TMDA/DMD/MDA/F/014
Rev #:00

THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

PUBLIC ASSESSMENT REPORT FOR FIRST RESPONSE (SYPHILIS ANTI-TP CARD TEST)

Version number 2.0, 18.05.2026

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Toll free: 0800110084

1. Introduction

First Response is a class C in-vitro diagnostic device/medical device belonging to the Clinical Microbiology labaratory specialty category. It is approved in Tanzania as a kit, for use in adults, children, elderly etc.by healthcare professionals.

1.1. Administrative Information

Registration number	TAN 24 MDR 0013
Brand Name (if relevant)	First Response
Common name	SYPHILIS ANTI-TP CARD TEST
Class of the device and rule applied	Class D as per Rule 3 for classification of In Vitro Diagnostic Devices
GMDN code and term	63969, Treponema pallidum immunoglobulin G (IgG)/IgM antibody IVD, kit, rapid ICT, Clinical
Name and complete address of the Market Authorization Holder	Premiere Medical Corporation Private Limited, A1-302, GIDC, Sarigam 396155, Dist. Valsad, Gujarat, India Tel: +91 9764751809
Name and address(es) of local responsible person (LRP).	ISW Group Limited, Ground Floor, Furaha Cinema House 14 Majengo Street, Furaha Road, P. O. Box 809, Singida. Tel: +255 758 174187 Email: iswgrouplimited@gmail.com

1.2. Assessment Procedure

The application for registration of First Response was submitted on 30.6.2023 The product underwent abridged assessment. Assessment was completed in 1 round of evaluation. First Response was registered on 04.12.2023.

2. Technical information

2.1. Intended use

The intended use of First Response as declared by the manufacturer and approved by TMDA is designed with a focus on detecting accurately Syphilis (treponema Pallidum) antigen-specific antibodies in serum/plasma/whole blood. First Response is approved for use in healthcare settings by trained professionals only.

2.2. Device details and features

First Response is a single device with no additional components or accessories. First Response has been registered as a kit which consists of Test device, Assay buffer, Accessories for performing the test (specimen transfer device, alcohol swab, lancet) and Instruction for use.

First Response is a manually operated device. It is used for diagnosis, screening of Syphilis. First Response operates by immunochromatography. The test out-put is qualitative.

The type of specimen used is serum, plasma or whole blood and is collected by venous blood collection and finger prick

2.3. Commercial presentation

There are three (03) approved commercial presentations as follows: One test device in the primary pouch. 25, 50 or 100 test devices are placed in a carton box

Additional contents include lancet, assay buffer, alcohol swab and instruction for use

2.4. Items required but not submitted

- New pair of disposable gloves and face mask for each test
- Sterile gauze pad.
- 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).

3. Storage instructions

3.1.1. Shelf-life

30 months.

3.1.2. Storage conditions

The recommended storage conditions are at 4-30^{0}C.

3.1.3. Shipping conditions

The recommended shipping conditions is not stated but calculated to be at 4-30^{0}C

4. Manufacturing site audit

The manufacturer of the device is Premiere Medical Corporation Private Limited,
A1-302, GIDC, Sarigam 396155, Dist. Valsad, Gujarat, India, Tel: +91 9764751809
Email: info@premieremedcorp.com

Quality audit of the manufacturing facility was conducted through site visit on not indicated
The site was found to be compliant to ISO 13485 requirements.

5. Performance Evaluation

5.1. Analytical Performance

The analytical performance characteristics of the device was established through the following test parameters: repeatability and reproducibility, analytical sensitivity and analytical specificity.

5.2. Clinical Performance

Clinical performance was conducted at Centers for Disease Control and Prevention during pre-qualification process. The following parameters were tested repeatability and reproducibility, clinical sensitivity and clinical specificity.

