

- 6) Do not use the test device if the pouch is not intact.
- 7) Do not use the sterile twist lancet if the seal is broken (Refer specimen collection section).
- 8) Do not use the test device if the desiccant color has changed from orange to green.
- 9) Do not smoke, eat or drink while handling specimens and performing a test.
- 10) Do not re-use the test device, alcohol swab, sterile twist lancet, and specimen transfer device as these are intended for single use only.
- 11) Perform the test by using kit assay buffer, any other buffer or fluid will invalidate the test results.
- 12) Do not allow the tip of assay buffer bottle to touch specimen well as it may contaminate the assay buffer.
- 13) Do not use the test device and assay buffer beyond the date of expiry.
- 14) Do not eat the desiccant.
- 15) Do not use any other specimen other than human Whole blood/Serum/Plasma. Do not mix and interchange different specimens.

Specimen Collection

- 1) **Venous blood collection:** Collect the Whole blood in the collection tubes containing anticoagulants like EDTA, Heparin, Sodium citrate or ACD by venipuncture.
- 2) **Plasma collection:** Collect the Whole blood in the collection tubes containing anticoagulants like EDTA, Heparin, Sodium citrate or ACD by venipuncture and centrifuge it at 3000 g for 10-15 minutes to obtain Plasma.
- 3) **Serum collection:** Collect Whole blood in the collection tubes without having any anticoagulants by venipuncture. Keep it in standing position for 30 minutes and centrifuge it at 3000 g for 10-15 minutes to obtain serum.
- 4) **Capillary whole blood specimen collection:**



Sidelock confirms integrity of lancet. Verify the seal before detaching the cap.

- Wear gloves and massage the fingertip gently. It will help to obtain a round drop of blood.
- Wipe the complete fingertip with the alcohol swab provided and wait until the fingertip dried completely.
- Verify the seal before detaching the cap. Sidelock confirms integrity of sterile twist lancet. Squeeze the fingertip then prick the lateral side (avoid callus) of the fingertip with sterile twist lancet provided. Safely dispose of the used sterile twist lancet in sharps container immediately after use.
- Wipe the first drop of the blood using sterile gauze. Without pressing too hard, gently squeeze fingertip once again to obtain the second drop of blood (~40-50 µl).
- Take the specimen transfer device provided and hold it vertically. Gently squeeze the bulb of specimen transfer device and immerse open end in the center of a blood drop and release the bulb slowly to draw up the blood up to the 20 µl marking line on the specimen transfer device.
- Do not use the specimen transfer device having no marking. After completion of specimen collection, take the sterile gauze and apply pressure to the wound site to stop the bleeding. The specimen transfer device is for single use only.

Note: Sterile twist lancet is for single use only. Do not share used sterile twist lancet with another person. Dispose of used sterile twist lancet in sharp box and alcohol swab in biohazard waste container immediately after use.

Do not use expired sterile twist lancet. Use of any expired sterile twist lancet may cause infections at the punctured skin due to the expiry of its sterility. Use new sterile twist lancet, alcohol swab and specimen transfer device and choose a different puncture site, if another finger pricking is required.

