

# Case Scenario on the Qualities of HIV Rapid Test Kits

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**Abstract:** The diagnosis of HIV in resource-limited settings is performed based on an algorithm employing 2–3 rapid diagnostic tests (RDTs). This strategy has allowed a lifesaving scale-up of HIV diagnosis, as it permits testing to be decentralized outside of the laboratory. Even though the situation is minimal, some individuals will be falsely diagnosed as HIV positive in this strategy. When the clinical conditions, patient history, and results are not concurred, samples repeatedly tested positive on screening assays can be tested by a supplementary assay, and if negative by using nucleic acid testing (NAT). In our case the scenario was different, the woman who had married a husband living with HIV, had signs and symptoms of HIV was tested for HIV and the first test-Stat-pack result was negative. In this case, the counselor who was strong-minded that the woman is positive did the second and third tests and the results were reactive. Finally, the result was determined by NAT testing, and it was positive for HIV. Looking at this incident and reading the case reports in other countries, we realized that clients' history and exposure to risk behaviors need to be considered before reporting that the client is negative for HIV. We also recommend that low- or middle-income countries to have supplementary testing technologies to prevent missed opportunities and to provide NAT testing for HIV-negative clients who had a history of exposure to HIV-positive individuals and had clinical manifestations of HIV.

**Keywords:** Rapid Diagnostic Test, False Negative Diagnosis, False Positive Diagnosis, Rapid Test for Recent Infection, NAT, Risk Behaviors

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## 1. Introduction

Human Immuno-deficiency Virus (HIV) testing is a cornerstone of HIV prevention, treatment, care, and other support services [1]. Improving HIV testing services is also a key to meeting the 95–95–95 UNAIDS targets by 2030 [2]. The UNAIDS ambitious target can be achieved through improving people's knowledge of their own HIV status and that of their partners to reduce risky behavior and for the success of the HIV response [1, 3]. In Ethiopia, access to HIV testing is improved due to diagnostic algorithms that employ Rapid Diagnostic Tests (RDTs) [4] but most of the time people get married without knowing their HIV status. Thus, the Purpose of this reflection paper is to share our

experience with an occurrence encountered by a 25-year-old woman, who had married a husband who is living with HIV. For this reflection, we used Gibb's reflection cycle for the detailed analysis of the incident.

## 2. Description of Cases

A 25 years old woman who is residing at Lemi Kura Woreda-2 in Addis Ababa, Ethiopia was married to her current husband without knowing their HIV status. She has been living with him since ten months back. One day, her neighbors told her, that her husband is living with HIV and taking Anti Retro Viral therapy (ART). As soon as she heard, she decided to be tested and she visited the Voluntary

Counseling and Testing (VCT) clinic of Lemi Kura Woreda-2 Health Center on April 10, 2022.

The VCT counselor did the pretest counseling and tested for HIV and the first test result was negative, but the counselor did the second test, as she was pre-determined that the woman is likely to be positive based on her history of exposure and her signs and symptoms of HIV and it was reactive. The counselor also proceeded with the third test, and the test result became reactive. Finally, she reported the result as positive and linked the client to the facility's ART care and treatment clinic.

In the ART clinic, the same phenomenon happened upon retesting; the screening test, Stat-Pack, became non-reactive. The providers, at the ART clinic, repeated the procedure, changing the kit's lot number thinking that the problem is from the test kit they used but the result was non-reactive. Then the providers at the ART clinic discussed the issues with the first counselor and they proceeded to the following test kits and the results were concordant with the results of the VCT clinic. In addition, the providers at the ART clinic tested the sample with Rapid Test For HIV-1 Recent Infection (RTRI) and it was positive for recent infection. Still, they were not comfortable with the issue of Stat-Pack.

Finally, they communicated the issue with the sub-city HIV/TB and Case-Based Surveillance (CBS) coordinator and the regional laboratory to look for a solution and way forward. The sub-city HIV/TB and CBS coordinator contacted us and shared the situation at length.