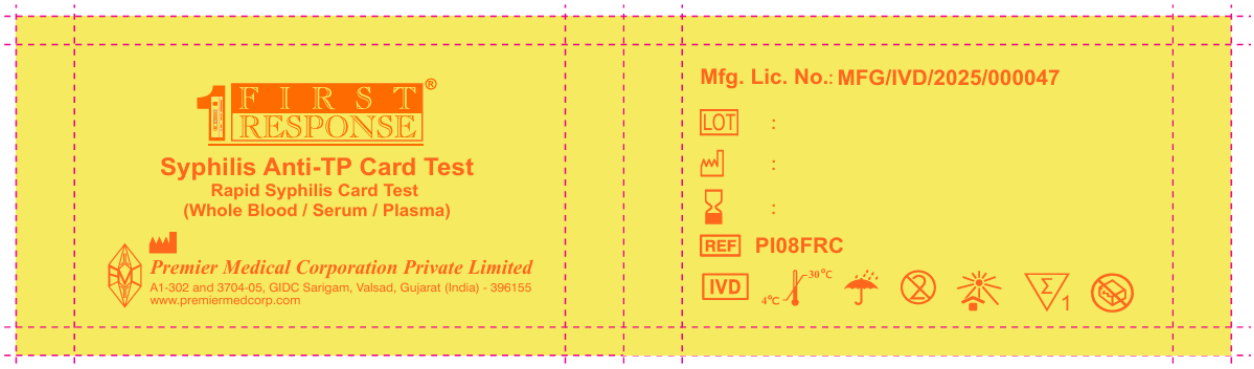
Based on results of the performance studies, it was concluded that the test sensitivity and specificity is 100% and 100% respectively. The studies further concluded that First Response is capable of consistently producing accurate and reliable test output.

6. Product label and instructions for use

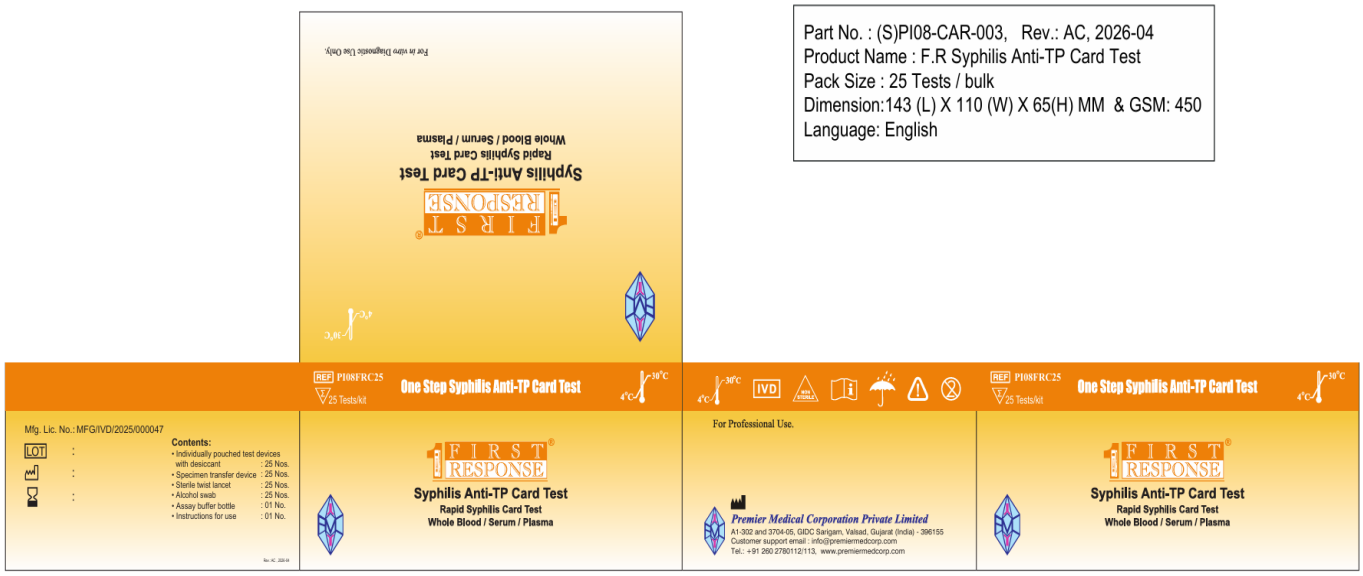
The content of the primary and secondary labels is in line with TMDA labeling requirements in terms of content, layout and design. The label contains sufficient information for proper identification of the device and post marketing follow up of the product in the market.