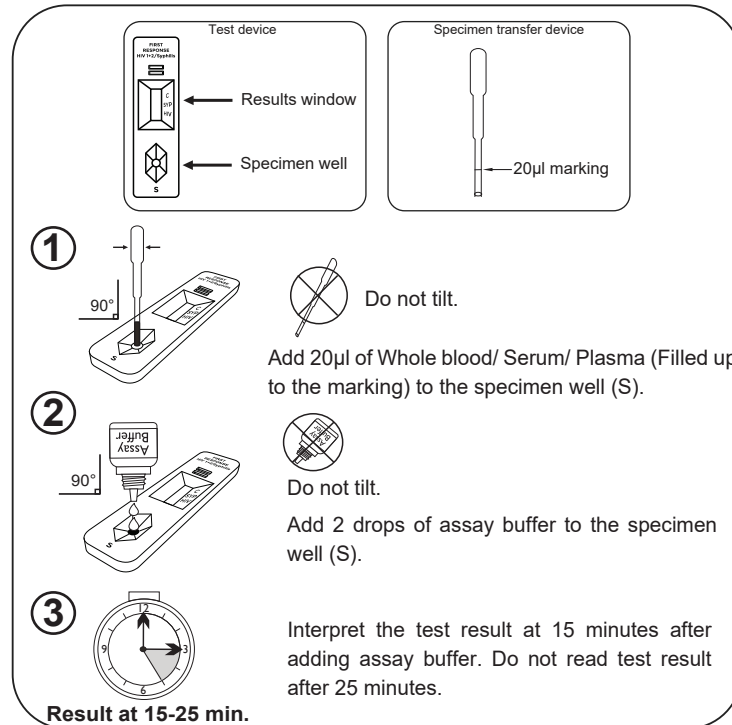
Specimen storage

- 1) Venous whole blood specimen should be used for testing immediately (within 1 hour) or shall be stored at 2-8°C for up to 72 hours (3 days). Do not use whole blood specimen stored for more than 3 days, it can cause a non-specific reaction. Do not freeze whole blood specimens. Note: Mix the whole blood specimens in the tube by inverting the tube 3 or 4 times before use.
- 2) If serum or plasma specimens are not immediately tested, then they should be refrigerated at 2-8°C. For storage period greater than 72 hours (3 days), freezing at ≤-20°C is recommended up to 4 months.
- 3) Venous whole blood, serum and plasma specimens stored at 2-8 °C must be brought to room temperature before use. Serum or plasma specimens stored at ≤-20°C must be thawed at 15 to 25°C. Avoid more than 2 freeze-thaw cycles.

- 4) Serum or plasma specimens containing precipitate may yield inconsistent test results. Such specimens must be centrifuged at 5000 g for 10 minutes and then use clear supernatants for testing.

Test Procedure

- 1) Ensure that the test device & other components are at room temperature (15°C to 30°C) before starting the procedure.
- 2) Open the device pouch, take out the test device from aluminum pouch. Do not use the test device if the desiccant color has changed from orange to green.
- 3) Label the test device with the patient identification number. Place the test device on a flat, clean and dry surface.
- 4) Take out the specimen transfer device from plastic bag provided inside the kit. Gently squeeze the bulb of specimen transfer device and immerse the open end in the specimen and release the bulb slowly to draw up the serum/plasma/capillary or venous whole blood up to 20µl marking line on the specimen transfer device.
- 5) Gently wipe away the excess specimen from the outer surface of the specimen transfer device with tissue paper before dispensing the specimen into the specimen well.
- 6) Gently squeeze the bulb of specimen transfer device to add 20 µl of venous or capillary whole blood/ serum/ plasma to the specimen well by gently touching the tips of the specimen transfer device to the sample pad. Caution: Dispose of used specimen transfer device and tissue paper as biohazard waste immediately after use.
- 7) Hold the assay buffer bottle vertically and add two drops of assay buffer to the specimen well (S).
- 8) Observe for development of purple colored lines in the results window. Interpret test results at 15 minutes after adding assay buffer to the specimen well (S).
- 9) Do not interpret the test result after 25 minutes.



Caution

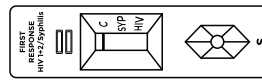
- Hold the specimen transfer device and assay buffer bottle vertically, else it can lead to inaccurate results.
- Exactly 2 drops of assay buffer should be added. Adding more than 2 drops of assay buffer may cause over flooding or reverse migration phenomenon, which may lead to inaccurate results of the test.
- Adding less than 2 drops of assay buffer may cause improper migration and poor background clearance which may lead to inaccurate results of the test.
- Do not read the test result after 25 minutes. Reading the result after the 25 minutes may give inaccurate results. After recording the results, dispose of the used test device as biohazard waste.

