berkeleyhealth HIV

Rapid self-test for the qualitative detection of antibodies to human immunodeficiency virus 1 and 2 (HIV1/HIV2) in whole blood

HIV VIRUS

Human immunodeficiency virus, or HIV, is a pathogen that attacks and suppresses the immune system by specifically affecting white blood cells. Without specific treatment, the virus weakens the subject's immune system to the point of inducing the development of acquired immunodeficiency syndrome, or AIDS. It is a syndrome that can occur in people with HIV even several years after the infection, when the immune system's efficiency dramatically falls, and the body loses its ability to fight even the most common infections.

WHO ARE THE INTENDED USERS

HIV 1/2 SELF-TEST can be used by anyone who has been, or suspects to have been exposed to the virus, people with HIV symptoms or anyone who wants to be aware of a possible infection. Antibody tests can take 23 to 90 days (window period) to detect HIV infection after an exposure.

WHY - BENEFITS

It is very important to support the prevention campaign against HIV, in order to prevent more serious disease, like AIDS, by testing and monitoring the population.

TEST PRINCIPLE

HIV 1/2 SELF-TEST is a rapid immunochromatographic assay, able to specifically detect the presence of antibodies against human immunodeficiency virus 1 and 2 (HIV1/ HIV2) in whole blood sample.

TECH SPECS

SENSITIVITY	SPECIFICITY	OVERALL ACCURACY
99%	99.7%	99.6%

CONTENT:

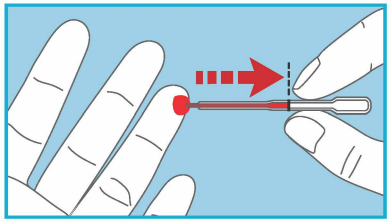
1 sealed aluminium pouch containing: 1 test device and 1 desiccant bag; 1 transparent plastic bag containing a pipette for blood collecting; 1 vial with dropper containing the diluent; 2 sterile lancets for blood sampling; 1 alcohol swab and 1 instructions for use leaflet.

CLINICAL EVIDENCES

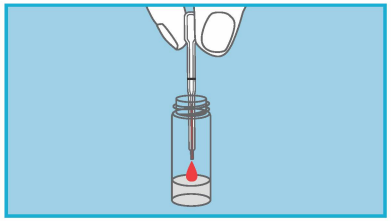
1. https://www.who.int/health-topics/hiv-aids/#tab=tab_1
2. European Centre for Disease Prevention and Control, HIV/AIDS surveillance in Europe (https://www.ecdc.europa.eu/en/all-topics-zhiv-infection-andaidssurveillance-and-disease-data/annual-hivaids-surveillance-reports)
3. https://www.hiv.gov/hiv-basics/overview/about-hiv-and-aids/symptoms-of-hiv
4. Debit et al., "HIV-1 Group O Genotypes and Phenotypes: Relationship to Fitness and Susceptibility to Antiretroviral Drugs"
5. https://www.cdc.gov/hiv/basics/hiv-testing/test-types.html

HOW TO USE IT

1) Take a blood sample after pricking the finger.



2) Put the blood collected with the pipette into the opened dropper vial.



3) Add 3 drops and wait 10 minutes before reading the result.