WHO Prequalification of In Vitro Diagnostics
PUBLIC REPORT

Product: First Response HIV1+2/Syphilis Combo Card Test
WHO reference number: PQDx 0364-010-00

First Response HIV1+2/Syphilis Combo Card Test with product codes I20FRC25, I20FRC30, I20FRC50, I20FRC60, and I20FRC100, manufactured by Premier Medical Corporation Private Limited, Rest of World regulatory version, was accepted for the WHO list of prequalified in vitro diagnostics and was listed on 24 June 2019.

Summary of WHO prequalification assessment for First Response HIV1+2/Syphilis Combo Card Test

<table>
<thead>
<tr>
<th>Date</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prequalification listing</td>
<td>24-Jun-2019</td>
</tr>
<tr>
<td>Dossier assessment</td>
<td>02-May-2019</td>
</tr>
<tr>
<td>Site inspection(s) of quality management system</td>
<td>12-Mar-2018</td>
</tr>
<tr>
<td>Product performance evaluation</td>
<td>Q1 of 2018</td>
</tr>
</tbody>
</table>

MR: Meets Requirements

This public report has since been amended. Amendments may have arisen because of changes to the prequalified product for which WHO has been notified and has undertaken a review. Amendments to the report are summarized in the following table, and details of each amendment are provided below.

<table>
<thead>
<tr>
<th>Version</th>
<th>Summary of amendment</th>
<th>Date of report amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.0</td>
<td>A new specimen transfer device having (20 μl marking line) is introduced to make it more user friendly”</td>
<td>19-Feb-2020</td>
</tr>
</tbody>
</table>

Intended use

According to the claim of intended use from Premier Medical Corporation Private Limited “First Response HIV 1+2 / Syphilis Combo Card Test is intended for use by healthcare professionals and trained user. 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 diagnosis of HIV and/or Syphilis. The product is intended to be used for
symptomatic, asymptomatic as well as pregnant women population. The test kit is not automated and does not require any additional instrument. Reactive specimens should be confirmed further with ELISA, Western Blot or TPHA ".

**Assay description**

According to the claim of assay description from Premier Medical Corporation Private Limited “First Response HIV 1+2 / Syphilis Combo Card Test is based on the principle of immunochromatography for qualitative detection of antibodies (IgG & IgM) specific for HIV 1&2 and/or Syphilis. The nitrocellulose membrane is coated with 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 control line “C”. When a serum or plasma or whole blood specimen is applied to the specimen well of 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 line as the antigen-antibody-CGC antigen complex forms with high degree of sensitivity and specificity.

*If the specimen contains antibodies to Treponema pallidum, the colored line will appear in the test area at test line “Syp”, corresponding to Syphilis line. If the specimen contains antibodies to HIV 1 and/or 2, the colored line will appear in the test area at test line “HIV”, corresponding to HIV 1+2 line”

**Test kit contents**

<table>
<thead>
<tr>
<th>Component</th>
<th>25 tests (product code I20FRC25)</th>
<th>30 tests (product code I20FRC30)</th>
<th>50 tests (product code I20FRC50)</th>
<th>60 tests (product code I20FRC60)</th>
<th>100 tests (product code I20FRC100)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test device pouch containing: 1 test device, 1 desiccant</td>
<td>25</td>
<td>30</td>
<td>50</td>
<td>60</td>
<td>100</td>
</tr>
<tr>
<td>Specimen transfer device</td>
<td>25</td>
<td>30</td>
<td>50</td>
<td>60</td>
<td>100</td>
</tr>
<tr>
<td>Assay buffer bottle</td>
<td>1 of 2.5 ml</td>
<td>1 of 2.5 ml</td>
<td>2 of 2.5 ml</td>
<td>4 of 2.5 ml</td>
<td>4 of 2.5 ml</td>
</tr>
<tr>
<td>Sterile twist lancets</td>
<td>25</td>
<td>30</td>
<td>50</td>
<td>60</td>
<td>100</td>
</tr>
<tr>
<td>Alcohol swabs</td>
<td>25</td>
<td>30</td>
<td>50</td>
<td>60</td>
<td>100</td>
</tr>
<tr>
<td>Instructions for use</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>
Items required but not provided