Internal Quality Control

The visualization of the purple colored Control Line in First Response® HIV 1+2 / Syphilis Combo Card Test indicates that the active ingredient of the strips are functional and the migration is successful. The control line is a procedural control serves to demonstrate functional reagents and correct migration of fluid. ②

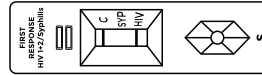
How to Interpret test results

Negative results

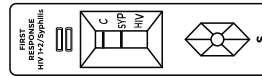


If only a single purple colored line appears, at control line "C" as in the figure, then the specimen is non-reactive for antibodies to Syphilis and HIV.

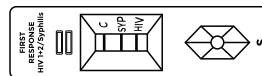
Positive results



HIV 1 and/or HIV 2

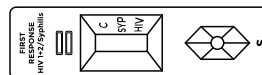


Syphilis Positive

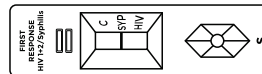


HIV 1 and/or HIV 2 and Syphilis Positive

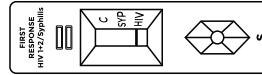
Invalid results



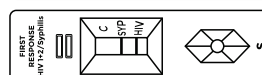
No presence of purple colored control line 'C' in the results window (irrespective of the presence of purple colored test lines) indicates an invalid result.



The directions may not be followed correctly or the test may have deteriorated.



The Invalid test results should be retested with a new test device.



Performance Characteristics

First Response® HIV 1+2 / Syphilis Combo Card Test has been tested using an in-house panel of Positive and Negative clinical specimens characterized by a commercial anti-HIV 1&2 ELISA kit and TPHA kit. First Response® HIV 1+2 / Syphilis Combo Card Test showed 100% sensitivity and 100% specificity. First Response® HIV 1+2 / Syphilis Combo Card Test showed 100% agreement with reference assays.

| Reference Method | Specimen details | First Response® HIV 1+2/Syphilis Combo Card | | | | |
|---|--|---|--------------|-------------------|-------------------|-------------|
| | | HIV Positive | HIV Negative | Syphilis Positive | Syphilis Negative | Total |
| ELISA RDT Commercially available | HIV Positive and Syphilis Negative Plasma specimens | | | | | |
| | HIV 1 Positive Plasma Specimen | 131 | 0 | 0 | 131 | 131 |
| | HIV 2 Positive Plasma Specimen | 6 | 0 | 0 | 6 | 6 |
| | Syphilis Positive and HIV Negative Plasma specimens | | | | | |
| | Syphilis Positive plasma Specimen | 0 | 46 | 46 | 0 | 46 |
| | HIV and Syphilis Positive Plasma specimens | | | | | |
| | HIV and Syphilis Positive plasma Specimen | 40 | 0 | 40 | 0 | 40 |
| | HIV and Syphilis Negative Plasma specimens | | | | | |
| | Negative Plasma Specimen | 0 | 370 | 0 | 370 | 370 |
| | Total Plasma specimens | 177 | 416 | 86 | 507 | 593 |
| | HIV Positive and Syphilis Negative Serum specimens | | | | | |
| | HIV 1 Positive Serum Specimen | 419 | 0 | 0 | 419 | 419 |
| | HIV 2 Positive Serum Specimen | 85 | 0 | 0 | 85 | 85 |
| | Syphilis Positive and HIV Negative Serum specimens | | | | | |
| | Syphilis Positive Serum Specimen | 0 | 101 | 101 | 0 | 101 |
| | HIV and Syphilis Negative Serum specimens | | | | | |
| | Negative Serum Specimen | 0 | 3455 | 0 | 3455 | 3455 |
| | Total Serum specimens | 504 | 3556 | 101 | 3959 | 4060 |
| | HIV Positive and Syphilis Negative Whole blood specimens | | | | | |
| | HIV Positive Whole blood specimen | 20 | 0 | 0 | 20 | 20 |
| | Syphilis Positive and HIV Negative Whole blood specimens | | | | | |
| | Syphilis Positive Whole blood specimen | 0 | 34 | 34 | 0 | 34 |
| | HIV and Syphilis Positive Whole blood specimens | | | | | |
| HIV and Syphilis Positive Whole blood Specimen | 31 | 0 | 31 | 0 | 31 | |
| HIV and Syphilis Negative Whole blood specimens | | | | | | |
| Negative Whole Blood Specimen | 0 | 217 | 0 | 217 | 217 | |
| Total Whole blood specimens | 51 | 251 | 65 | 237 | 302 | |

