in cartridge; ~30 minutes	Ultra-rapid PCR	Electrochemical	Pressure-driven macrofluidics	CT/NG (CE-IVD/FDA)	TV; MG
Sexual Health Click Test (Visby Medical)	Multiplex; Level 1	Integrated in device; ~30 minutes	Real time PCR	Electrochemical	Pressure-driven microfluidics (rotary valves)	CT/NG/TV (FDA)	NA

CE-IVD: Conformité Européene (CE)-marked in vitro diagnostic medical device; CPA: cross priming amplification; CT: *Chlamydia trachomatis*; FDA: U.S. Food and Drug Administration; HPV: human papillomavirus; HSV: herpes simplex virus; iNAAT: isothermal nucleic acid amplification test; LAMP: loop-mediated amplification; MG: *Mycoplasma genitalium*; NA: not available; NASBA: nucleic acid sequence-based amplification; NG: *Neisseria gonorrhoeae*; PCR: polymerase chain reaction; TAT: turnaround time; TV: *Trichomonas vaginalis*; VL: viral load.

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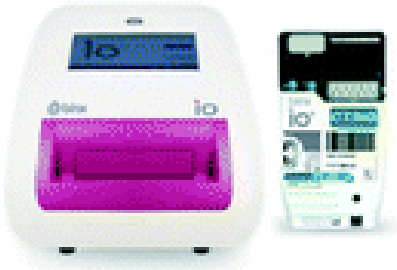
Platform	(A)  GeneXpert	(B)  SAMBA II	(C)  *io*	(D)  Sexual Health Test	(E)  Solana
Company	Cepheid	DRW	binx health	Visby Medical	Quidel
Assay	CT, CT/NG, TV, HIV	HIV	CT, CT/NG	CT/NG/TV	TV
Turnaround Time	< 120 min[54] < 63 min[55]	< 120 min	30 min	30 min	< 40 min
Sample Type	Vaginal Swab[54,55] Endocervical Swab[54,55] Urine[54,55] Blood[56] Dried Blood Spot[56]	Blood[59]	Vaginal Swab[61,62] Urine (Male)[62]	Vaginal Swab[64]	Vaginal Swab[66] Urine[66]
Sensitivity	Female: 97.4 – 98.7% (CT)[54] 95.6 – 100% (NG)[54] 99.5 – 100% (TV)[55] Male: 97.5% (CT)[54] 98.0% (NG)[54] 97.2% (TV)[55]	97.3%[59]	96.1% (CT)[61] Female: 96.1% (CT)[62] 100% (NG)[62] Male: 92.5% (CT)[62] 97.3% (NG)[62]	97.6% (CT)[64] 97.2% (NG)[64] 99.2% (TV)[64]	Swab, Asymptomatic: 100%[66] Swab, Symptomatic: 98.6%[66] Urine, Asymptomatic: 98.0%[66] Urine, Symptomatic: 92.9%[66]
Approval	FDA & CE	CE	FDA & CE	FDA	FDA & CE

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From the journal:
Lab on a Chip

Bridging the gap between development of point-of-care nucleic acid testing and patient care for sexually transmitted infections

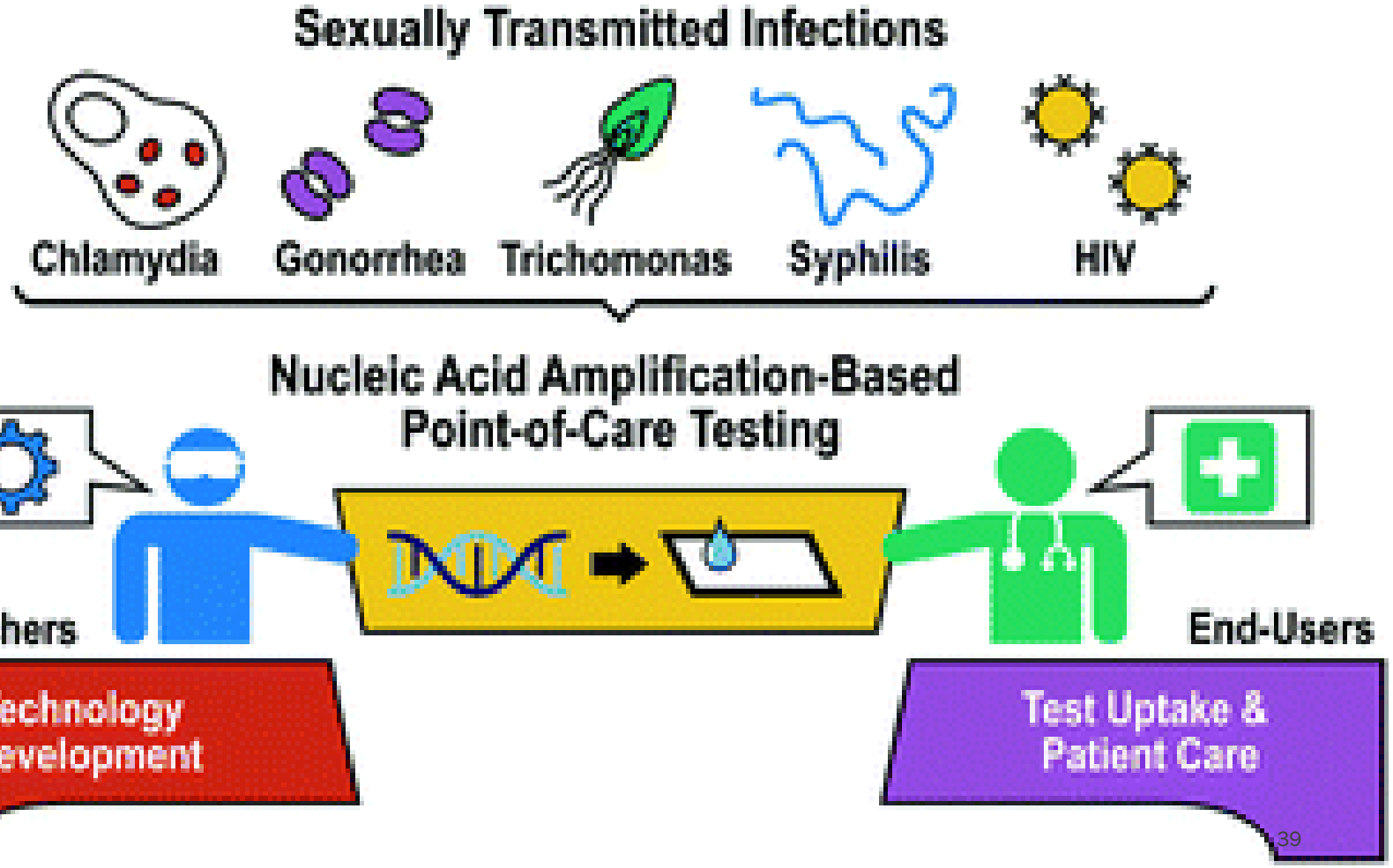
Check for updates

Kuangwen Hsieh, †[a] Johan H. Melendez, †[b] Charlotte A. Gaydos [b] and Tza-Huei Wang [*acd]

Author affiliations

Abstract

The incidence rates of sexually transmitted infections (STIs), including the four major curable STIs – chlamydia, gonorrhea, trichomoniasis and, syphilis – continue to increase globally, causing medical cost burden and morbidity especially in low and middle-income countries (LMIC). There have seen significant advances in diagnostic testing, but commercial antigen-based point-of-care tests (POCTs) are often insufficiently sensitive and specific, while near-point-of-care (POC) instruments that can perform sensitive and specific nucleic acid amplification tests (NAATs) are technically complex and expensive, especially for LMIC. Thus, there remains a critical need for NAAT-based STI POCTs that can improve diagnosis and curb the ongoing epidemic. Unfortunately, the development of such POCTs has been challenging due to the gap between researchers developing new technologies and healthcare providers using these technologies. This review aims to bridge this gap. We first present a short introduction of the four major STIs, followed by a discussion on the current landscape of commercial near-POC instruments for the detection of these STIs. We present relevant research toward addressing the gaps in developing NAAT-based STI POCT technologies and supplement this discussion with technologies for HIV and other infectious diseases, which may be adapted for STIs. Additionally, as case studies, we highlight the developmental trajectory of two different POCT technologies, including one approved by the United States Food and Drug Administration (FDA). Finally, we offer our perspectives on future development of NAAT-based STI POCT technologies.