- New pair of disposable gloves and face mask.
- Permanent Marker pen and timer
- Extra lancets and alcohol swabs, if needed
- Sharp disposable box and biohazardous waste container
- Venipuncture blood collection kit (if whole blood is collected by venipuncture
- Sterile gauze pads

Storage
The test kit should be stored at 4-30 °C.

Shelf-life upon manufacture
24 months.

Warnings/limitations
Refer to current version of manufacturer’s instructions for use.

Prioritization for prequalification

Based on the established eligibility criteria, First Response HIV 1+2 / Syphilis Combo Card Test was given priority for WHO prequalification assessment.

Dossier assessment

Premier Medical Corporation Private Limited submitted a product dossier for First Response HIV1+2/Syphilis Combo Card Test as per the “Instructions for compilation of a product dossier” (PQDx_018 version 3). The information (data and documentation) submitted in the product dossier was reviewed by WHO staff and external technical experts (assessors) appointed by WHO.

The manufacturer's responses to the nonconformities found during dossier screening and assessment findings were accepted on 02 May 2019.

Based on the product dossier screening and assessment findings, the product dossier for First Response HIV1+2/Syphilis Combo Card Test meets WHO prequalification requirements.
Manufacturing site inspection

A comprehensive inspection was performed at the site of manufacture Premier Medical Corporation Private Limited, Sarigam, Gujarat, India of First Response HIV1+2/Syphilis Combo Card Test in March 2018 as per the “Information for manufacturers on prequalification inspection procedures for the sites of manufacture of diagnostics” (PQDx_014 version 4). The inspection found that the manufacturer had an acceptable quality management system and good manufacturing practices in place that ensured the consistent manufacture of a product of good quality.

The manufacturer's responses to the nonconformities found at the time of the inspection were accepted on 30 August 2018.

Based on the site inspection and corrective action plan review, the quality management system for First Response HIV1+2/Syphilis Combo Card Test meets WHO prequalification requirements.

Product performance evaluation

First Response HIV 1+ 2/Syphilis Combo card test (Premier Medical Corporation Private Limited) is a single use, rapid, qualitative lateral flow immunochromatography assay for the detection of HIV-1/2 and syphilis antibodies in human serum/plasma, whole blood (finger stick, EDTA, heparin or sodium citrate). A volume of 20 µL of specimen is needed to perform the assay. This type of assay requires no sophisticated equipment and can therefore be performed in laboratories with limited facilities and non-laboratory settings. Reading of the results can be done visually i.e. subjectively read.

First Response HIV 1+ 2/Syphilis Combo card test (Premier Medical Corporation Private Limited) was evaluated by WHO in the first quarter of 2018 at the Institute of Tropical Medicine, Belgium, using serum/plasma specimens.

In this limited evaluation on a panel of 400 clinically-derived specimens, compared to the reference assays (HIV reference algorithm: Vironostika HIV Ag/Ab [bioMérieux] EIA and Enzygnost Anti-HIV 1/2 Plus [Siemens Healthcare Diagnostics] EIA or Genscreen HIV-1/2 Version 2 [Bio-Rad]; followed by INNO-LIA HIV I/II Score [Fujirebio Inc.]; Syphilis reference algorithm: Vitros Syphilis TPA Assay [Ortho Clinical Diagnostics], followed by SERODIA-TP.PA [Fujirebio Inc.]), the following results were obtained:
### Performance characteristics in comparison with an agreed reference standard