The package insert and instructions for use includes all the relevant information to ensure correct and safe use of the device by intended user.

6.1. Primary pack



6.2 Secondary pack



6.3 Instructions for use/Package insert

Kindly see the IFU on the last page

7. Risk – Benefit Analysis

On basis of the data submitted, the current state of knowledge and compliance of the manufacturer to ISO 13485, the benefit of the product outweighs the risks associated with its use when used in accordance to the manufacturer instruction. First Response is recommended for registration.

8. Post-approval updates

8.1. Variation applications

Reference number	Date submitted	Change requested	Recommendation	Granting date
NA	NA	NA	NA	NA

8.2. Feedback from pharmacovigilance, post marketing surveillance and enforcement activities

Type of feedback	Impact	Response
No any recorded Adverse Event	NA	NA

8.3. Re-registration applications

NA

CHANGE HISTORY

Version number	**Date**	**Description of update**	**Section(s) Modified**	**Approval date**

Precision

a) Within-run precision was determined by using 5 replicates of 9 different specimens containing different concentrations of antibodies. Within-run, precision was observed as 100%.

b) Between-run, precision was determined by using the 9 different specimens containing different concentrations of antibody in 5 different replicates with 3 different lots of test devices. Between run, precision was observed as 100%.

External Evaluation Report

Place of Evaluation	Year of testing	Sensitivity	Specificity
Virus Research Institute, Uganda	2018	100%	100%
Zimbabwe (Pregnant women whole blood specimen)	2019	100%	100%

Limitations & Interferences

1) The anti-coagulants such as heparin, EDTA and citrate do not affect the test result.
2) Do not use hemolytic whole blood specimen, it gives reddish background even after the end of test time.
3) Interpret a faint line as a postive line. Repeat the test in case of a very faint test line (purple colored) or if you have any doubt for test line.
4) False negative results may arise because of hook effect due to a very high titer of antibody in the specimen. Repeat the test by using 1:10 dilution of the same specimen (01 portion) in respective non-reactive specimen matrix (09 portion).
5) First Response® Syphilis Anti-TP Card Test is for in vitro diagnostic use only.
6) First Response® Syphilis Anti-TP Card Test will only indicate the presence of antibodies to *Treponema pallidum* in the specimen and should not be used as the sole criteria for the diagnosis of *Treponema pallidum* infection.
7) For confirmation, further analysis of the specimens should be performed, such as ELISA, TPHA or western blot analysis. As with all diagnostic tests, results must be interpreted together with other clinical information available to the physician.
8) A non-reactive result does not eliminate the possibility of infection with *Treponema pallidum*. The specimen may contain a low level of antibodies that cannot be detected by First Response® Syphilis Anti-TP 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 *Treponema pallidum* antibodies after more than 21 days since the original testing.