VL technologies/platforms
High-throughput laboratory platforms for VL

A sustainable viral load network improves: patient outcome, treatment adherence, and viral load suppression.

cobas® 6800 system

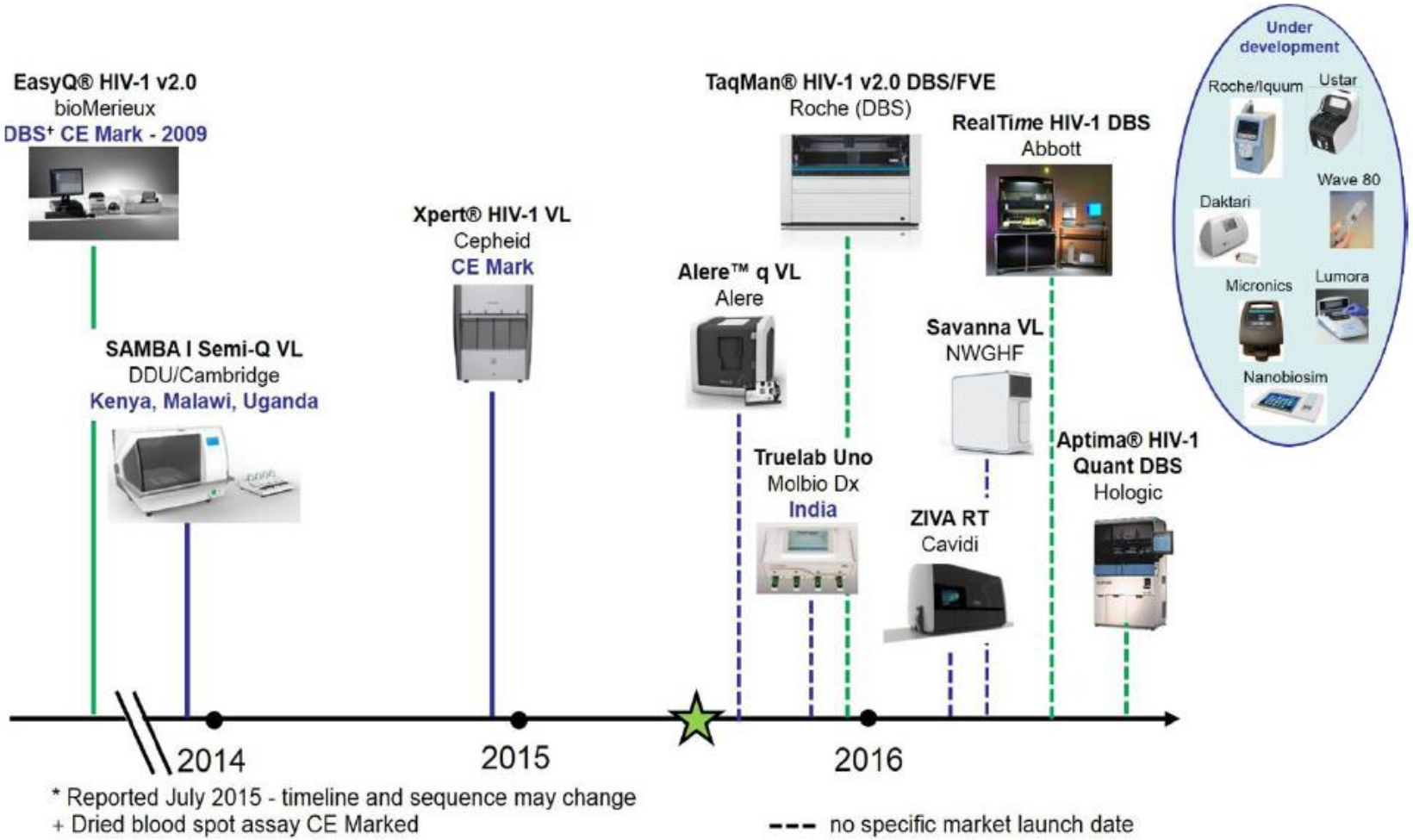
cobas® 8800 system

Figure 51. VERSANT® kPCR Molecular System

Source: Photo courtesy of Siemens Healthcare Diagnostics Inc. ©

Figure 60. QIAsymphony™ RGQ system

Appendix 4: Point-of-care (POC) viral load (VL) technologies in the pipeline



■ Τα υπάρχοντα μοριακά tests εμφανίζουν περιορισμούς που σχετίζονται με το εξειδικευμένο προσωπικό, τη διάρκεια εξέτασης και το υψηλό κόστος.

■ Διεξάγεται ερευνητική προσπάθεια για να γίνουν πιο απλά και κατάλληλα για point of care.

EID technologies/platforms
High-throughput platforms for EID

Table 1. Technical specifications for commercial tests for EID

Assay name	COBAS® TaqMan® HIV-1 Qualitative Test v2.0	Abbott RealTime Qualitative HIV-1 CE-IVD
Type of assay	Real-time PCR, qualitative identification of HIV-1 DNA and RNA (total nucleic acid, TNA)	Real-time PCR, qualitative detection of HIV-1
HIV subtypes amplified	HIV-1 Group M, subtypes A through H; HIV-1 Group N, HIV-1 Group O	HIV-1 Group M subtypes A, B, C, D, CRF01-AE, F, CRF02-AG, G, subtype H and Group N, and Group O
Intended use	HIV-1 infant diagnosis; adult aid in diagnosis	Aid in the diagnosis of HIV-1 infection in paediatric and adult subjects
Specimen type	1.0 mL plasma 70 µl DBS; 1 spot/test	200 µL plasma 0.1 mL for DBS (2 spots 50 µL each)
Limit of detection	Plasma: 16.5 cp/mL DBS: 222 cp/mL	110 cp/mL for plasma 2500 cp/mL for DBS
Sensitivity	N/A	100% for plasma 100% for DBS
Specificity	100%	100% for plasma 100% for DBS