<table>
<thead>
<tr>
<th></th>
<th>HIV-1/2</th>
<th>Syphilis</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sensitivity %</strong></td>
<td>Initial (95% CI)</td>
<td>Final (95% CI)</td>
</tr>
<tr>
<td>(N=200)</td>
<td>100% (98.2% - 100%)</td>
<td>100% (98.2% - 100%)</td>
</tr>
<tr>
<td><strong>Specificity %</strong></td>
<td>99.0% (96.4% - 99.9%)</td>
<td>99.5% (97.2% - 100%)</td>
</tr>
<tr>
<td>(N=200)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Invalid rate</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Inter-reader variability</strong></td>
<td>0.5%</td>
<td></td>
</tr>
</tbody>
</table>

In addition, analytical performance characteristics were assessed using commercially available panels and the following results were obtained:

### Additional performance characteristics

<table>
<thead>
<tr>
<th></th>
<th>HIV-1/2</th>
<th>Syphilis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity during seroconversion in comparison with a benchmark assay</td>
<td>Seroconversion sensitivity index of 0, therefore detection is 0 specimens earlier/later than the benchmark assay (Enzygnost Anti-HIV 1/2 Plus) in average on 8 seroconversion panels</td>
<td>Seroconversion sensitivity index of -1, therefore detection is 1 specimen earlier than the benchmark assay (Vitros Syphilis TPA Assay) on one seroconversion panel</td>
</tr>
<tr>
<td>Analytical sensitivity on a mixed titer panel in comparison with an agreed reference standard</td>
<td>25 of 25 specimens were correctly classified.</td>
<td>17 of 17 specimens were correctly classified.</td>
</tr>
<tr>
<td>Lot to lot variation on a dilution panel</td>
<td>Acceptable</td>
<td>Acceptable – except for one 2-dilution difference in one of 10 dilution panels</td>
</tr>
</tbody>
</table>
### Key operational characteristics

<table>
<thead>
<tr>
<th>Validated specimen types</th>
<th>Serum, plasma (EDTA, heparin or sodium citrate), venous whole blood, capillary whole blood</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of steps</td>
<td>3 without precision required</td>
</tr>
<tr>
<td>Time to result</td>
<td>15 minutes</td>
</tr>
<tr>
<td>Endpoint stability</td>
<td>10 minutes (do not interpret after 25 minutes after addition of buffer)</td>
</tr>
<tr>
<td>Internal QC</td>
<td>Yes, control line on the test device</td>
</tr>
<tr>
<td>In-use stability of reagents</td>
<td>Assay buffer (opened &amp; unopened) &amp; the unopened test device are stable until the expiry date printed on the label when stored at 4-30°C.</td>
</tr>
</tbody>
</table>
Labelling

1. Labels
2. Instructions for use
1. Labels

1.1 Sterile safety lancet label

1.2 Alcohol swab labels
1.3 Assay buffer label

![Assay buffer label diagram]

1.4 Aluminum pouch labels

![Aluminum pouch labels diagram]

1.5 Outside box labels
Product: First Response HIV 1+2 / SYPHILIS Combo Card Test
Pack size: 25 Tests

Contents:
- Individually pouched test devices with desiccant
- Specimen transfer device
- Sterile lancet
- Alcohol swab
- Assay buffer bottle
- Instructions for use

Mfg. Lic. No.: 
LOT: 

First Response 
HIV 1+2 / SYPHILIS Combo Card Test 
Anti HIV 1+2 / SYPHILIS Antibody Detection Card Test (Whole Blood/Serum/Plasma)
Product: First Response HIV 1+2 / SYPHILIS Combo Card Test
Pack size: 30 Tests

Contents:
- Individually pouched test devices with desiccant
- Specimen transfer device
- Sterile lancet
- Alcohol swab
- Assay buffer bottle
- Instructions for use

Manufacturer:
Premier Medical Corporation Private Limited
A1 - 302, GIDC, Sarigam 396155, Dist. Valsad, Gujarat, INDIA
Customer support email: info@premiermedcorp.com
Tel.: +91 260 2780112/113, www.premiermedcorp.com
Product: First Response HIV 1+2 / Syphilis Combo Card Test
Pack size: 50 Tests
Product: First Response HIV 1+2 / SYPHILIS Combo Card Test
Pack size: 60 Tests

Contents:
• Individually pouched test devices with desiccant
• Specimen transfer device
• Sterile lancet
• Alcohol swab
• Assay buffer bottle
• Instructions for use: 60 Nos.
Content:
- Individually pouched test devices with desiccant
- Specimen transfer device
- Sterile lancet
- Alcohol swab
- Assay buffer bottle
- Instructions for use: 100 Nos.