SYMBOL LEGENDS

Symbol	Explanation of symbol	Symbol	Explanation of symbol
	Consult instructions for use		Contains sufficient for < n > tests
	Non Sterile	REF	Product Code
IVD	In vitro diagnostic medical device	LOT	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:

1) Holmes KK, Lemon SM, Mardh P, Piot P, Sparling PF, Stamm WE. Wasserheit JM, Weisner PF. Chapters 33-36. In Sexually transmitted diseases, 3rd ed. New York: McGraw-Hill, 1999.
2) Hook EW III Stephens J. Ennis DM. Azithromycin compared with penicillin G benzathine for treatment of incubating syphilis. AnnIntern Med 1999 Sept 21; 131(6):434-437.
3) Johns DR, Tierney M, Felsenstein D. Alteration in the natural history of neurosyphilis by concurrent infection with the human immunodeficiency virus. NEngl J Med 1987; 316:1569-72.
4) WHO, 2011. Sexually transmitted infections. Geneva: World Health Organization.
5) Aledort JE et al. 2006. Reducing the burden of sexually transmitted infections in resource-limited settings: the role of improved diagnostics. Nature, 444: 59-72.
6) Newcombe, Robert G. "Two-Sided Confidence Intervals for the Single Proportion: Comparison of Seven Methods," Statistics in Medicine, 17, 857-872 (1998).
7) http://vassarstats.net/clin1.html#def , Richard Lowry.
8) TGS-5: Designing Instruction for use for in vitro diagnostic medical devices.

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".

Manufactured by

Premier Medical Corporation Private Limited
A1-302, GIDC, Sarigam 396155. Dist. Valsad, Gujarat, INDIA.
Customer support E-mail : info@premiermedcorp.com
Tel.: +91 2602780112/113 •Website : www.premiermedcorp.com

• ISO 13485 & EN ISO 13485 Certified Company

Part No.(S)PI08-INS-001, Rev.: AB ENGLISH
Note : Instructions for use will be printed in local language of the country using the test, if required.

FIRST RESPONSE® SYPHILIS ANTI-TP CARD TEST

Rapid Syphilis card test for the detection of antibodies to *Treponema pallidum* in human whole blood/serum/plasma

REF **PI08FRC25, PI08FRC50 & PI08FRC100**

4°C – 30°C IVD

Intended use

First Response® Syphilis Anti-TP Card Test is intended for use by healthcare professionals and trained users. It is a rapid, qualitative, screening, in vitro diagnostic test for detection of antibodies of all classes specific to *Treponema pallidum* in human serum, plasma or whole blood. The test kit is not automated and does not require any additional instrument. Reactive specimens should be confirmed by ELISA or TPHA.

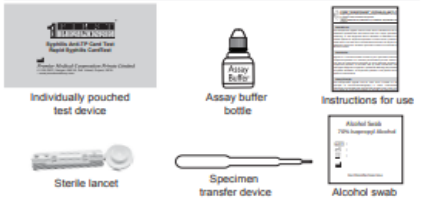
Introduction

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/or by blood transfusion. The serological diagnosis of syphilis is performed by detecting the presence of specific antibodies to *Treponema pallidum* in the patient serum, plasma or whole blood.

Assay Principle

First Response® Syphilis Anti-TP Card Test is based on the principle of immunochromatography. The nitrocellulose membrane is precoated with recombinant antigens (P47, P45, P17, P15) specific for *Treponema pallidum* on the test line of the device. When serum or plasma or whole blood specimen is applied to the specimen well of the device, it reacts with colloidal gold particles conjugated with *Treponema pallidum* recombinant antigens. This Conjugated antigen-antibody complex moves through the nitrocellulose membrane and bind to the corresponding immobilized recombinant antigens on the nitrocellulose membrane at the test line. If the specimen contains antibodies to *Treponema pallidum*, the purple colored line will appear in the test area, showing a positive result. The absence of the purple colored line indicates that the specimen is non-reactive for the *Treponema pallidum*, showing a negative result. Purple colored control line will appear irrespective of reactive or non-reactive specimens. The purple colored control line will serve to validate test device performance.

Materials Provided



Individually pouched test device | Assay buffer bottle | Instructions for use | Sterile lancet | Specimen transfer device | Alcohol swab

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

Materials provided	PI08FRC25	PI08FRC50	PI08FRC100
Test device pouch containing: 1 test device, 1 desiccant	25 Nos.	50 Nos.	100 Nos.
Specimen transfer device	25 Nos.	50 Nos.	100 Nos.
Assay buffer bottle	1 No.	2 Nos.	4 Nos.
Sterile lancets	25 Nos.	50 Nos.	100 Nos.
Alcohol swabs	25 Nos.	50 Nos.	100 Nos.
Instructions for use	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.
- 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).