| Reference Method | Specimen details | | First Response® HIV 1+2 / Syphilis Combo Card Test | | | |
|----------------------------------|--|-----------------|--|-----------------|---------------|-------------------------|
| | | | Positive | Negative | Total Result | 95% Confidence Interval |
| ELISA RDT Commercially available | Test Marker | Parameter | Plasma Specimens | | | |
| | | | HIV | Sensitivity 177 | 00 | 177 |
| | Syphilis | Sensitivity 86 | 00 | 86 | (94.67%-100%) | |
| | | Specificity 00 | 507 | 507 | (99.06%-100%) | |
| | Serum Specimens | | | | | |
| | HIV | Sensitivity 504 | 00 | 504 | (99.05%-100%) | |
| | | Specificity 00 | 3556 | 3556 | (99.86%-100%) | |
| | Syphilis | Sensitivity 101 | 00 | 101 | (95.43%-100%) | |
| | | Specificity 00 | 3959 | 3959 | (99.87%-100%) | |
| | Whole blood Specimens (Capillary and venous blood) | | | | | |
| | HIV | Sensitivity 51 | 00 | 51 | (91.27%-100%) | |
| | | Specificity 00 | 251 | 251 | (98.12%-100%) | |
| Syphilis | Sensitivity 65 | 00 | 65 | (93.04%-100%) | | |
| | Specificity 00 | 237 | 237 | (98.01%-100%) | | |

Seroconversion Panel Testing

The Analytical sensitivity of the First Response® HIV 1+2 / Syphilis Combo Card Test was carried out by testing commercially available Seroconversion panel. The commercially available HIV/Syphilis combo rapid lateral flow test was used as a reference kit for comparative performance study. Twenty-two (22) seroconversion panel was tested, in-house.

| Analytical Sensitivity - In - House Evaluation | | | | | | | |
|--|-----------------|--|----------|-------------------|---|----------|-------------------|
| Total Seroconversion Panels | Total Specimens | First Response® HIV 1+2 / Syphilis Combo Card Test | | | Reference HIV/Syphilis Combo rapid lateral flow test. | | |
| | | Positive | Negative | Detection Index** | Positive | Negative | Detection Index** |
| 22 | 130 | 36 | 94 | 0.27 | 35 | 95 | 0.26 |

** Detection Index = Total number of positive specimen by test kit / Total number of specimens.

Cross-Reactivity Study

First Response® HIV 1+2 / Syphilis Combo Card Test was tested with other diseases/conditions, which may give cross-reactivity with the test. The following 18 potential cross-reacting diseases/conditions did not affect the performance of the First Response® HIV 1+2 / Syphilis Combo Card Test.

| Specimen details | HIV Negative | HIV Positive | Syphilis Negative | Syphilis Positive | Specimen details | HIV Negative | HIV Positive | Syphilis Negative | Syphilis Positive |
|----------------------------------|--------------|--------------|-------------------|-------------------|--|--------------|--------------|-------------------|-------------------|
| <i>P.falciparum</i> Positive | 05 | Not Tested | 05 | Not Tested | HSV 1/2 Positive [†] | 05 | 16 | 05 | 08 |
| Pan Malaria Positive | 05 | Not Tested | 05 | Not Tested | HTLV- I Ab Positive [†] | 07 | 08 | 07 | 04 |
| Dengue NS1 Positive [†] | 05 | 08 | 05 | 04 | HTLV- II Ab Positive [†] | 09 | 08 | 09 | 04 |
| Pregnant Woman [†] | 320 | 02 | 321 | 01 | HSV - I IgG Positive [†] | 08 | 08 | 08 | 04 |
| CMV Positive [†] | 03 | 08 | 03 | 04 | Rubella IgG & IgM Positive [†] | 15 | 16 | 15 | 08 |
| ANA Positive [†] | 04 | 08 | 04 | 04 | HBV Positive [†] | 103 | 08 | 103 | 04 |
| HAV Positive [†] | 04 | 08 | 04 | 04 | Chikungunya Positive [†] | Not tested | 08 | Not tested | 04 |
| EBV Positive [†] | 02 | 08 | 02 | 04 | Anti-malarial drug medication [†] | 04 | 08 | 04 | 04 |
| HCV Positive [†] | 103 | 08 | 103 | 04 | Anti-TB drug medication [†] | 05 | 10 | 05 | 05 |