Product: First Response HIV 1+2 / SYPHILIS Combo Card Test
Pack size: 100 Tests
2. Instructions for use

1 English version of the IFU was the one that was assessed by WHO. It is the responsibility of the manufacturer to ensure correct translation into other languages
Note: Sterile twist lancet is for single use only. Do not share used sterile twist lancet, alcohol swab and specimen transfer device and choose a different lancet, if another finger pricking is required.

Do not use expired sterile twist lancet. Use of any expired sterile twist lancet may puncture site, if another finger pricking is required.

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 specimen/plasma/serum whole blood up to 20 µl marking line on the specimen transfer device.

Do not use the test device and assay buffer beyond the date of expiry. Do not allow the tip of assay buffer bottle to touch specimen well as it may give inaccurate results. After recording the results, dispose of the used test device and other components as biohazard waste.

Internal Quality Control

If three purple colored lines appear, one at the control line 'C', second at the line Syphilis 'SYP' and third at the test line HIV 'HIV' as in the figure, then the specimen is reactive for antibodies to HIV 1 and/or HIV 2 and Syphilis. Note: Interpret faint lines as the reactive lines.

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 & 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. The following cross-reactivity study was carried out by testing commercially available Serocversion panel. The commercially available HIV/Syphilis combo rapid lateral flow test was used as a reference kit for comparative performance study.

Specific inhibition of the strips by interfering substances. The following 08 potential interfering substances did not affect the performance of the First Response® HIV 1/2 / Syphilis Combo Card Test.

Cross-Reactivity Study

Specimen Collection

1) Venous whole blood 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.

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 and centrifuge it at 3000 g for 10-15 minutes to obtain Serum.

4) Capillary whole blood specimen collection:

• Wear gloves and massage the fingertip gently. It will help to obtain a round drop of blood.

• Wipe the complete fingertip with sterile twist lancet. Squeeze the fingertip then prick the lateral side (avoid callus) of the fingertip with sterile twist lancet. Squeeze the fingertip then prick the lateral side (avoid callus) of the fingertip with sterile twist lancet. 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. Detach the protective cap of the sterile twist lancet. Squeeze the finger then press the lateral side (avoid callus) of the fingertip with sterile twist lancet provided. Squeeze the finger then press the lateral side (avoid callus) of the fingertip with sterile twist lancet provided. After completion of specimen collection, take the sterile gauge and apply pressure to the wound site to stop the bleeding. After completion of specimen collection, take the sterile gauge 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 erythema of 16 hours.

Specimen storage

1) Venous whole blood specimen should be used for testing immediately (within 1 hour) or shall be stored at 2-8°C and 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 specimen.

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 or 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 incorrect test results. Such specimens must be centrifuged at 5000 g for 15 minutes and then use clear supernatants for testing.

Test Procedure

1) Ensure that the test device & other components are at room temperature (2-25°C) before use. Do not use the test device and specimen transfer device as these are intended for single use only.

2) Open the test device pouch, take out the test device from aluminium 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 specimen/plasma/serum whole blood up to 20 µl marking line on the specimen transfer device.

5) Gently wipe the access 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 specimen to the specimen well by gently touching the open end of the test device to the specimen well after detaching the cap. Caution: Dispose of used specimen transfer device and tissue paper as biohazard 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). Do not interpret the test result after 25 minutes.

Result at 15-25 min.