Storage and Stability

1) First Response® Syphilis Anti-TP Card Test kit should be stored at 4-30°C.
2) Do not freeze the kit or components.
3) The kit is sensitive to humidity and heat. Do not store the kit at temperature above 30°C and in humid conditions.
4) Assay buffer (opened & unopened) & the unopened test device are stable until the expiry date printed on the label when stored at 4-30°C.
5) Perform the test immediately after removing the test device from the aluminium pouch.
6) The shelf life of the kit is as indicated on the outer package.

Precautions

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

Warnings

1) For in vitro diagnostic use only.
2) Read the instructions carefully before performing the test, any deviation will invalidate the test results.
3) Apply standard biosafety precautions for handling and disposal of potentially infective material.
4) 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.
5) Devices and assay buffer of a different lot must not be used.
6) Do not use the test device if the pouch is not intact.
7) Do not use the lancet if the seal is broken.
8) Do not use the test device if the desiccant found saturated.
9) Do not smoke, eat or drink while handling specimens and performing a test.
10) Do not re-use the test device, alcohol swab, lancet and specimen transfer device as 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, it contaminates 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.

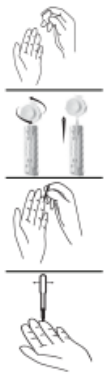
Specimen Collection

1) **Venous blood collection:** Collect the Whole blood in the collection tubes containing anticoagulants like EDTA, Heparin or Sodium citrate by venipuncture.

2) **Plasma collection:** Collect the Whole blood in the collection tubes containing anticoagulants like EDTA, Heparin or Sodium citrate by venipuncture and centrifuge it at 3000 rpm for 10-15 minutes to obtain Plasma.

3) **Serum collection:** Collect the 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 rpm for 10-15 minutes to obtain serum.

4) **Capillary 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 the alcohol swab provided and wait until the fingertip dried completely.
- Detach the protective cap of the lancet. Squeeze the fingertip then prick the lateral side of the fingertip with sterile lancet provided. Safely dispose of the used lancet.
- Wipe the first drop of the blood using sterile gauze. Without pressing too hard, gently squeeze your fingertip once again to obtain a large second drop of blood.
- 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.
  After completion of specimen collection, take the sterile gauze and apply pressure to the wound site to stop the bleeding.

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

Do not use expired lancet. The use of any expired lancet may cause any infection at the punctured skin due to cease to exist its sterility.

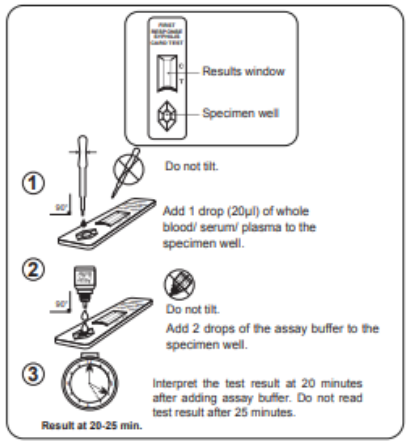
Use new lancet and choose a different puncture site, if repeat the finger prick.

Specimen storage

1) Whole blood specimen may be used for testing immediately (within 1 hour) or may be stored at 2-8°C for maximum up to 72 hours (3 days). Do not use 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, they should be refrigerated at 2-8°C. For storage periods greater than 72 hours (3 days), freezing at -20°C is recommended up to 4 months. They should be brought to room temperature prior to use.
3) Serum or Plasma specimens containing precipitate may yield inconsistent test results. Such specimens must be centrifuged at 5000 rpm for 10 minutes and use clear supernatants for testing.