Figure 28. *m*2000*sp* instrument

Figure 29. *m*24*sp* instrument

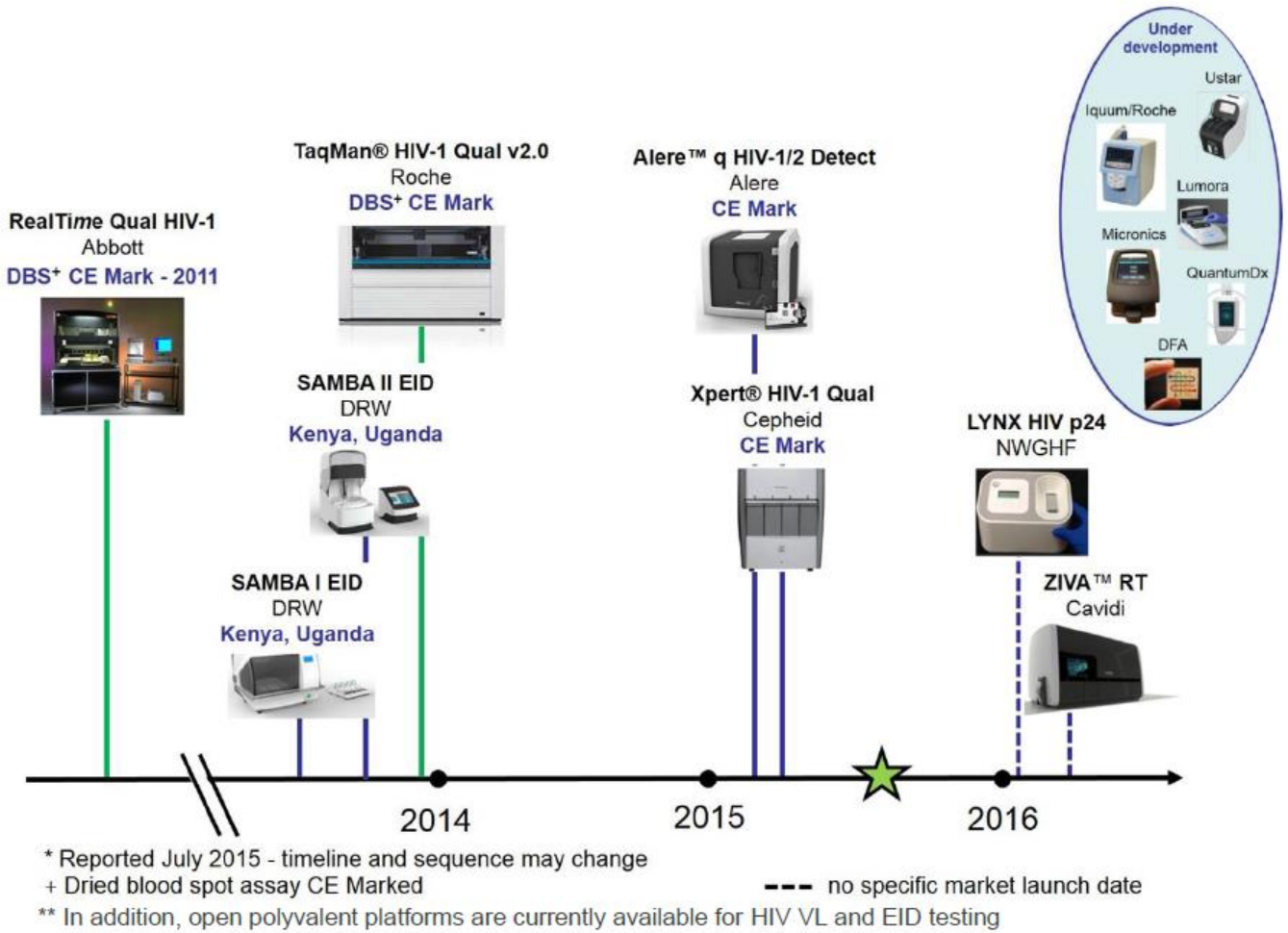
30. *m*2000*rt* instrument

Figure 25. COBAS® AmpliPrep® system

Figure 26. COBAS® TaqMan® 96

Figure 27. COBAS® TaqMan® 48

Appendix 3: Early infant diagnosis (EID) technologies in the pipeline



- Νέες πλατφόρμες έγκαιρης διάγνωσης νεογνών (on-the-spot)
- *POC platform για ταυτόχρονη* ανίχνευση και μέτρηση ιικού φορτίου θα εξυπηρετεί και τη διάγνωση της HIV πρωτολοίμωξης

Figure 63. GeneXpert® 4-4 module instrument (left) and Xpert® HIV-1 Viral Load cartridge (right)

Figure 64. Xpert® HIV-1 Viral Load workflow

The Cepheid Xpert® HIV-1 Viral Load test received CE-IVD clearance in December 2014.

Figure 65. Alere™ q Analyser

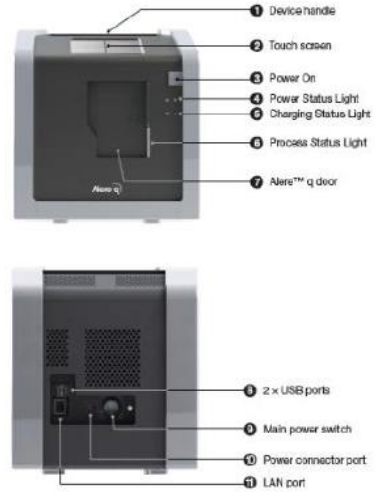


Figure 69. EOSCAPE-1 analyzer and EOSCAPE-HIV™ cartridge

Figure 68. Savanna Platform for HIV Viral Load

Figure 67. cobas® Liat™ test procedure

SAMPLE

Add your patient sample to the **cobas**® Liat assay tube with provided transfer pipette.

SCAN

Scan assay tube using built-in barcode reader.

START

Insert assay tube into the **cobas**® Liat Analyzer.

Results are generated in 20 minutes or less.

Truelab™ Real Time micro PCR System (Molbio Diagnostics Pvt Ltd)

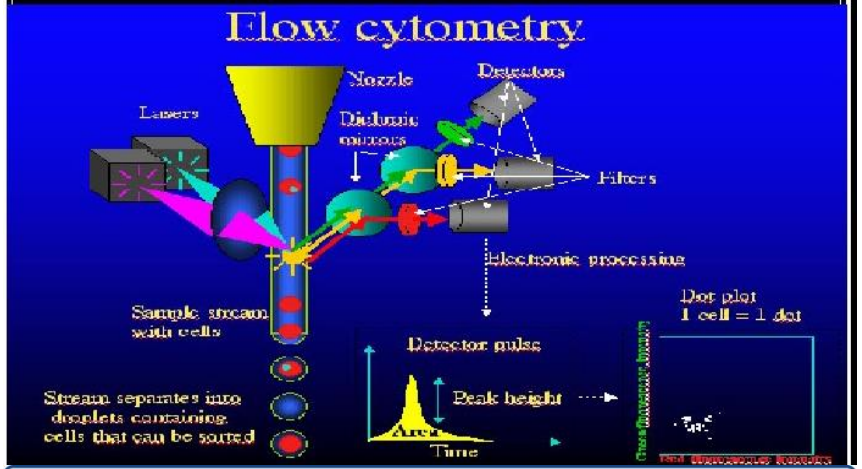
Figure 70. Truelab™ Uno Real Time micro PCR System

Συλλογή δείγματος (αίμα,ορός ή πλάσμα)
Trueprep™ MAG Sample Prep Device & Trueprep™ Mag sample prep kits
20–25 min. ανά δείγμα

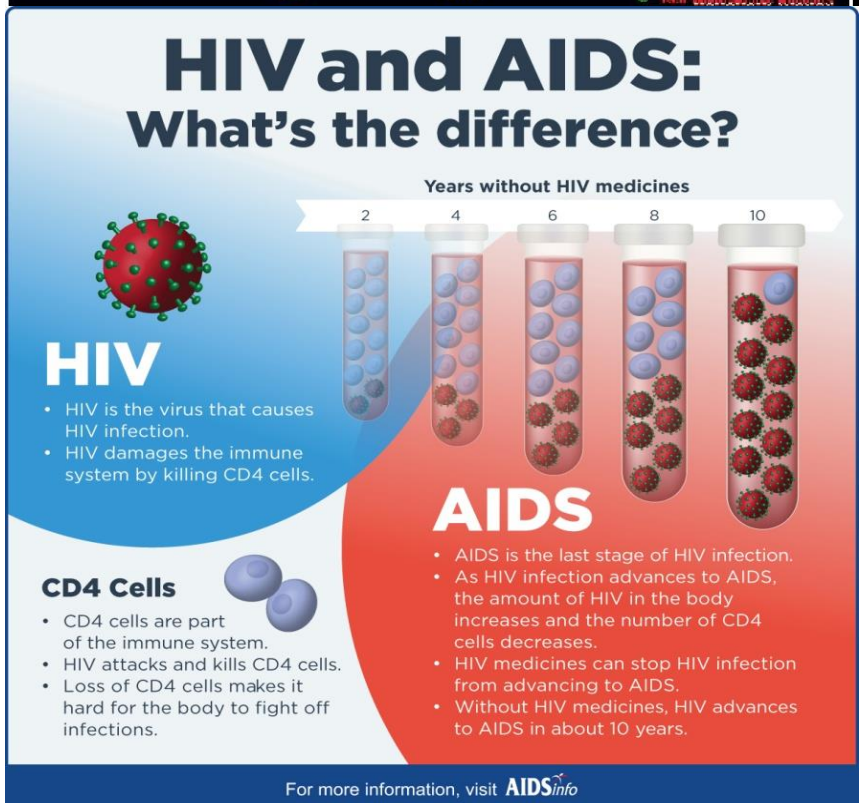
Figure 73. Ustar RT CPA HIV-1 viral load system

