

# Frequently asked questions – Testing for HIV, including HIV self-testing, in the context of pre-exposure prophylaxis (PrEP)

**This document is intended for testing providers, and for HTS clients.**

HIV testing in the context of antiretroviral (ARV) drugs has become complex.

1. Although not recommended, individuals with a known HIV-positive status on antiretroviral therapy (ART) may seek HIV testing services to “check” their HIV status.
2. Individuals who are HIV-negative and take ARVs (i.e. oral pre-exposure prophylaxis (PrEP)) to prevent HIV acquisition are recommended to test quarterly.

This set of frequently asked questions will focus on the second situation.

WHO recommends certain testing for individuals (HIV-negative individuals who are at high risk of HIV acquisition) who take PrEP:

- testing is required to rule out HIV infection prior to initiating PrEP. Once an individual has been initiated on PrEP, HIV testing is suggested every three months and whenever restarting PrEP after cessation to rule in or rule out HIV infection.
- individuals on PrEP with an HIV-inconclusive status should be retested in 14 days. Individuals on PrEP with an HIV-positive diagnosis will need to be placed on fully suppressive antiretroviral therapy (ART).
- other testing recommended in the context of PrEP initiation and monitoring are serum creatinine to check kidney function, surface antigen for hepatitis B (and other markers) to determine Hepatitis B status, testing for certain sexually transmitted infections such as syphilis, gonorrhea and chlamydia, as well as antibodies to hepatitis C and pregnancy where indicated.

*WHO (2017)*

# Messages for testing providers

1

**What testing strategy does WHO recommend for testing PrEP users?**

WHO recommends following the WHO HIV testing strategies for diagnosis (WHO, 2015).

This public health approach will minimize the chance for confusion that may arise if different testing strategies are used for PrEP vs non-PrEP users.

2

**What testing algorithm does WHO recommend for testing PrEP users?**

WHO recommends following the validated testing algorithm(s) for HIV diagnosis designated by the national authorities. This will use a combination of serology assays for detection of antibodies to HIV and/or HIV antigens (rather than to HIV itself).

A non-reactive self-test is not sufficient to initiate PrEP.

3

**To reduce the risk of a false negative result, should a 4<sup>th</sup> generation antigen/antigen assay be used for testing in the context of PrEP?**

There is always a small risk that the level of antibodies to HIV in early infection (window period) will be too low to be detectable. But this is a risk related to HIV diagnosis in any individual, not just PrEP users.

When your client/patient is taking PrEP as prescribed, his/her risk of acquiring HIV infection is rather low, so if his/her test result is non-reactive on a serology assay – such as a HIV-1/2 rapid diagnostic test – the likelihood of this test result being incorrect is very low.

**A non-reactive test result during the window period (i.e. time period between HIV infection and when antibodies can be detected by serology assays) does not mean the assays are not performing as expected. This reflects the low levels of antibodies during the window period which leads to reduced likelihood of any assay to be able to detect HIV infection.**

Fourth generation assays that detect both antigen and antibodies are widely used for HIV screening in the context of blood and blood product screening. However, recent data shows the clinical sensitivity for antigen detection may be lower than previously reported (Fransen K et al. 2017). Therefore, the clinical utility of 4<sup>th</sup> generation assay may be less for HIV diagnosis than expected.

Addition of a 4<sup>th</sup> generation assay should be considered in the context of the complexity that it adds to the testing strategy. Current WHO testing strategies must be adapted to include a p24 antigen assay (with neutralization step) to rule in or rule out HIV antigenemia when a 4<sup>th</sup> generation assay is included.

4

**To reduce the risk of a false negative result, should a NAT assay (like HIV viral load) be used for testing in the context of PrEP?**

Nucleic acid testing (NAT) assays are intended to detect HIV itself rather than antibodies to HIV (as is the case for serology assays). Studies in individuals undergoing seroconversion show NAT assays are more sensitive relative to serology assays (Patel P et al., 2010). But there are no currently available assays, including NAT assays, that can detect HIV infection in the very early period of HIV infection.

In resource limited settings, the clinical utility<sup>1</sup> of NAT assays within a testing algorithm for PrEP testers may be less than expected as NAT assays may only be used to rule in HIV infection. If the NAT test result is “HIV undetectable”, this does not conclusively rule out HIV infection. Hence, NAT assays are not used for HIV diagnosis.

In any case, the risk of HIV acquisition while taking PrEP consistently and correctly is very low.

<sup>1</sup> Clinical utility = the extent that introduction of a specific assay improves health outcomes relative to the current best alternative. (Bossuyt PM et al., 2012)

**5**

**What can be done to mitigate false positive results for testing in the context of PrEP?**

PrEP users may acquire HIV if they have stopped taking PrEP or take PrEP inconsistently, or very rarely if they have acquired a drug resistant virus. Any PrEP user with reactive test results should undergo additional testing following the national validated testing algorithm(s). This means multiple assays may be conducted with the results that don't agree with each other. For these "problem cases", it is important to gather data, with knowledge of the patient, such as demographics, clinical history, HIV-1 antigen levels, and viral load or CD4 count at time of testing. Retesting is recommended after 14 days.

**6**

**What factors contribute to false non-reactive results or delayed detection of HIV among PrEP users who might acquire HIV?**

The purpose of ARVs is to reduce viral replication, therefore, the amount of virus available for detection by NAT assays is limited. The limited presence of the virus leads to reduced antibody production which is the target for detection in serology assays.

## Messages for PrEP users

**7**

**Are test kits for HIV self-testing suitable for PrEP users?**

For PrEP initiation, a negative HIV self-testing result is not sufficient. If you have a negative self-test result, although it is likely to be correct, you will be tested again at the PrEP service before starting PrEP as per WHO recommendations WHO (2017). The same recommendation applies for PrEP users who are re-starting PrEP.

WHO recommends retesting for ongoing PrEP users, every 3 months. Test kits for HIV self-testing should not replace facility-based testing WHO (2017).

**8**

**What if I receive a reactive HIV test result while taking PrEP?**

Regular testing is recommended for PrEP users and there is the small chance that you may receive a reactive test result, as no assay will be 100% specific for HIV infection.

Do not stop taking PrEP and go to a health facility for additional testing following the national validated testing algorithm(s).

# References

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