### 3. Feelings About the Incident

We had such an experience before, and we told the providers to report it as negative when the first screening test result is non-reactive, as we considered it as a rule violation. But in this case, the provider at the VCT clinic was not happy to tell the negative result to the client as she, had pre-determined that the client was positive. When we heard about the situation, we didn't want to do the same as we did before. Rather, we went to the health facility and conducted a thorough discussion with the providers and health facility managements, then the team decided to repeat the test, thinking that the problem might be technical, the kit itself, or from the sample.

### 4. Evaluation

As soon as, we arrived at the health facility, we employed testing of the kit with a known positive sample to assure the quality of the test kit and the result was reactive. Then, we did a test of a new sample collected from the client, considering that the problem might be technical, but the result was non-reactive too. Finally, we recognized that the problem is not from the HIV test kit and the testers. We proceeded to think about the sample that it might have got something, which made it impossible to be reactive to stat-pack that in turn needs further scientific explanation and evidence. Then, the team decided that the client needed to

have viral load testing. She gave a sample for viral load and the test result was found to be "high viral load". As a result, the providers get the assurance to put the client on ART and the client started ART.

## 5. Analysis

Antibodies to HIV can be measured by a variety of techniques, including rapid diagnostic tests (RDT) and enzyme immunoassays (EIA) [5] to detect an immune response to the virus. The use of simple rapid detection tests (RDTs) for HIV was recommended in 1992[6] for resource-limited settings as they allow for real-time, point-of-care HIV testing [7, 8]. Since then, the diagnosis of HIV in resource-limited settings has been performed based on an algorithm employing 2–3 rapid diagnostic tests (RDTs). This strategy has allowed a lifesaving scale-up of HIV diagnosis, as it permits testing to be decentralized outside of the laboratory [4, 9]. However, even though the situation is minimal, some individuals will be falsely diagnosed as HIV positive in this strategy [10]. The mechanism causing false positive reactions on serological tests is that of non-HIV antibodies cross-reacting with the test antigens [11] compounded by misdiagnosis [12] and incorrect interpretation of weak positive test lines [13].

Therefore, when the clinical conditions, patient history, and results are not concorded, samples repeatedly tested positive on screening assays can be tested by a supplementary assay, such as Western Blot (WB) or indirect immunofluorescence assay (IFA), and if negative by using nucleic acid testing (NAT) [8, 14] to rule out a false negative result due to early seroconversion. But neither of which are suitable for use in peripheral laboratories.

Considering this, a new methodology to confirm positive HIV screening tests, using serial sample dilution of RDTs, postulated by decreasing the sensitivity of the HIV RDT by serially diluting the sample, to screen out false positive samples, and correctly identify true positives [15].

In our case the scenario was different, the woman who had married a husband living with HIV was tested for HIV and the result of the first test (stat-pack) was negative. In this case, the counselor did the second test, as she was strong-minded that the woman is positive, and the second and third tests were reactive. Finally, the counselor reported the result as positive and linked the client to HIV care and treatment clinic. The retesting results at the ART clinic also go the same, as that of the counselor. But the providers at the ART clinic were not confident to put the client on ART, as they knew the consequence of misclassification of the results. Then the result was determined by NAT testing, and it was positive for HIV.

## 6. Conclusion

After looking at this incident and reading the case reports in other countries, the team realized that there is something that countries need to consider in the selection criteria of the

HIV testing algorithm. The team also recommends that low- or middle-income countries need to have supplementary testing technologies to prevent missed opportunities and to provide NAT testing for HIV-negative clients who had a history of exposure with HIV-positive individuals, other risk behaviors, and who had clinical manifestations for HIV. Moreover, the team also believes that the scenario has a replicative potential for all HIV service-delivering facilities so that it will be applied at a larger scale and contributes to case detection, epidemic control, prevention, care, and treatment programs.

## 7. Action Plan

This is quite necessary to ensure testers' competency through the provision of a Proficiency test (PT) and regular supportive supervision. Routine checking of the test kits is also compulsory. Ensuring the client's current clinical conditions when there are HIV-negative clients, who had a history of exposure to HIV-positive partners and other risk behaviors had better be eligible for further testing to rule out their true HIV status.

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