Figure 74. Gene-RADAR® Platform

Flowcytometry for Estimation of CD 4 lymphocytes



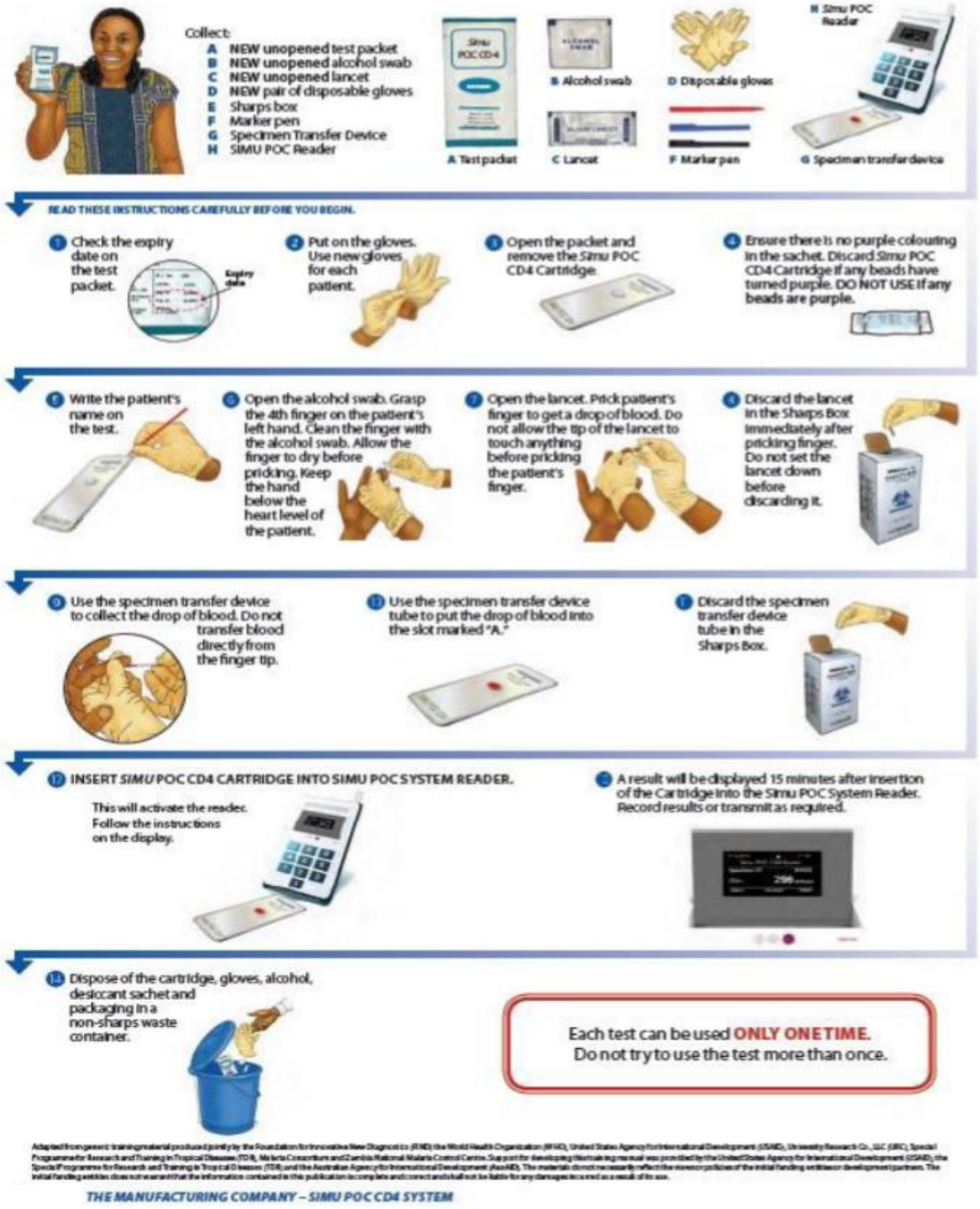
HIV and AIDS:
What's the difference?



C. Example of a job aid for HIV point-of-care CD4 testing

How To Do the *Simu* POC CD4 System

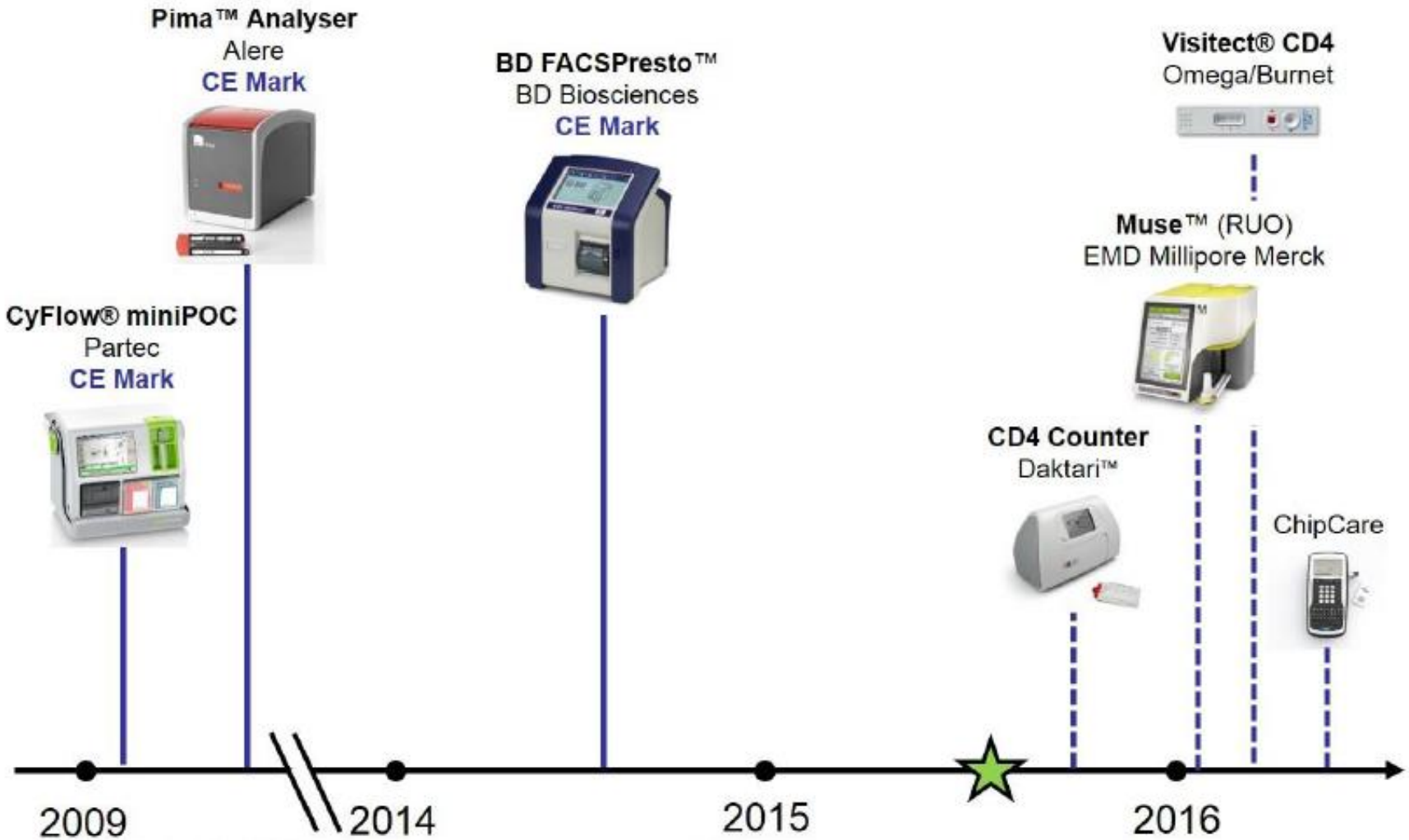
for the enumeration of CD4 cells in whole blood



