Research Article

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Health Science Journal
ISSN 1791-809X

2022
Vol. 16 No. 5: 945

DOI: 10.36648/1791-809X.16.5.945

Evaluation of a Rapid in vitro Diagnostic Test Device for HIV 1.2 Rapid Test Kits

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Citation: Lei Z, Feng Y, Junzhe Z (2022) Evaluation of a Rapid in vitro Diagnostic Test Device for HIV 1.2 Rapid Test Kits. Health Sci J. Vol. 16 No. 5: 945.

Abstract

Objective: The aim of this evaluation report was to explore the reliability and performance of the All Test HIV 1.2 Rapid Test Kits for the qualitative detection of antibodies to Human Immunodeficiency Virus type 1 (HIV-1) and type 2 (HIV-2) in serum or plasma to aid in the diagnosis of HIV infection.

Method: Run a rapid in vitro diagnostic test device for detection of HIV 1.2 Rapid Test Kits in Serum or Plasma and compare to a leading commercial ELISA HIV test using clinical specimens for validation of the performance.

Results: The results show that the relative sensitivity of the HIV 1.2 Rapid Test Kits in Serum or Plasma is >99.9% and the relative specificity is 99.8%.

Conclusion: The HIV 1.2 Rapid Test Kits (Serum/Plasma) is a rapid test to qualitatively detect the presence of antibodies to HIV-1 and/or HIV-2 in serum or plasma specimens. The test utilizes latex conjugate and multiple recombinant HIV proteins to selectively detect antibodies to the HIV 1.2 in serum or plasma.

Keywords: Human Immunodeficiency Virus; HIV; Rapid Test; infectious Disease

Received: 23-May-2022, Manuscript No. Iphsj-22-12796; **Editor assigned:** 25-May-2022, PreQC No. Iphsj-22-12796 (PQ); **Reviewed:** 10-Jun-2022, QC No. Iphsj-22-12796, **Revised:** 15-Jun-2022, Manuscript No. Iphsj-22-12796(R); **Published:** 22-Jun-2022, DOI: 10.36648/1791-809X.16.5.945

Introduction

The human immunodeficiency virus (HIV) is a virus that damages the body's immune system by destroying a type of white blood cell that helps the body fight infection [1]. This can put the person living with HIV at risk of serious infections and certain cancers. It is now clear from several studies that seeking treatment as soon as possible after becoming infected with HIV is better than waiting. HIV-infected patients who are treated early have fewer complications from HIV infection and are less likely to infect other people than those who delay treatment. Studies also show that people who know they are HIV-positive may change their behaviours to decrease the risk of infecting others. The U.S. Centers for Disease Control and Prevention (CDC) now recommends that all people between the ages of 13 and 64 get tested for HIV, regardless of risk.1 [2].

HIV is the etiologic agent of Acquired Immune Deficiency Syndrome (AIDS). The vision is surrounded by a lipid envelope that is derived from host cell membrane. Several viral glycoproteins are located on the envelope. Each virus contains two copies of positive-sense genomic RNAs. HIV-1 has been isolated from patients with AIDS and AIDS-related complex, and from healthy people with high potential risk for developing AIDS [3]. HIV-2 has been isolated from West African AIDS patients and from seropositive asymptomatic individuals [4].

HIV Prevention

For people living with HIV to fully benefit from effective combination antiretroviral therapy, they need to know they are infected with HIV and need to receive regular HIV care and to receive and adhere to effective antiretroviral therapy. Testing and treatment strategies for HIV prevention argue that expanded testing and early treatment of HIV infection can significantly reduce current HIV transmission and curb the HIV epidemic [2]. HIV testing is also recommended at least once a year for those at higher risk of becoming infected with HIV. The current guidelines include:

- people who use injection drugs and share needles or syringes;
- people who have unprotected sex (vaginal, anal or oral) with men who have sex with men (MSM), or with people who have sex with multiple partners or anonymous partners;
- people who exchange sex for drugs or money;
- people who have been diagnosed with hepatitis, tuberculosis (TB), or an STI (sexually-transmitted infections) such as chlamydia, gonorrhoea or syphilis;

- And people who have unprotected sex with someone with any of the above risk factors.

