The results were as follows:.

	Cady Hiv Rapid Test		
	Positive	Negative	Total
Reference (ELISA)			
Positive samples (N=225)	225	0	225
Positive samples (N=118)	2	116	118

In a comparison of the HIV test versus ELISA of serum, results gave sensitivity of 100% (225/225) and specificity of 98.3% (116/118) for One Step HIV1/2 Whole Blood/Serum/Plasma Test.

1.Precision

- Within run precision was determined by using 10 replicates of four different specimens containing different concentrations of antibody. The negative and positive values were correctly identified 100% of the time.
- Between run precision was determined by using 3 different batches of test devices testing the four different specimens containing different concentrations of antibody. The negative and positive results were correctly identified 100% of the time.

Warning/ Precaution

· Wear protective gloves while handling specimens wash thoroughly afterwards.
· Do not mix reagents from different lot.
· For professional in vitro diagnostic use only. Do not use after expiration date.
· Do not eat, drink or smoke in the area where the specimens or kits are handled.
· Humidity and temperature can adversely affect results.
· Dispose all the samples and kits properly as per the instruction after test in accordance in GLP.
· Follow the testing procedure exactly as mention in the insert.

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

BIBLIOGRAPHY

·Janssen R. S. et. al. New testing strategy to detect early HIV-1 infection for use in incidence estimates and for clinical and prevention purposes. JAMA (1998) 280(1): 42-48. ·CDC. Update: HIV Counseling and Testing using Rapid Tests-United States, 1995. MMWR 1998; 47(11).

·Gale R. Burstein, Jonathan Pincus et al. A rapid review of rapid HIV antibody tests. Current Infectious Disease Reports, Volume 8, Number 2, March 2006, Pages 125-131.

·Bernard M. Branson. State of the Art for Diagnosis of HIV Infection. Clinical Infectious Diseases 2007; 45: S221–S225

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

Doc. No: R/IFU/RDT/HIV/01
Rev No: 00
Date of Issue: 10-10-2022
25 Test Kits

REVITAL HEALTHCARE (EPZ) LIMITED,
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Revital®

CADY® HIV 1/2 RAPID TEST KIT

INTENDED USE

CADY HIV 1/2 Rapid Test is a one step rapid test for the qualitative detection of HIV 1/2 antibodies in human whole blood/serum/ plasma at specified cut-off level.

SUMMARY

HIV (human immunodeficiency virus) is the pathogen of AIDS (acquired immune deficiency syndrome). HIV belongs to a family of retroviridae genus lentivirus, and there are two groups, HIV-1 and HIV-2 is highly mutagenous and can be divided into 9 subtypes of mutations in its membrane protein, which are A, B, C, D, E, F, G, H and O. HIV-2 has 60% nucleotide acid homology with HIV-1, but they are different in their ability of infection, HIV-1 is the most prevailing virus strain. Once infected, it mutates quickly and has bad prognosis, and it will be carried for in all life; HIV-2 has longer latent period, and relative weaker in its pathogenesis.

PRINCIPLE OF TEST

The CADY HIV 1/2 Rapid Test Device (Serum/Plasma/whole blood) is a rapid immunochromatographic test for the visual detection of HIV antibodies in whole blood/serum/plasma samples in the diagnosis of HIV infection. One step HIV test cassette adopts double antigen sandwich method. When the specimen is added into the test device, the specimen is absorbed into the device by capillary action, mixes with the antigen-dye conjugate, and flows across the pre-coated membrane, in which HIV 1/2 antigens are coated respectively. When the HIV 1/2 antibody levels are at or above the target cutoff (the detection limit of the test), HIV 1/2 antibodies in the specimen binds to the antigen-dye conjugate and are captured by HIV 1 or/and 2 antigens immobilized in the relative site of test region (T) of the device. This produces a colored test band in the appropriate test region and indicates a appositive result. When the HIV 1/2 antibody levels are zero or below the target cut off .There is not a visible colored band in the test region (T) of the device. This indicates a negative result.To serve as a procedure control, a colored line will appear at the control region (C), if the test has been performed properly.

SPECIMEN

Human Serum/Plasma/Whole Blood Use non haemolysed serum /plasma collected without prolonged venous stasis. For long term storage, specimens should be kept below -20°C. Specimen are stable for at least 3 days when stored at 2 - 8°C.

CONTENT OF THE KITS

1. Individual sealed pouch, each containing:
   · Test device · Desiccant .10 µL Dropper
2. One 5ml buffer solution .
3. Leaflet with instructions for use.
4. Lancet
5. Alcohol Swab

MATERIALS REQUIRED BUT NOT PROVIDED

•Timer

SPECIMEN COLLECTION & PREPARATION

Whole blood collected collected by fingerstick:

- Select the finger for puncture, usually the side of the forth finger. Clean the area to be lanced with an alcohol pad. Allow the finger to dry thoroughly.
- Using a sterile lancet, puncture the skin just off the centre of the finger pad. Hold the finger downwards. Apply gentle pressure beside the point of the puncture. Avoid squeezing the finger to make it bleed. Wipe away the first drop of blood with a sterile swab. Allow a new drop of blood to form. If blood flow is inadequate, the subject's finger may have to be gently massaged at the finger base to produce a droplet of sufficient volume. Avoid 'milking' the finger.
- Take a sample dropper provided, while gently squeezing the tube, immerse the open end in the blood drop and gently release the pressure to draw blood into the dropper. Whole blood samples collected by finger stick should be used immediately after collection.