Adapted from generic training material produced jointly by the Foundation for Innovative New Diagnostics (FIND), the World Health Organization (WHO), United States Agency for International Development (USAID), University Research Co., LLC (URC), Special Programme for Research and Training in Tropical Diseases (TDR), Malaria Consortium and Zambia National Malaria Control Centre. Support for developing this training manual was provided by the United States Agency for International Development (USAID), the Special Programme for Research and Training in Tropical Diseases (TDR), and the Australian Agency for International Development (AusAID). The materials do not necessarily reflect the views or policies of the Initial Funding entities or Bill & Melinda Gates Foundation partners. The Initial Funding entities does not warrant that the information contained in this publication is complete and correct and shall not be liable for any damages incurred as a result of its use.

THE MANUFACTURING COMPANY – SIMU POC CD4 SYSTEM

Appendix 2: Point-of-care (POC) CD4 technologies in the pipeline



The ChipCare Corporation initial test – absolute CD4 count – will stage HIV-positive patients for treatment. Research on blood analyte tests for neglected tropical diseases, sexually transmitted infections (STIs) and vaccination coverage is ongoing.

Figure 24. ChipCare hand-held platform

Figure 21. Visitect® CD4 lateral flow strip

Figure 23. Daktari™ CD4 Counter

Figure 22. Visitect® CD4 reader

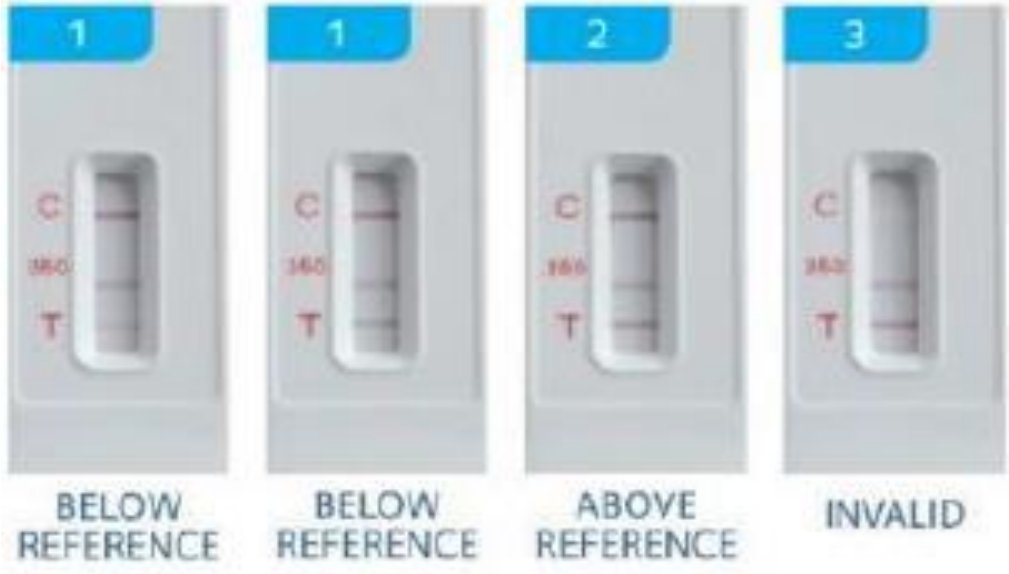


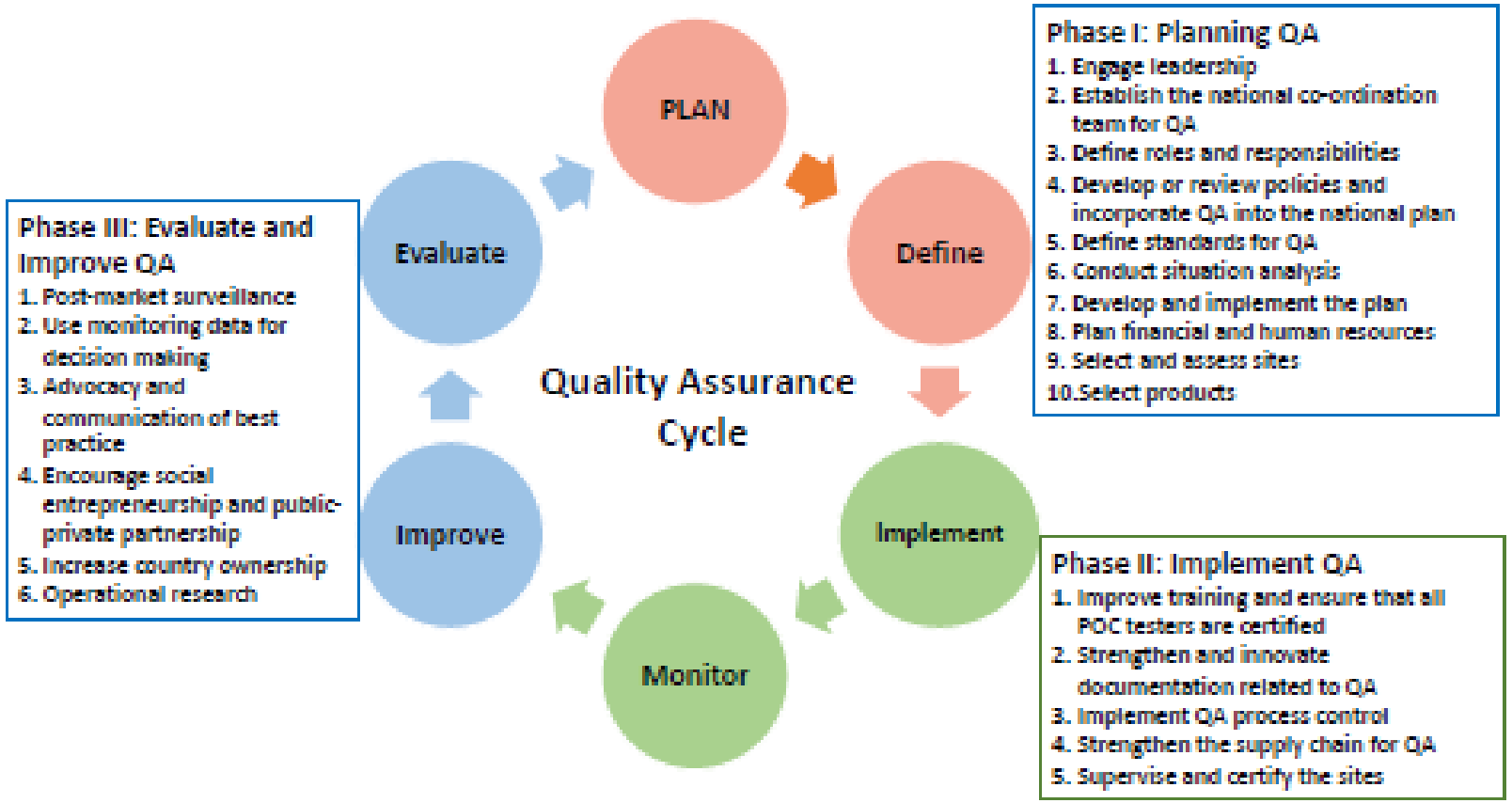
Table 5.1: Sources of error at a point-of-care (POC) testing site