If the infection is not treated, it becomes chronic HIV infection. Often, there are no symptoms during this stage. If it is not treated, eventually the virus will weaken the infected person's immune system, progressing to AIDS and further infections.

HIV Rapid Test Kit Materials and Method

There are two categories of HIV tests: conventional and rapid. Conventional tests are those in which blood or oral fluid is collected and then sent to a laboratory for testing. Results from conventional tests are typically available in a few hours to a few days. Rapid tests, however, can be performed directly at the point-of-care and yield results in 15-20 minutes, allowing healthcare providers to share results.

Quickly with patients

The HIV1.2 Rapid Test Kits (Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of antibodies to HIV-1 and HIV-2 in serum or plasma to aid in the diagnosis of an HIV infection.

The HIV 1.2 Rapid Test Kits is performed using serum or plasma collect from whole blood. The first step is to separate serum or plasma as soon as possible to avoid haemolysis. The instructions note to only use clear non-haemolysed specimens. Next, one drop of serum or plasma is added to the specimen area and then one drop of buffer solution. The intensity of the color in the Test line region (T) will vary depending on the concentration of HIV antibodies present in the specimen. Therefore, any shade of color in the Test line region (T) should be considered a positive result. A colored line will always appear at the Control (C) location on the cassette to indicate that the assay worked correctly. The test result is obtained in 10 minutes or less.

All Test HIV 1.2 Rapid Test Kit has correctly identified specimens of a seroconversion panel and was compared to a leading commercial ELISA HIV test kit using clinical specimens. The results show that the relative sensitivity of the HIV 1.2 Rapid Test Kit is >99.9% and the relative specificity is 99.8%.

Within-run precision was determined by using 15 replicates of four specimens: a negative, a low positive, a medium positive and a high positive. The negative, low positive, medium positive and high positive values were correctly identified >99% of the time. Between-run precision was determined by 15 independent assays on the same four specimens: a negative, a low positive, a medium positive and a high positive. Three different lots of the HIV 1.2 Rapid Test cassette (Serum/Plasma) were tested over a 3-day period using negative, low positive, medium positive and high positive specimens. The specimens were correctly identified >99% of the time **(Table 1)**.

Table 1. All Test HIV 1.2 Rapid Test Compared to ELISA HIV Test Kit.

Method		ELISA		Total Results
HIV 1.2 Rapid Test (Serum/Plasma)	Results	Positive	Negative	
	Positive	158	2	160
	Negative	0	998	998
Total Results		158	1000	1158

Relative sensitivity: >99.9% (97.5%CI*: 98.1%~100.0%)
Relative specificity: 99.8% (95%CI*: 99.3%~99.9%)
Accuracy: 99.8% (95%CI*: 99.4%~99.9%)

Detection of HIV antibodies in serum and plasma specimens is the most efficient and common method to determine whether an individual has been exposed to HIV and to screen blood and blood products for HIV [4]. Despite the differences in their biological characteristics, serological activities and genome sequences, HIV-1 and HIV-2 show strong antigenic cross-reactivity [5, 6]. Most HIV-2 positive sera can be identified by using HIV-1 based serological tests.

Summary

The All Test HIV 1.2 Rapid Test Kits tested in this evaluation performed well. The tests showed both excellent sensitivity and specificity. However, the laboratory evaluation could differ from test performance outside of a laboratory due to the limited sample range and close monitoring that is carried out by healthcare professionals. From the results of tested samples, it presents that the HIV 1.2 Rapid Test Kit developed by Hangzhou All Test Biotech Co., Ltd meets the requirements of intended use.

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