Note : [†] Naturally appeared HIV and Syphilis positive specimens.

* Spiked HIV and Syphilis positive specimens.

Potential interference substances

The First Response® HIV 1+2 / Syphilis Combo Card Test was tested with potential interfering substances. The following 08 potential interfering substances did not affect the performance of First Response® HIV 1+2 / Syphilis Combo Card Test. However, Haemolysed specimens and lipaemic specimens showed poor background clearance, hence not recommended for testing. Lipaemic specimens can be used for the testing after centrifugation. Such specimens must be centrifuged at 5000 g for 10 minutes and use the supernatants for testing.

| Specimen Details | HIV Negative | HIV Positive | Syphilis Negative | Syphilis Positive | Specimen Details | HIV Negative | HIV Positive | Syphilis Negative | Syphilis Positive |
|-------------------------------------|--------------|--------------|-------------------|-------------------|---|--------------|--------------|-------------------|-------------------|
| Lipaemic specimen ^{**} , # | 25 | 08 | 25 | 04 | Low Hematocrit specimens | 05 | Not tested | 05 | Not tested |
| Icteric specimens [†] | 05 | 08 | 05 | 04 | Whole blood specimen in ACD anticoagulant | 182 | Not tested | 182 | Not tested |
| Haemolytic specimens ^{**} | 05 | Not tested | 05 | Not tested | RF Ab Positive [†] | 09 | 08 | 09 | 04 |
| High Hematocrit specimens | 05 | Not tested | 05 | Not tested | dsDNA Antibody Positive Plasma [†] | 01 | 08 | 01 | 04 |

Potential interference Drug substances

The details of interfering drug molecules are mentioned in the following table. Each interfering drug molecule substances were spiked at the final concentration of 250µg/ml in HIV 1, HIV 2 and Syphilis, positive as well as negative specimens, respectively. No false positive or false negative results were observed with any of drug molecules when tested with First Response® HIV 1+2 / Syphilis Combo Card Test.

| | | | | |
|--------------------|-------------------------------|-----------------|-------------------|------------------------|
| Diclofenac | Naproxen IP | Acetaminophen | Rifampicin | Ibuprofen |
| Folic acid | Pantoprazole | Pyrazinamide | Metformin | Aspirin |
| Ecosprin | Hydrochlorothiazide | Cholecalciferol | Isoniazid | Ampicillin Sodium salt |
| Magnesium sulphate | Ascorbic Acid (Limec) | Ritonavir | Ferrous Ascorbate | Nevirapine |
| Daruvir | Cyclobenzaprine Hydrochloride | | | |

Precision

The precision of the First Response® HIV 1+2 / Syphilis Combo Card Test was determined by using the 21 different specimens containing different concentrations of antibodies in 5 different replicates with 3 different lots of test devices. Between-run and within-run precision were observed 100%.