Systematic errors	Personal errors
• Standard operating procedures (SOPs) not explicit enough	• Distractions at work
• Inadequate training	• Recording errors
• Lack of supervision	• Mixing up specimens
• Supervisors signing off on results without checking	• Not following SOPs
• Temperature of incubators, fridges and freezers not monitored	• Transcription errors
• Too much workload	• Not reporting results to the person who should be taking action on the test results

Organization of QA programmes for POC testing WHO, in collaboration with the CDC and other partners, developed a handbook on how POC QA programmes should be planned, defined, implemented, monitored, improved and evaluated in a continuous cycle of quality improvement. Although the handbook was developed for HIV tests, it can be applied to all POC tests. How countries develop their POC testing QA programme is dependent upon the organization of their laboratory system, human and financial resources, and their experience with organizing QA programmes for HIV POC tests.

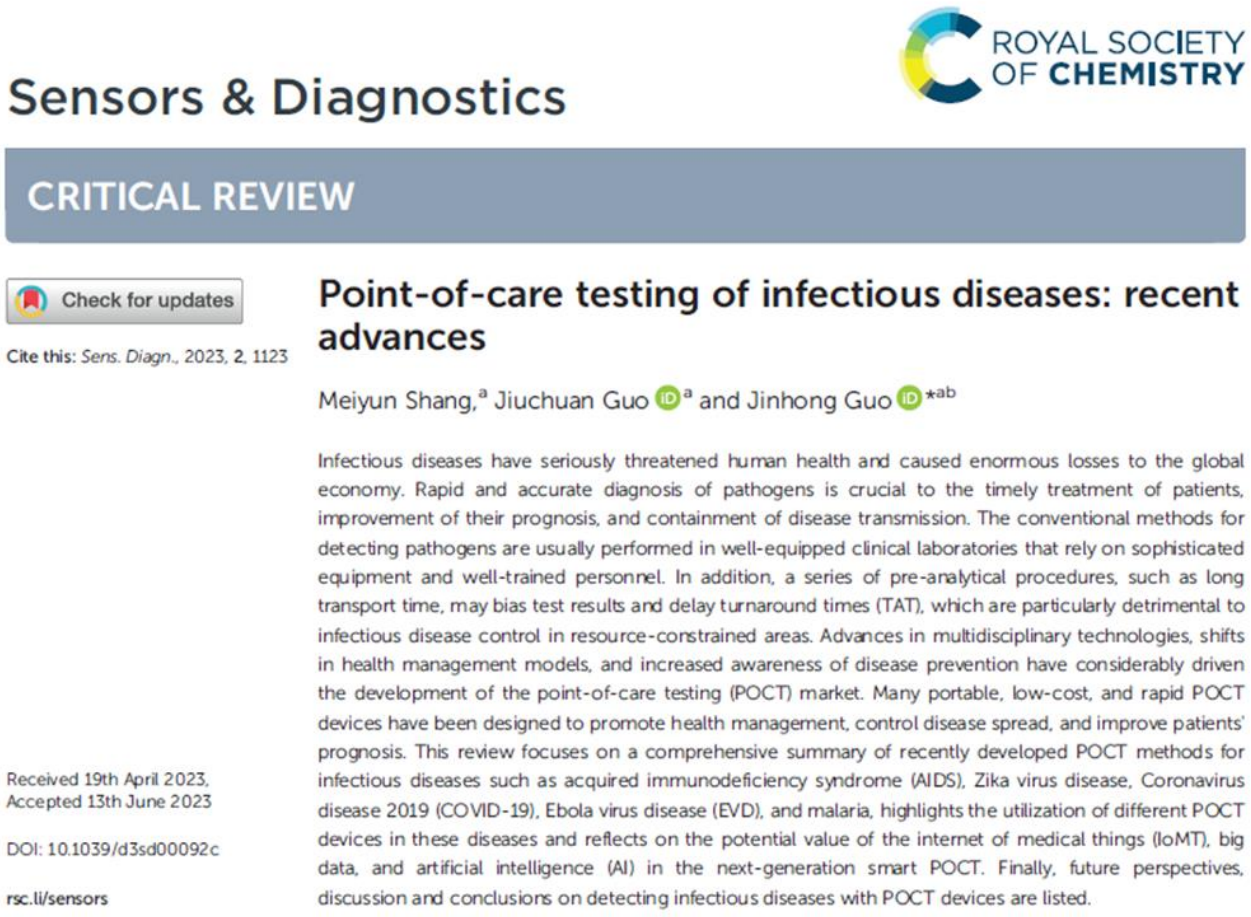
The most important starting point for a POC testing programme is that it should be integrated within the national laboratory network.

Fig. 5.4: The quality assurance (QA) cycle for point-of-care (POC) testing



Sources: Fonjungo et al; 2016 (9), WHO, 2015 (12).

INTEGRATION OF ADVANCED TECHNOLOGIES



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Point-of-care testing of infectious diseases: recent advances

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Infectious diseases have seriously threatened human health and caused enormous losses to the global economy. Rapid and accurate diagnosis of pathogens is crucial to the timely treatment of patients, improvement of their prognosis, and containment of disease transmission. The conventional methods for detecting pathogens are usually performed in well-equipped clinical laboratories that rely on sophisticated equipment and well-trained personnel. In addition, a series of pre-analytical procedures, such as long transport time, may bias test results and delay turnaround times (TAT), which are particularly detrimental to infectious disease control in resource-constrained areas. Advances in multidisciplinary technologies, shifts in health management models, and increased awareness of disease prevention have considerably driven the development of the point-of-care testing (POCT) market. Many portable, low-cost, and rapid POCT devices have been designed to promote health management, control disease spread, and improve patients' prognosis. This review focuses on a comprehensive summary of recently developed POCT methods for infectious diseases such as acquired immunodeficiency syndrome (AIDS), Zika virus disease, Coronavirus disease 2019 (COVID-19), Ebola virus disease (EVD), and malaria, highlights the utilization of different POCT devices in these diseases and reflects on the potential value of the internet of medical things (IoMT), big data, and artificial intelligence (AI) in the next-generation smart POCT. Finally, future perspectives, discussion and conclusions on detecting infectious diseases with POCT devices are listed.