Test Procedure

1) Ensure that the test device & other components are at room temperature (20°C to 30°C) before starting the procedure.
2) Take the test device and the specimen transfer device from the Kit. Do not use the test device if the desiccant found saturated.
3) Label the test device with the patient identification number. Place the test device on a flat, clean and dry surface.
4) Add one drop (20µl) of Whole blood/ Serum/ Plasma to the specimen well using the specimen transfer device.
   Caution: Dispose of used specimen transfer device as biohazard waste immediately after use.
5) Hold the assay buffer bottle vertically and add two drops of the assay buffer to the specimen well.
6) Observe for development of purple colored lines in the results window.
7) Interpret test results at 20 minutes after adding assay buffer to the specimen well.
8) Do not interpret the test result after 25 minutes.



Caution

- Hold the specimen transfer device and assay buffer bottle vertically, else it may lead to inaccurate result.
- 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 result of the test.
- Adding less than 2 drops of assay buffer may cause improper migration and poor background clearance which may lead to inaccurate result of the test.
- Do not read the test result after 25 minutes. Reading the result after the 20-25 minutes window 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® Syphilis Anti-TP Card Test indicates that the active ingredient of the strips are functional and the migration is successful. The purple colored control line in First Response® Syphilis Anti-TP Card Test is not meant for specimen addition monitoring.

How to Interpret test results

Negative Results

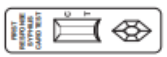
If only a single purple colored line appears, at the control line 'C' as in the figure, then the specimen is non-reactive for antibodies to Syphilis.

Positive Results

If two purple colored lines appears, one at the control line 'C' and other at the test line 'T' as in the figure, then the specimen is reactive for antibodies to Syphilis.

Syphilis Positive — Interpret the faint line as a reactive line

Invalid Results



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

Performance characteristics

First Response® Syphilis Anti-TP Card Test has been tested using an in-house panel of positive and negative clinical specimens characterized by a commercially available reference test kit. First Response® Syphilis Anti-TP Card Test showed 100% sensitivity and 100% specificity. First Response® Syphilis Anti-TP Card Test showed 100% agreement with reference assays.

Commercially available reference test kit	Specimen details	First Response® Syphilis Anti-TP Card Test		
		Syphilis Positive	Syphilis Negative	Total
	Syphilis Positive Plasma specimens			
	Syphilis Positive Plasma Specimen	46	0	46
	Syphilis Negative Plasma specimens			
	Syphilis Negative Plasma Specimen	0	395	395
	Total Plasma specimens	46	395	441
	Syphilis Positive Serum specimens			
	Syphilis Positive Serum Specimen	255	0	255
	Syphilis Negative Serum specimens			
	Syphilis Negative Serum Specimen	0	3431	3431
	Total Serum specimens	255	3431	3686
	Syphilis Positive Whole blood specimens			
	Syphilis Positive Whole blood specimen	200	0	200
	Syphilis Negative Whole blood specimens			
	Syphilis Negative Whole Blood Specimen	0	454	454
	Total Whole blood specimens	200	454	654

Commercially available reference test kit	Specimen details		First Response® Syphilis Anti-TP Card Test			
	Test Marker	Parameter	Positive	Negative	Total Result	95% Confidence Interval
	Plasma Specimens					
	Syphilis	Sensitivity	46	00	46	(90.39% - 100%)
		Specificity	00	395	395	(98.79% - 100%)
	Serum Specimens					
	Syphilis	Sensitivity	255	00	255	(98.15% - 100%)
		Specificity	00	3431	3431	(99.86% - 100%)
	Whole blood Specimens					
	Syphilis	Sensitivity	200	00	200	(97.85% - 100%)
		Specificity	00	454	454	(98.95% - 100%)

Seroconversion panel testing

The analytical sensitivity of the First Response® Syphilis Anti-TP Card Test was carried out by testing commercially available Seroconversion panel. The commercially available rapid test is used as a reference kit for comparative performance study. Three seroconversion panel were tested, in-house.