External Evaluation Report

| Place of Evaluation | Year | Sensitivity | | Specificity | |
|---|------|--------------------------|------------------------|------------------------|-------------------------|
| | | Syphilis | HIV | Syphilis | HIV |
| Zimbabwe (Plasma) | 2015 | 100% (92.94%-100%) | 100% (95.60%-100%) | 100% (98.00%-100%) | 100% (97.59%-100%) |
| Ghana (Serum/Plasma) | 2017 | 100% (94.29%-100%) | 100% (94.29%-100%) | 100% (96.88%-100%) | 100% (96.88%-100%) |
| WHO evaluation (Serum/Plasma) | 2018 | 99.0% (96.4% - 99.9%) | 100% (98.2% - 100%) | 100% (98.2% - 100%) | 99.5% (97.2% - 100%) |
| Ghana (Capillary vs Venus whole blood specimen) | 2018 | 100% (87.35%-100%) | 100% (96.19%-100%) | 100% (97.71%-100%) | 100% (96.07%-100%) |
| Zimbabwe (Pregnant women whole blood specimen) | 2019 | 100% (87.01%-100%) | 100% (96.55%-100%) | 100% (98.06%-100%) | 100% (96.69%-100%) |

Limitations

- Do not use anti-coagulants other than heparin, EDTA, and sodium citrate.
- Do not use the haemolysed specimen. A haemolysed specimen may give reddish background even after the end of test time.
- Interpret a faint line as a positive line. Repeat the test in case of a very faint test line or if have any doubt for the test line.
- Although a positive result may indicate an infection of HIV 1 and/or HIV 2 or Syphilis (*Treponema pallidum*), a diagnosis of diseases can only be made on clinical grounds. This test should not be used as the sole criteria for the diagnosis of HIV/ *Treponema pallidum*.
- For confirmation, further analysis of the specimens should be performed, such as ELISA, or western blot analysis for HIV and TPHA for Syphilis. As with all diagnostic tests, results must be interpreted together with other clinical information available to the physician.
- False negative results may arise because of hook effect due to a very high titer of antibody in a specimen. Repeat the test by using 1:10 dilution of the same specimen (01 portion) in respective non-reactive specimen matrix (09 portions).
- A non-reactive result does not eliminate the possibility of infection with HIV1/2 and/or *Treponema pallidum*. The specimen may contain a low level of antibodies that cannot be detected by First Response® HIV 1+2 / Syphilis Combo Card Test. If a test result is non-reactive and clinical symptoms persists, additional testing using other reference method is recommended and/or retested for HIV antibodies after more than 21 days since the original testing.
- Some HIV infected persons on antiretroviral medication may produce false negative results when tested with rapid diagnostic tests.

| SYMBOL LEGENDS | | | |
|----------------|------------------------------------|--------|--|
| Symbol | Explanation of symbol | Symbol | Explanation of symbol |
| | Consult instructions for use | | Contains sufficient for < n > tests |
| | Non Sterile | | Product Code |
| | In vitro diagnostic medical device | | Lot Number |
| | Store at 4-30 °C | | Manufacturer |
| | Caution | | Date of manufacture (YYYY-MM) |
| | Keep dry | | Expiration Date (YYYY-MM) |
| | Do not reuse | | Do not use if test device pouch is damaged |
| | Keep away from sunlight | | |

References:

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- Mwumvaneza Mutagoma, Eric Remera, Dieudonné Sebuhero, Steve Kanters, David J. Riedel, and Sabin Nsanzimana, "The Prevalence of Syphilis Infection and Its Associated Factors in the General Population of Rwanda: A National Household-Based Survey," Journal of Sexually Transmitted Diseases, vol. 2016, Article ID 4980417, 8 pages, 2016. <https://doi.org/10.1155/2016/4980417>.

Product Disclaimer & Warnings

Every warnings and precaution should be taken into consideration before using the test. Failure to consider "Precaution, Warning, and Limitations" may not ensure the diagnostic ability and accuracy of this product. The test result may accordingly be affected by environmental factors and/or user error outside of the control of the Manufacturer and Distributor.

A definitive clinical diagnosis should not be based on the results of a single test, but it should be made by the physician after all clinical and laboratory findings have been evaluated.

"In no event shall our company or its distributor is liable for any direct, indirect, punitive, unforeseen, incidental, special consequential damages, to property or life, whatsoever arising out of or connected with an incorrect diagnosis, whether positive or negative, in the use or misuse of this product". In the event of performance changes or product malfunction, please contact manufacturer.