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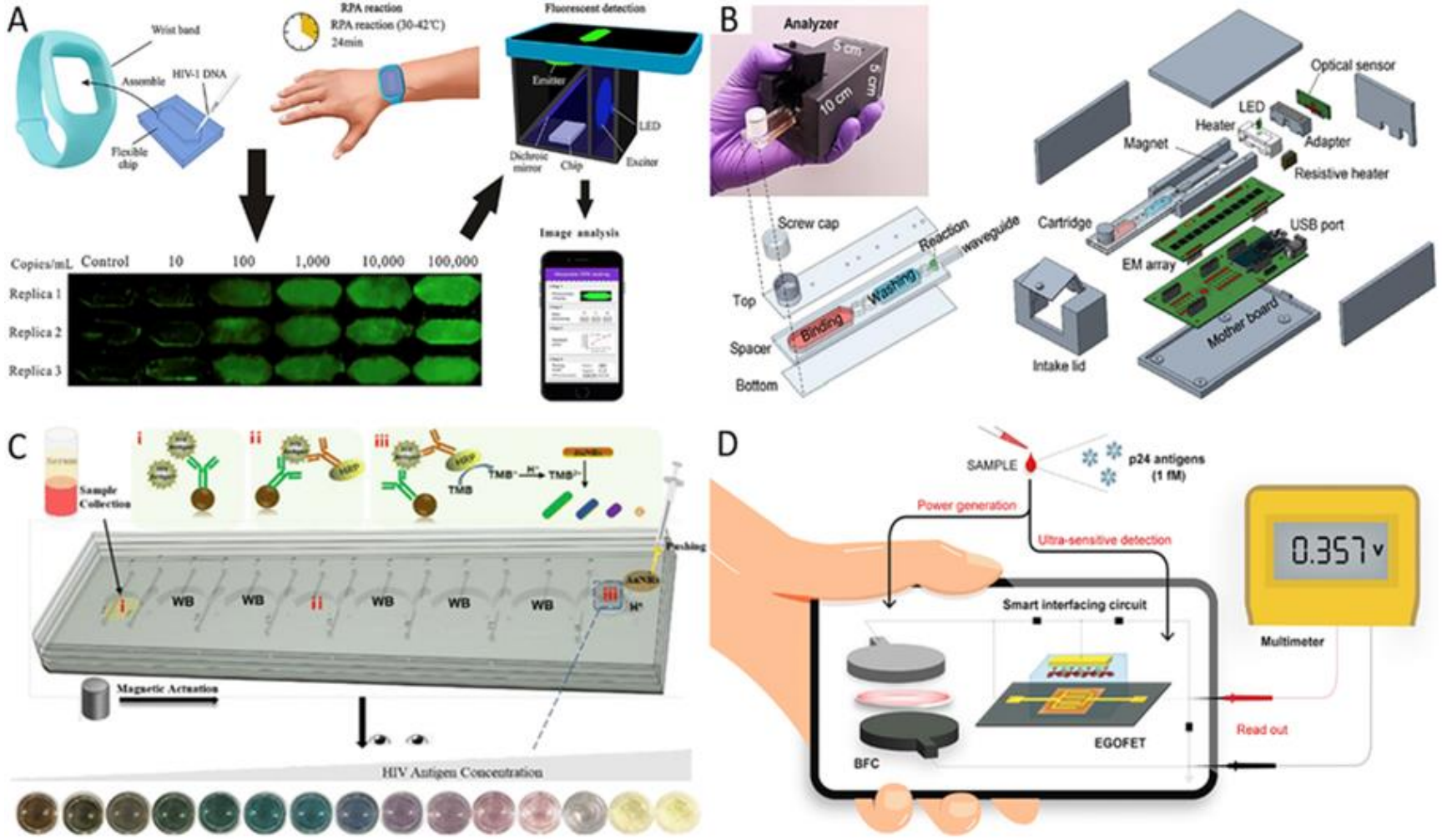
rsc.li/sensors

- To increase their effectiveness and accuracy, POCT devices are increasingly using contemporary technologies like the **Internet of Things (IoT), artificial intelligence (AI)**, and **machine learning**. IoT-enabled devices enable seamless connection, enabling real-time data transmission and analysis. AI and machine learning algorithms help in interpreting test results, providing accurate diagnoses. These advancements enhance the effectiveness and precision of POCT devices, thereby improving patient management.
- POCT devices are increasingly being utilized in **personalized medicine and remote monitoring**. These devices enable healthcare professionals to tailor treatments based on individual patient characteristics, optimizing therapy outcomes. In remote monitoring scenarios, patients can perform tests using POCT devices in the comfort of their homes, with **the results transmitted to healthcare providers**. This approach improves patient engagement, **reduces hospital visits, and enhances disease management**.



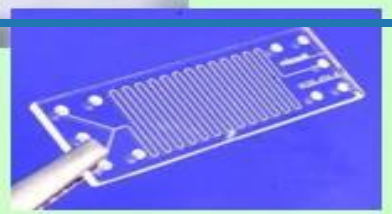
Advances in HIV POCT diagnosis. (A) The operational procedure of RPA-based wearable device for HIV-1 detection. (B) Overall design of the analyzer and microfluidic cartridge and their exposure views. (C) The principle of microfluidic integrated multicolor immunosensor for detecting HIV-24 antigen. i–iii are three reservoirs used to complete the immunoassay. (D) Schematic illustration of a self-powered smart sensing platform mainly consisting of EGOFET sensors and BFCs.

ADVANCEMENTS IN POCT TECHNOLOGY

- **rapid molecular diagnostic tests**. These tests utilize nucleic acid amplification techniques, such as polymerase chain reaction (PCR), to detect the genetic material of infectious agents. Rapid molecular tests can provide results within minutes, allowing for immediate diagnosis and timely initiation of treatment.
- **miniaturization of diagnostic devices**. Portable and handheld POCT devices are now available, enabling healthcare providers to perform tests at the point of care, whether it be in a clinic, hospital, or even remote settings. These devices are user-friendly and require minimal training, making them accessible to a wide range of healthcare professionals. The ability to perform tests on-site eliminates the need for sample transportation and reduces turnaround time, leading to faster diagnosis and treatment decisions.
- **microfluidic technology** have revolutionized POCT. Microfluidic devices allow for the precise manipulation of small volumes of fluids, enabling multiple tests to be performed simultaneously on a single device. This multiplexing capability enhances the efficiency of infectious disease diagnosis by enabling the detection of multiple pathogens in a single sample. It also conserves resources and reduces costs by minimizing the amount of reagents and samples required.
- **The integration of POCT technology with digital platforms**. Mobile applications and cloud-based systems now allow for seamless data transfer and real-time monitoring of test results. This integration facilitates remote consultation and collaboration between healthcare providers, improving patient management and reducing the burden on healthcare systems.

Point of Care Diagnostics

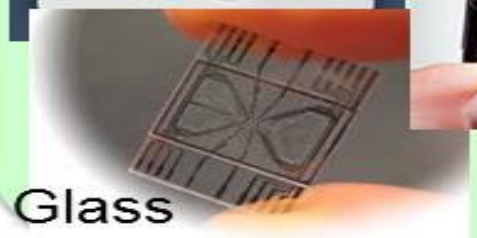
Assay Automation



Laboratory Tests

Instrument Miniaturization

Low cost sensor



Access to "Cloud" Computing

POCT will improve access to needed HIV and associated diagnostics, but these assays are not without limitations that should be noted and reported. There is a need to integrate these technologies cost-effectively and efficiently into clinical algorithms and existing laboratory networks.

Barrier for POCT	Example
Economic	It may be more expensive to place test instruments at the POC, as compared to laboratories. Some POCTs may be priced at a level that is unaffordable in many countries. Private care providers may receive incentives from laboratories for each test that they order; this means they can earn more by sending their patients to labs rather than do any POC testing.
Policy-related	Existing guidelines and policy documents may not provide clear recommendations on how to include POC tests in algorithms that are in place. Lack of a strong evidence-base on POCTs can result in weak evidence and uncertain policy recommendations.
Regulatory	Poor regulation of diagnostics may result in easy availability of suboptimal and poor quality rapid tests on the market; this makes it challenging to scale up validated POCTs.
Laboratory capacity	Some POCTs may require peripheral labs with sufficient capacity to run them (e.g., nucleic acid amplification tests). Poor laboratory capacity poses a barrier for scale-up of such technologies.
Infrastructure	Clinics and primary care centers often lack infrastructure such as constant power supply, refrigerators, storage space, waste disposal units, phlebotomy supplies, and temperature control; this makes it hard to implement some types of POCTs.
Quality control and quality assurance	Even simple POC tests require quality assurance and training before they can be performed. Primary care providers may not have the expertise or training to do them with quality assurance.
Work-flow balance	Staff shortages and high workload may reduce uptake of POCT. Health care providers are overburdened with a high volume of patients, and work-flow and time constraints do not permit easy use of POC tests.
Training	Unqualified and informal care providers may lack the knowledge and training needed to implement even simple RDTs. Erroneous results then erode the health system's faith in POCT. Lack of continuous, ongoing proficiency training can result in diminishing performance of POCT programs.
Supply chain	Supply chain deficiencies can lead to suboptimal or poor quality POC tests, which, in turn, may discredit POCT.
Infection risk	Health providers may be unwilling to do tests that may expose health care workers to the risk of infection.
Administrative/operational	It is not easy for health providers to seek reimbursement from insurance providers and third-party payers when POC tests are used in community or home settings.
Technical/medical	Doctors and front-line care providers in some settings may prefer clinical diagnosis and empiric treatment over diagnostic certainty. Widespread empiric treatment of common diseases reduces the felt need for any testing, POCT or otherwise.
Awareness	Health workers and care providers may not be aware of the various tests that are now available for POC use. Thus, they may still refer their patients to laboratories for testing.
Health system-related	Laboratory professionals in hospitals and larger health care facilities are opposed about any testing that is done outside of lab settings. They fear this will impact their own business, and they also worry about relinquishing control over testing.
Fit with user needs	Available rapid tests are often single disease focused when primary care providers are more worried about syndromes of unknown etiology (e.g., febrile illness, chronic cough). So, available tests may not quite meet user needs.
Cultural/societal	Perceived lack of confidentiality and stigma may reduce acceptance of POC testing in the community (e.g., HIV rapid tests).