Analytical Sensitivity - In - House Evaluation

Total Seroconversion/ performance panels	Total Specimens	First Response® Syphilis Anti-TP Card Test			Reference CE-marked rapid lateral flow test		
		Positive	Negative	Detection Index**	Positive	Negative	Detection Index**
3	44	36	8	0.81	36	8	0.81

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

WHO International Standard for Syphilis were tested in First Response® Syphilis Anti-TP Card Test which shows 100% Sensitivity

WHO International Standard		
1st IS for human syphilitic plasma IgG NIBSC code:05/122 0.3 IU/ml	First Response® Syphilis Anti-TP Card Test	Reference CE-marked rapid lateral flow test
	Positive	Positive

Cross reactivity study

First Response® Syphilis Anti-TP Card Test was tested with other diseases/conditions, which may give cross-reactivity with the test. The following 19 potential cross-reacting diseases/conditions did not affect the performance of First Response® Syphilis Anti-TP Card Test.

Specimen Details	Syphilis Negative	Syphilis Positive	Specimen Details	Syphilis Negative	Syphilis Positive
P. falciparum Malaria Positive	05	Not Tested	HIV-1 Positive	415	Not Tested
P.vivax Malaria Positive	05	Not Tested	HIV-2 Positive	91	Not Tested
Dengue NS1 Positive#	05	05	HSV 1/2 Positive#	13	10
Pregnant Woman ^	154	24	HTLV-I Ab Positive#	07	05
CMV Positive#	05	05	HTLV-II Ab Positive#	09	05
ANA Positive#	05	05	Rubella IgG & IgM Positive#	15	10
HAV Positive#	05	05	Thyroiditis specimens#	10	10
EBV Positive#	05	05	Anti-malarial drug medication#	03	03
HBV Positive#	103	05	Anti-TB drug medication#	03	03
HCV Positive#	103	05			

^ Note: Pregnant women specimens which is naturally appeared in Syphilis positive specimens.
# Spiked Syphilis positive specimens.

Potential interference substances

First Response® Syphilis Anti-TP Card Test was tested with potential interfering substances. The following 08 potential interfering substances did not affect performance of the test. However, Hemolysed specimens and lipemic specimens showed poor background clearance, hence not recommended for testing. The lipemic specimens can be used for testing after centrifugation. Such specimens must be centrifuged at 5000 rpm for 10 minutes and use the supernatants for testing.

Specimen Details	Syphilis Negative	Syphilis Positive	Specimen Details	Syphilis Negative	Syphilis Positive
Lipemic specimen#	25	05	Low Hematocrit specimens	05	Not Tested
Icteric specimens#	05	05	Whole blood specimen in ACD anticoagulant ^	185	08
Hemolytic specimens	05	Not Tested	RF Ab Positive#	09	09
High Hematocrit specimens	05	Not Tested	dsDNA Antibody Positive Plasma#	01	05

^ Note: Naturally appeared Syphilis positive specimens.
# Spiked Syphilis positive specimens.

Potential interference drug substances

The details of interfering drug molecules are mentioned in the following table. Each interfering drug molecule substances were spiked at a final concentration of 250µg/ml in 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® Syphilis Anti-TP Card Test.

Abacavir	Cyclobenzaprine Hydrochloride	Folic acid	Metformin	Rifampicin
Acetaminophen	Darunavir	Hydrochlorothiazide	Naproxen IP	Ritonavir
Ampicillin Sodium salt	Diclofenac	Ibuprofen	Nevirapine	
Ascorbic Acid (Limec)	Ecosprin	Iron chloride	Pantoprazole	
Aspirin	Ergocalciferol	Isoniazid	Penicillin G Benzathine	
Cholecalciferol	Ferrous Ascorbate	Magnesium sulphate	Pyrazinamide	