INTERFERENCE

The following potential interference were analysed during the performance and the results indicates no interference by them. These includes;

·Albumin
·Bilirubin
·Haemoglobin
·Glucose
·Uric Acid Concentration
·Lipids
·Ascorbic Acid
·Caffeine
·Ethanol
Methanol

LIMITATIONS

1.The CADY SOLO HIV 1/2 rapid test device is for in vitro use only.
2.The test should be used for the detection of antibodies of HIV in a specimen.
3.The CADY SOLO HIV 1/2 rapid test device (serum/plasma) will only indicate the presence of antibodies to HIV in the specimen and should not be used as the sole criteria for the diagnosis of HIV-1 and should not be used as the sole criteria for the diagnosis of HIV-1 and/or -2 infections.
4.For confirmation, further analysis of the specimens should be performed, such as ELISA and /or western blot analysis. As with all diagnosis tests, all results must be interpreted together with other clinical information available to the physician.
5.If the test result is negative and clinical symptoms persist, additional follow-up tests using other clinical methods are recommended.
A negative result at any time does not preclude the possibility of HIV-1 or/and -2 infection.

BIBLIOGRAPHY

1.Chang, SY, Bowman, BH, Weiss, JB, Garcia, RE and white, TJ. The origin of HIV-1 isolates HTLV-IIIB, Nature.
2.Arya, SK, Beaver, B, Jagodzinski, L, ensoli B, kanki, PJ, Albert, J, Fenyo, EM, Biberfeld, G, Zagury. JF and Laure, F. New human and simian HIV-related retroviruses possess functional transactivator (tat) gene. Nature (1987).

IFU No.: R/IFU/RDT/HIV/15
Issue Date: 01/10/2023
Rev.00

INDEX OF SYMBOLS

Symbol	Meaning	Symbol	Meaning
	Caution/Warning (Read instruction before use)		Date of Expiry
	Manufacturer	LOT	Batch/Lot Number
	Date of Manufacturing		Don't re-use
REF	Catalogue number	IVD	Invitro Diagnostic device
	Temperature Limitation		Consult IFU
	Keep away from sunlight		Do not use if package damaged
	NON-STERILE	CE	CE Syymbol
EC REP	Name and address of European union representative		

IFU No.: R/IFU/RDT/HIV/15
Issue Date: 01/10/2023
Rev.00

REVITAL HEALTHCARE (EPZ) LIMITED,
LR NO. 5025/1239 TAKAUNGU,
P.O BOX 80713-80100 MOMBASA, KENYA ,
Email: info@rhcare-epz.com,
Website: www.revitalhcare.com .
Consumer Complaint cell/Coordinator: +254722412900

Revital®

CADY SOLO ™ HIV 1/2 RAPID TEST

INTENDED USE

Testing for the detection of specific antibody subtypes to Human Immunodeficiency Virus-1 and/or-2 in fingerstick whole blood through self-administered methods. This self-test is designed for personal use, allowing individuals to screen for HIV antibodies in a private and convenient manner.

INTENDED USER

1.Individual

CLINICAL SIGNIFICANCE

HIV is the etiologic agent of Acquired immune Deficiency Syndrome (AIDS). The virion is surrounded by a lipid 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 a high potential of risk for developing AIDS. HIV-2 has been isolated from West African AIDS patients and from seropositive asymptomatic individuals. Both HIV-1 and -2 elicit an immune response. Detection of HIV antibodies in serum /plasma/ whole blood is the most efficient and common way to determine whether an individual has been exposed to HIV and to screen blood and blood products for HIV. Despite the differences in their biological characteristics, serological activities and genome sequences of HIV-1 and -2 show strong antigenic cross -reactivity. Most HIV-2 positive sera can be identified by using HIV-1 based serological tests. The HIV 1/2 3-line Test device (Serum/Plasma/whole blood) is a rapid test to qualitatively detect the presence and subtype of antibody to HIV-1 and/or -2 in serums/plasma/whole blood specimen. The test utilizes a combination of multiple recombinant HIV proteins coated particles and multiple recombinant HIV proteins to selectively detect antibody to the HIV-1 and HIV-2 in serum, plasma and whole blood.

TEST PRINCIPLE

The HIV 1/2 3-line Test Device (Serum/Plasma/whole blood) is a qualitative, membrane based immunoassay for the detection of antibody HIV in serum or plasma. The membrane coated with recombinant HIV antigens on the test line region of the device. When a serum or plasma specimen is applied at one end of the membrane, it reacts with recombinant HIV antigen coated particle that has already been applied to the specimen pad at the same end. The mixture then migrates chromatographically towards the other end of the membrane and reacts with the recombinant HIV antigens on the membrane in the test line region. If the serum or plasma contains antibodies to HIV-1 or HIV-2, a colored line will appear in the test line regions for either HIV-1 and/or HIV-2, showing a positive result. The absence of the colored line indicates that the serum or plasma does not contain the anti-HIV antibodies, showing a negative result. To serve as a procedural control, a colored line will always appear at the control line region if the test has been performed properly.