Manufactured by
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• ISO 13485 & EN ISO 13485 Certified Company

Part No.(S)I20-INS-007, Rev.: AB, Date:2020-02-17

ENGLISH

Note : Instructions for use will be printed in local language of the country using the test, if required.



FIRST RESPONSE® HIV 1+2 / SYPHILIS COMBO CARD TEST

Rapid immunochromatographic Card Test for detection of Antibodies to HIV and/or Syphilis in human whole blood/ serum/ plasma

REF I20FRC25, I20FRC30, I20FRC50, I20FRC60 & I20FRC100

Intended Use

First Response® HIV 1+2 / Syphilis Combo Card Test is intended for use by healthcare professionals and qualified laboratory personnel. It is a rapid, qualitative screening, in vitro diagnostic test for the detection of antibodies (IgG & IgM) specific to HIV (type 1 & 2) and *Treponema pallidum* in human serum, plasma or venous and capillary whole blood. The test can be used as an aid in the diagnosis of HIV and/or Syphilis. The product can be used for symptomatic, asymptomatic and pregnant women population. The test kit is not automated and does not require any additional instrument. Reactive specimens should be confirmed by supplemental testing with ELISA, Western Blot or TPHA.

Introduction

HIV (Human Immunodeficiency Virus) is recognized as the etiologic agent of Acquired Immune Deficiency Syndrome (AIDS). The virus is transmitted by sexual contact, exposure to infected blood, certain body fluids or tissues, and from mother to fetus or child during the perinatal period.

Syphilis is a venereal disease caused by the spirochete bacterium *Treponema pallidum*. It is ordinarily transmitted by sexual contact. It can also be transmitted congenitally by the transplacental passage of mother to the fetus and by blood transfusion. In a case where a patient is infected with HIV as well as Syphilis, it increases the chances of HIV transmission by increasing viral shedding and seminal viral load. The prevalence of HIV is 3 times more in patients infected with Syphilis compared to those not infected with Syphilis infection(14). Incorporating Syphilis screening in HIV prevention programs will help to prevent mother to child transmission of HIV and Syphilis. This can be achieved by the implementation of a simple and affordable dual testing strategy for HIV and Syphilis which could improve screening uptake and accessibility of testing to accelerate time to treatment.

WHO has reported a significantly high number of HIV and Syphilis co-infection in mother to child transmission (MTCT) in Africa. Therefore, the WHO has announced in June 2012 that Prevention of Mother to Child Transmission (PMTCT) should not be considered alone for HIV but considered for HIV and/or Syphilis both, with a vision to eliminate new HIV infections to children by 2015(12). To achieve this vision each pregnant woman should be tested for Syphilis and HIV both rather than HIV only. Development of a single test device containing HIV and Syphilis antigens will solve the issue defined above and will also be a useful step in achieving WHO's ambitious goal.

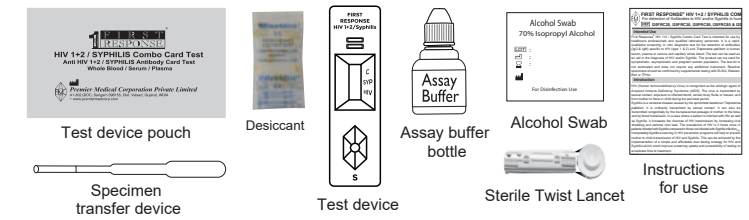
Assay Principle

First Response® HIV 1+2 / Syphilis Combo Card Test is based on the principle of immunochromatography for the qualitative detection of antibodies(IgG & IgM) specific for HIV 1&2 and/or Syphilis. The nitrocellulose membrane is coated with a cocktail of recombinant antigen for HIV 1 (gp41) and HIV 2 (gp36) at test line "HIV" and Recombinant TP antigen (P47, P45, P17, P15) specific for *Treponema pallidum* at the test line "Syp" and control reagent coated at the control line "C". When serum or plasma or whole blood specimen is applied to the specimen well of the test device, the cocktail of recombinant HIV 1+2 (gp41 & gp36) antigen - colloidal gold conjugate (CGC) & recombinant *Treponema pallidum* antigens colloidal gold conjugate will react with HIV and/or Syphilis specific antibodies, if present in the specimen. The antibody-CGC antigen complex and assay buffer move along the membrane chromatographically to the test regions and form a visible purple colored line as the antigen-antibody-CGC antigen complex forms with a high degree of sensitivity and specificity. If the specimen contains antibodies to *Treponema pallidum*, the purple colored line will appear in the test area at test line "Syp", corresponding to the Syphilis line. If the specimen contains antibodies to HIV 1 and/or 2, the purple colored line will appear in the test area at test line "HIV", corresponding to HIV 1+2 line.