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CHALLENGES AND FUTURE DIRECTIONS

- Ρυθμιστικά ζητήματα και τυποποίηση

Η εξέλιξη στις συσκευές POCT απαιτεί ισχυρά κανονιστικά πλαίσια και τυποποιημένες κατευθυντήριες γραμμές για την εφαρμογή και χρήση των νέων τεχνολογιών. Οι προσπάθειες τυποποίησης εξασφαλίζουν σταθερή απόδοση, αξιοπιστία και ασφάλεια, ενισχύοντας την εμπιστοσύνη στην τεχνολογία POCT.

- Ζητήματα απορρήτου και ασφάλειας κατά τη μετάδοση και αποθήκευση δεδομένων

Με την αυξανόμενη συνδεσιμότητα και ενσωμάτωση των συσκευών POCT με ηλεκτρονικά συστήματα, η διασφάλιση του απορρήτου και της ασφάλειας των δεδομένων καθίσταται ζωτικής σημασίας. Οι πληροφορίες των ασθενών πρέπει να προστατεύονται επαρκώς κατά τη μεταφορά και αποθήκευση των δεδομένων. Η προστασία ευαίσθητων δεδομένων υγειονομικής περίθαλψης απαιτεί κρυπτογράφηση, έλεγχο ταυτότητας και συμμόρφωση με τους νόμους περί προστασίας δεδομένων.

- Ενσωμάτωση των συσκευών Point-of-Care Testing στα υφιστάμενα συστήματα υγειονομικής περίθαλψης

Η απρόσκοπτη ενσωμάτωση των συσκευών POCT στα υπάρχοντα συστήματα υγειονομικής περίθαλψης θέτει τεχνικές και υλικοτεχνικές προκλήσεις. Η συνεργασία μεταξύ κατασκευαστών συσκευών, προγραμματιστών λογισμικού και παρόχων υγειονομικής περίθαλψης είναι απαραίτητη για τη διαλειτουργικότητα με συστήματα EHR, εργαστηριακά συστήματα πληροφοριών και άλλες πλατφόρμες υγειονομικής περίθαλψης. Η ενσωμάτωση θα πρέπει να επικεντρωθεί σε φιλικές προς το χρήστη διεπαφές, τυποποίηση δεδομένων και διαλειτουργικότητα για την πλήρη αξιοποίηση των δυνατοτήτων των συσκευών POCT.

- Συνεχής έρευνα και ανάπτυξη για καινοτομία στην τεχνολογία των POCT

Οι επενδύσεις σε νέες τεχνολογίες βιοανίχνευσης, νανοϋλικά, πλατφόρμες που βασίζονται σε έξυπνα τηλέφωνα και αλγόριθμους τεχνητής νοημοσύνης θα προωθήσουν την καινοτομία και θα βελτιώσουν τις επιδόσεις των συσκευών POCT. Η συνεργασία μεταξύ της βιομηχανίας, της ακαδημαϊκής κοινότητας και των παρόχων υγειονομικής περίθαλψης είναι απαραίτητη για την προώθηση της τεχνολογίας POCT και την κάλυψη των κλινικών αναγκών.

Προκλήσεις

- **Προώθηση/Προσφορά HIV εξέταση (**integrated testing)
- Διασφάλιση απρόσκοπτου **δωρεάν και ανώνυμου έλεγχο** για HIV
  - ✓Διευκόλυνση της πρόσβασης στην εξέταση HIV (user-friendly)
  - ✓Υποστήριξη εργαστηρίων διάγνωσης και παρακολούθησης
  - ✓Περιορισμός του στίγματος και των διακρίσεων
  - ✓Υπηρεσίες σε άτομα που πλήττονται από την ανθρωπιστική κρίση
- **Περιορισμός του φαινομένου καθυστερημένης διάγνωσης** και του **χρόνου διασύνδεσης** σε κατάλληλες υπηρεσίες παρακολούθησης και θεραπείας.
- **Συνεχιζόμενη εκπαίδευση** επαγγελματιών υγείας για εξειδικευμένα ζητήματα που αφορούν στην εξέταση
- Ανάγκη υιοθέτησης και προσαρμογής **νέων μεθόδων και τεχνολογιών**
- **Σχεδιασμός στοχευμένων παρεμβάσεων** και υπηρεσιών υγείας & φροντίδας των ατόμων με HIV λοίμωξη
- Ενίσχυση των προγραμμάτων πρόληψης και βελτίωση της αποτελεσματικότητας τους με ενσωμάτωση δεικτών ποιότητας
- Διασφάλιση της **ποιότητας σε ολιστικής φροντίδας** και **ενημέρωση σε θέματα σεξουαλικής και αναπαραγωγικής υγείας**
- Εποπτεία και αξιολόγηση-δείκτες
- Εθνική στρατηγική για τον HIV – Αλλαγή/προσαρμογή της νομοθεσίας-προσαρμογή στο σήμερα

Partner notification/opt-out (?)/ rapid tests (self-testing and home-testing)

CONCLUSIONS

- **Rapid and accurate diagnosis enables prompt initiation of appropriate treatme**nt, reducing the spread of infectious diseases and improving patient outcomes. The accessibility and portability of POCT devices expand diagnostic capabilities, particularly in resource-limited settings or during outbreaks.
- **The ability to perform multiplex testing on a single device** enhances diagnostic efficiency and conserves resources. Overall, these advancements empower healthcare providers with the tools to make informed and timely decisions, ultimately leading to better patient care.
- These technologies provide **high sensitivity and specificity**, minimizing the chances of false-positive or false-negative results. Accurate diagnosis aids in appropriate patient management and prevents unnecessary treatments or interventions.
- The **portability and ease of use of these tests make them suitable for point-of-care settings**, enabling healthcare professionals to perform tests directly at the patient's bedside or in remote areas with limited access to laboratory facilities.
- The interpretation of immunoassay results can be subjective, requiring careful consideration by healthcare professionals.
- **Interventions that prevent and treat HIV, sexually transmitted infections and viral hepatitis can be both cost-effective and cost-saving, especially when combined and provided in an integrated manner.**
- Integration of screening for HIV and infectious and noncommunicable diseases has been found to be cost-effective in multiple settings, as has integration of HIV services with family planning and sexual and reproductive health interventions. Integration of HIV with certain non-health services also promises multiple benefits, including in humanitarian settings and as part of social protection schemes section on Integration of HIV in social protection.

ΕΥΧΑΡΙΣΤΩ ΓΙΑ ΤΗΝ ΠΡΟΣΟΧΗ ΣΑΣ