KIT COMPONENTS

1.Test device, individually packaged, it contains test kit cassette, silica gel and a dropper)
2.One buffer
3.One copy of IFU
4.Alcohol Swabs
5.One-Time Use Blood Lancet

DESCRIPTION OF COMPONENTS:

1.Nitrocellulose Membrane: The membrane coated with recombinant HIV-1 & HIV-2 antigens on the test line region of the device and Antibody for Control.
2.Gold Conjugate Pad: Gold conjugated HIV-1 & HIV-2 Recombinant antigen for test and Antibody for control are coated on Glass fiber pad
3.Sample Release Pad
4.Absorbent Pad

WARNINGS & PRECAUTIONS

For In Vitro Diagnostic Use Only
1.This package insert must be read completely before performing the test. Failure to follow the insert may lead to inaccurate test results.
2.Do not open the sealed pouch unless ready to conduct the assay.
3.Do not use expired devices or components.
4.Use only one specimen per device. Do not combine specimens.
5.Do not use components from any other test kit/lot as substitutes for components in this kit/lot.
6.Do not use hemolyzed blood specimens for testing.
7.Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
8.Users of this test should follow US CDC Universal Precautions for prevention of transmission of HIV, HBV and other bloodborne pathogens: https://www.cdc.gov/niosh/topics/bbp/universal.html
9.Do not smoke, drink or eat in areas where specimens or kit reagents are being handled.
10.Dispose of all specimens and materials used to perform the test as bio hazardous waste.
11.Test results should be read 15-20 minutes after a specimen is applied to the sample well of the device. Reading the test result after 20 minutes should be considered invalid and must be repeated.
12.Do not perform the test in a room with strong air flow, i.e. electric fan or strong air-conditioning.

STORAGE AND STABILITY:

·The kit has a 24-month shelf life and should be stored between 1 and 30°C.
·When stored according to instructions, the kit's components remain stable until the expiration date is shown on the outside label. The component with the shortest expiration date determines the kit's expiration date. Once the extraction Solution has been used, the kit's expiration date is unaffected. Do not utilize kit components after the kit as a whole has expired.
·If kept chilled, make sure the pouched item is at room temperature before opening.
·Keep the kit from freezing.

SPECIMEN COLLECTION AND PREPARATION:

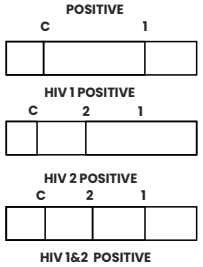
a.The CADY SOLO™ HIV 1/2 Rapid Test Device can be performed using whole blood.
b.Testing should be performed immediately after the specimens have been collected.

Direction For Use

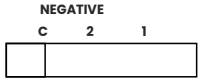
Allow test device, buffer, specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.
1.Remove the test device from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed immediately.
2.Place the test device on a clean and flat surface. Hold the dropper vertically and transfer 1 drops (10 µl) for whole Blood to the sample well (S) of the test device, then add 2 drops (70 µl) of buffer from the dropper bottle to the sample well (S) of the device and start the timer. Avoid trapping air bubbles in the sample well (S).
3.Wait for the red line(s) to appear. The test line should be read at 15 minutes. It is important that the background is clear before the result is read.

INTERPRETATION OF RESULTS

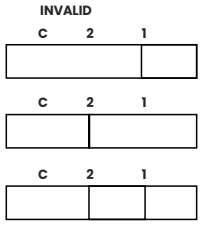
1.POSITIVE: Two or three distinct red lines appear. The presence of a band at 'C' and bands at '1' and/or '2' within the result window, no matter which band appear first, indicates a positive result for HIV-1 or/ HIV-2 respectively.



2.NEGATIVE: One red line appears in the control region (C). No apparent red or pink line appears in the test regions (1 and 2).



3.INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributors.



NOTE: the intensity of the red colour in the test line region (T) will vary depending on the concentration of anti-HIV 1/2 antibodies present in the specimen. However, neither the quantitative value not the rate of increase in anti-HIV 1/2 antibodies can be determined by this qualitative test.

QUALITY CONTROL

Internal Control: The C band, a built-in control function, is present in this test. After adding the specimen and sample diluent, the C line forms. If not, go over the entire process and run the test again using a different device.
External Control: In particular, under the following circumstances, Good Laboratory Practice advises using the external controls, positive and negative, to ensure the proper performance of the assay:
a.Before evaluating the samples, the new operator uses the kit.
b.The test kit is from a fresh batch.
c.Kits from a fresh shipment are used.
d.The kit was stored at a temperature that was higher than 30°C and lower than 1°C.
e.The test area's temperature is outside of the range of 15°C and 30°C.

PERFORMANCE CHARACTERISTICS

SPECIFITY AND SENSITIVITY

The CADY SOLO HIV 1/2 Rapid test kit has been compared to a leading commercial Asan rapid test using clinical specimens and has successfully detected specimens of a performance panel. The results indicate that the CADY SOLO HIV 1/2 Rapid Test Cassette's (Whole Blood/Serum/Plasma) relative sensitivity is >100% and its relative specificity is 99.2%.

Lot No.	Total No. Of Negative Sample Tested	Observed True Negative	Observed False Positive	% Specificity
HVS 230501V	250	248	02	99.2%
HVS 230502V	250	248	02	99.2%
HVS 230503V	250	248	02	99.2%
220807-Asan	250	250	00	100%

Lot No.	Total No. Of Positive Sample Tested	Observed True Positive	Observed False Negative	% Sensitivity
HVS 230501V	250	250	00	100%
HVS 230502V	250	250	00	100%
HVS 230503V	250	250	00	100%
220807-Asan	250	250	00	100%

Linearity: Not Applicable; this device is a qualitative determination assay. Hence Linearity is not applicable.
The limit of detection: Not Applicable; this device is a qualitative determination assay. Hence Linearity is not applicable.

CROSS-REACTION

The CADY SOLO HIV 1/2 Rapid test kit has been tested by HAMA, RF, HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, HCV, HIV, H. Pylori, MONO, CMV, Rubella and TOXO positive specimens. The results showed no cross-reactivity.