The presence of both test lines indicates that the specimen contains antibodies to HIV as well as *Treponema pallidum*. The absence of the purple colored line at both test line regions indicates that the specimen is non-reactive for HIV and *Treponema pallidum*, showing a negative result. The purple colored Control line will appear irrespective of a reactive or non-reactive specimen. The control line is a procedural control, serves to demonstrate functional reagents and correct migration of fluid.



Materials Provided



Note: Materials provided other than assay buffer bottle are for single use only.

| Materials provided | I20FRC25 | I20FRC30 | I20FRC50 | I20FRC60 | I20FRC100 |
|--|----------|----------|----------|----------|-----------|
| Test device pouch containing: 1 test device, 1 desiccant | 25 Nos. | 30 Nos. | 50 Nos. | 60 Nos. | 100 Nos. |
| Specimen transfer device | 25 Nos. | 30 Nos. | 50 Nos. | 60 Nos. | 100 Nos. |
| Assay buffer bottle (2.5 ml) | 1 No. | 1 No. | 2 Nos. | 4 Nos. | 4 Nos. |
| Sterile twist lancets | 25 Nos. | 30 Nos. | 50 Nos. | 60 Nos. | 100 Nos. |
| Alcohol swabs | 25 Nos. | 30 Nos. | 50 Nos. | 60 Nos. | 100 Nos. |
| Instructions for use | 1 No. | 1 No. | 1 No. | 1 No. | 2 Nos. |

Materials Required but Not Provided

- New pair of disposable gloves and face mask for each test conducted/specimen collected by Fingerstick.
- Sterile gauze pad and tissue paper.
- Permanent marker pen and timer.
- Extra sterile twist lancets, alcohol swabs, and specimen transfer devices, if needed.
- Sharp disposable box and biohazardous waste container.
- Venipuncture blood collection kit (if whole blood is collected by venipuncture).

Storage and Stability

- First Response® HIV 1+2 / Syphilis Combo Card Test kit should be stored at 4-30°C.
- Do not freeze the kit or components.
- The kit is sensitive to humidity and heat. Do not store the kit at the temperature above 30°C and in humid conditions.
- Assay buffer (opened & unopened) & the unopened test device are stable until the expiry date printed on the label when stored at 4-30°C.
- Perform the test immediately after removing the test device from the aluminium pouch. If the desiccant color has changed from orange to green, do not use the test device.
- Test device is stable until the printed expiry date on the pouch/external secondary packaging.

Precautions

- Wear protective gloves and face mask while handling specimens.
- Dispose of used gloves as biohazard waste. Wash hands thoroughly afterward.
- Avoid splashing or aerosol formation.
- Clean up spills thoroughly using an appropriate disinfectant.
- Decontaminate and dispose of all used specimens, test devices, alcohol swabs, and specimen transfer devices as infectious waste, in a biohazardous waste container. Dispose of used sterile twist lancets in a sharps box and face mask in a waste container.

Warnings

- For in vitro diagnostic use only.
- Read the instructions carefully before performing the test, any deviation will invalidate the test results.
- Apply standard biosafety precautions for handling and disposal of potentially infective materials including human biological specimens irrespective of the disease state.
- Do not drink the assay buffer. It contains sodium azide as a preservative which may be toxic if ingested. When disposed of through sink, flush with a large quantity of water.
- Devices and assay buffer of a different lot must not be used.