Caution: Do not use 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 overflowing 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 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 and assay buffer.

Internal Quality Control

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

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

If two purple colored lines appear, one at the control line 'C' and other at the test line Syphilis 'SYP' as in the figure, then the specimen is reactive for antibodies to HIV 1 and/or HIV 2 and non-reactive for antibodies to Syphilis.

If two purple colored lines appear, one at the control line 'C', second at the line Syphilis 'SYP' and third at the test line HIV 'HIV' as in the figure, then the specimen is reactive for antibodies to HIV 1 and/or HIV 2 and Syphilis.

Invalid results

No presence of purple colored control line 'C' in the results window (irrespective of the presence of purple colored test line 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.

Venous whole blood, serum and plasma specimens stored at 2-8 °C must 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. Do not use whole blood specimen stored for more than 3 days, it can cause a non-specific reaction. Do not freeze whole blood specimen.

Plasma collection:

Centrifuge it at 3000 g for 10-15 minutes to obtain Plasma.

Plasma containing anticoagulants like EDTA, Heparin, Sodium citrate or ACD by venipuncture and store at 2-8 °C.

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.

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 the First Response® HIV 1/2 / Syphilis Combo Card Test.

The results are shown in the table by showing the Positive, Negative and Specificity details of the test.

Note: Normally appear HIV and Syphilis positive specimens.

Note: Seroconversion Panel Testing

Specimens details

First Response® HIV 1+2 / Syphilis Combo Card Test showed 100% agreement with reference kit for comparative performance study. Twenty-two (22) seroconversion panel was tested, in-house.

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-reactive diseases/conditions did not affect the performance of the First Response® HIV 1/2 / Syphilis Combo Card Test.
Between-run and within-run precision were observed 100% of antibodies in 5 different replicates with 3 different lots of test devices.

2) Do not use the haemolysed specimen. A haemolysed specimen may give drug molecules when tested with First Response® HIV 1+2 / Syphilis Combo Card.

Potential interference Drug substances

Since the original testing.

level of antibodies that cannot be detected by First Response® HIV 1+2 / Syphilis Combo Card Test.

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

Cautions

Do not reuse.

Keep away from sunlight.

Potential interference Drug substances

Hydrochlorothiazide

Cyclobenzaprine Hydrochloride

Daruvir

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 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 sexually transmitted concomitantly 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 (14). Incorporating Syphilis screening in existing 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 each pregnant woman should be tested for Syphilis and HIV both rather than HIV alone. 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.

ASA J 2015(12). To achieve this vision each pregnant woman should be tested for Syphilis and HIV both rather than HIV alone. 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.

2) Do not use the haemolysed specimen. A haemolysed specimen may give drug molecules when tested with First Response® HIV 1+2 / Syphilis Combo Card.

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 blood specimens. 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.

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 and Treponema pallidum. The nitrocellulose membrane is coated with a cocktail of recombinant antigen for HIV 1 (gp120) and HIV 2 (gp36) at test line “HIV” and Recombinant TP antigen (P47, P45, P17, P15) specific for Treponema pallidum at the control line “C”. The test device with serum or plasma blood specimen is applied to the specimen well of the test device, the cocktail of recombinant HIV 1+2 (gp120 & gp36) -antibody- colloidal gold conjugate and Recombinant Treponema pallidum antigens colloidal gold conjugate will react with HIV and/or Syphilis specific antibodies, if present in the specimen. The antibody-OCG antigen complex and assay buffer move along the membrane strip until it arrives at the test line and forms a visible red line as the antigen-antibody-OCT 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 “SYPHILIS”, corresponding to the Syphilis line. If the specimen contains antibodies to HIV 1+2 or 2, the purple colored line will appear in the test area at test line “HIV”, corresponding to the HIV 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.

Specifications

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 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 sexually transmitted concomitantly 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 (14). Incorporating Syphilis screening in existing 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 each pregnant woman should be tested for Syphilis and HIV both rather than HIV alone. 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.

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