Whole blood collected by venipuncture:

- Using standard phlebotomy procedure, collect a venipuncture whole blood specimen using a blood collection tube with suitable anticoagulant.
- It is recommended that specimens should be tested immediately. Do not leave the specimens at room temperature for prolonged periods. If the specimens are not tested immediately, they may be stored at 2-8°C. It is not suitable to test the whole blood samples which have been stored at 2-8°C for more than 7 days

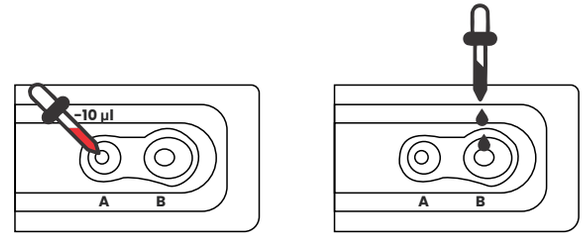
Serum and plasma:

- Using standard phlebotomy procedure, collect a venipuncture whole blood specimen using a blood collection tube. If collecting plasma use a blood collection tube containing suitable anticoagulant.
- Separate the serum/plasma from blood as soon as a possible to avoid hemolysis.
- Test should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C. for long-term storage, specimens should be kept below -20°C.
- Bring specimens to room temperature before testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly. Only clear, non-hemolyzed specimens can be used.

TEST PROCEDURE

Allow the device, buffer and specimen to equilibrate to room temperature (10-30°C) prior to testing.

1. Remove the test cassette from the foil pouch by tearing at the notch and place it on the level surface.
2. Slowly add 10ul (the second tick mark line) of whole blood or serum or plasma to the sample well (A) and then add 2 drops of dilution buffer to the buffer well (B).
3. As the test begins to work, you will see purple color move across the result window in the center of the test device. Wait for 15 minutes and read the results. Do not read results after 30 minutes



sa

INTERPRETATION OF RESULTS

Positive (+)

A rose-pink band is visible in the control region and one or two bands in the appropriate test region. It indicates a appositive result for the HIV 1/2 antibodies of that specific test zone.

1. Type 1 positive: One color band presents in Test region (T1) away from control region and one band in control region indicates HIV Type 1 positive.

2. Type 2 positive: One color band presents in Test region (T2) close to control region and one band in control region indicates HIV Type 2 positive.

3. Type 1 and/or Type 2 positive: both two test bands present in Test region (T1+T2) and one band in control region indicate HIV Type 1 and/or Type 2 positive. - If the color intensity of the test band in Test region (T1) is darker than the band in the Test region(T2), you can interpret the result as HIV Type 1 postive.

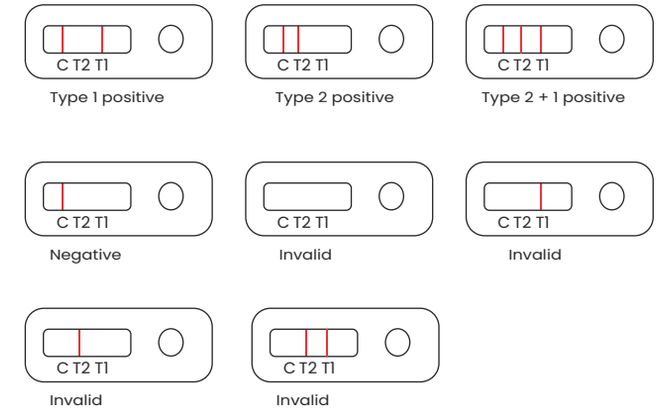
- If the color intensity of the test band in Test region (T2) is darker than the band in the Test region(T1), you can interpret the result as HIV Type 2 positive.

Negative (-)

A rose-pink band is visible in the control region. No colour band appears in the appropriate test region. It indicates that the concentration of the HIV 1/2 antibodies of that specific test zone is zero or below the detection limit of the test.

Invalid

If no colour band is visible in the control region, the test is invalid. Another test should be run to re-evaluate the specimen. If the test still fails, please contact the distributor or the store, where you bought the product with the lot number.



Note: there is no meaning attributed to line colour intensity or width.

Quality Control

Though there is an internal procedural control line in the test device of control region, the use of external controls is strongly recommended as good laboratory testing practice to confirm the test procedure and to verify proper test performance. Positive and negative control should give the expected results. When testing the positive and negative, the same assay procedure should be adopted.

LIMITATIONS OF PROCEDURE

1. This test has been developed for testing whole blood/serum/plasma samples only.
2. This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of HIV.
3. A negative result does not rule not out infection by HIV because the antibodies to HIV may be absent or may not be present in sufficient quantity to be detected at early stage of infection.
4. If be a positive result, suggest doing confirmation using EIA or western blot assay.

PERFORMANCE CHARACTERISTICS

1. Sensitivity and specificity

Totally 343 samples, including 193 samples which are HIV and HCV antibody positive; 32 samples which are HIV positive and HCV negative; 79 samples which are HIV Negative and HCV positive; 39 samples which are HIV and HCV negative. Test these samples using ELISA method and colloidal gold method