Syphilis Rapid Test
(Serum / Plasma)

INTENDED USE
First View Syphilis Rapid Antibody test (Device) is an immunoassay for the rapid visual detection of antibodies to Treponemapallidum human serum/plasma to aid in the diagnosis of Syphilis.

SUMMARY
Syphilis is a sexually transmitted infection caused by the bacterium Treponemapallidum. The signs and symptoms of syphilis depend on one of the four stages (primary, secondary, latent and tertiary).
Syphilis is a notifiable disease in many countries, including Canada, the European Union and the United States. Syphilis has been serologically diagnosed by anti Treponemapallidum Antibody tests with the advantage of having improved specificity. The Bioline Syphilis Rapid Antibody Test was developed to detect antibodies to Treponemapallidum antigens in serum/plasma.

PRINCIPLE
After addition of the serum/plasma sample to the sample well of the device containing a test strip, the sample moves on to the conjugate pad containing colloidal gold particles conjugated with recombinant treponemapallidum specific antigens (15, 17, 47 kDA) and Mouse IgG. If the sample contains detectable levels of the Treponemapallidum antibodies, it reacts with the gold conjugated recombinant Treponemapallidum specific antigens to form a complex. This complex moves further and reacts with recombinant Treponemapallidum specific antigens (15, 17, 47 kDA) pre-coated test line on the nitrocellulose membrane area to form colored band. The mouse IgG conjugated colloidal gold particles move further to the goat anti-mouse IgG coated control area to form a colored band (Control line). The appearance of test line and control line in respective area indicates the positive result. Appearance of only control line indicates a negative result. The control line acts as a procedural control and should always appear if the test it performed as per the procedure and reagents are working properly

REAGENTS AND MATEREIALS PROVIDED
First View Syphilis Test cards contain the following:
- Test Device with activated silica gel
- Plastic Dropper.
- Assay Buffer Bottle
- Package Insert (Instruction for use)

MATERIALS MAY BE REQUIRED BUT NOT PROVIDED
- Positive Control
- Negative Control

MATERIALS REQUIRED BUT NOT PROVIDE
- Timer
- Digital Clock
- Specimen collection container Tube

WARNINGS AND PRECAUTIONS:
For in Vitro Diagnostic Use

- This package insert must be read completely before performing the test.
- The test device should remain in the sealed pouch until use
- Do not use expired devices.
- Do not use the kit if the cassette package is damaged or the seal is broken.
- Bring all reagent to room tempreature (15-30°C) before use.
- Do not use hemolyzed blood specimens for testing.
- Wear personal protective equipment,such as gloves and lab coats when handling kit reagents.wash hands thoroughly after performing the test.
- Do not smoke,drink or eat in areas where specimens or kit reagents are being handled.
- Dispose of all specimens and material used to performe the test as bio-hazardous waste.

REAGENT PREPARATION AND STORAGE
INSTRUCTIONS: All reagents are ready to use as supplied. Store unused test device unopened at 2-30 °C, ensure that the test device brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit to temperature 30°C.

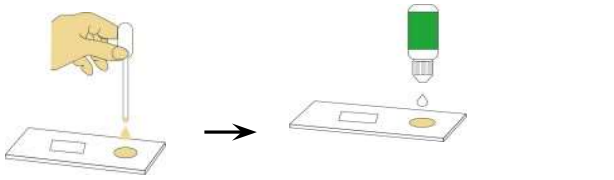
SPECIMEN COLLECTION, STORAGE AND HANDLING
Consider any materials of human origin as infectious and handle them using standard bio-safety procedures.

1. Plasma
- **Step 1:** Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively, in Vacutainer®) by venipuncture.
- **Step 2:** Separate the plasma by centrifugation.
- **Step 3:** Carefully withdraw the plasma into a new pre-labeled tube.

2. Serum
- **Step 1:** Collect blood specimen into a red top collection tube (containing no anti coagulants in Vacutainer®) by venipuncture.
- **Step 2:** Allow the blood to clot.
- **Step 3:** Separate the serum by centrifugation.
- **Step 4:** Carefully withdraw the serum into a new pre-labeled tube.

Test specimens as soon as possible after collecting store specimens at 2-8°C if not tested immediately for up to 5 days. The specimens should be frozen at -20°C for longer storage.

DIRECTIONS FOR USE
Allow test cassette, specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.
1. Bring the pouch to room temperature before opening it.
2. Remove the test cassette from the sealed pouch and place it on flat dry surface.
3. **For Serum or Plasma Specimen**: Hold the dropper vertically and transfer **1 drop** of Serum or Plasma (**approximately 25µl**) to the specimen area, then add **1 Drop** of buffer **(approximately 40µl),** and start the timer, see illustration below.



1 Drop of Serum/Plasma **1 Drop of Buffer** **Result 15 min**

4. Wait for the colored line(s) to appear. The test result should be read at 15 minutes.

Note. ***Do not interpret the result after 20 minutes*.**

INTERPRETATION OF RESULTS

Positive Results:
The presence of two colored bands ("T" band and "C" band) within the result window indicates a positive result
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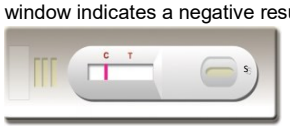
Negative Results:
The presence of only one colored band ("C" band) within the result window indicates a negative result.



Invalid Results:
If No band is visible within the result window after performing the test, the result is considered invalid. It may be due to not following the directions correctly or the test may have deteriorated beyond the expiration date. It is recommended that the specimen should be retested using a new test kit.

QUALITY CONTROL
A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The First View Syphilis Rapid Test Card (Serum/Plasma) is for *in vitro* diagnostic use only. The test should be used for the detection of *TP* antibodies in serum or plasma specimens only. Neither the quantitative value nor the rate of increase in *TP* antibodies can be determined by this qualitative test.
2. The First View Syphilis Rapid Test Card (Serum/Plasma) will only indicate the presence of *TP* antibodies in the specimen and should not be used as the sole criteria for the diagnosis of *TP* infection.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of *TP* infection.

PERFORMANCE CHARACTERISTICS
1. Clinical Performance The First View Syphilis Rapid Test Card (Serum/Plasma) has been compared to a leading commercial Syphilis test using clinical specimens. The results show that the relative sensitivity of the First View Syphilis Rapid Test Card (Serum/Plasma) is >99%, and the relative specificity is >99%.

Method		Leading commercial Syphilis Test	
First View Syphilis Rapid Test Card (Serum/Plasma)	Results	Positive	Negative
	Positive	169	1
	Negative	1	259
Total Results		170	260

Relative Sensitivity: 99.4%
Relative Specificity: 99.6%
Accuracy : 99.5%

2. Acceptance Criteria.

Sr. No.	Test(s) Conducted	As per CDSCO´s Specifications for Syphilis Rapid Test.
1	Sensitivity	>= 85%
2	Specificity	>= 93%

3. Cross-reactivity
The Syphilis Rapid Test Cassette (Serum/Plasma) has been tested by HAMA, Rheumatoid factor (RF), HAV, and HBsAg, HIV, H. Pylori, MONO, CMV, Rubella and TOXO positive specimens. The results showed no cross-reactivity.

EXPECTED VALUES

The First View Syphilis Rapid Test Card (Serum/Plasma) has been compared with a leading commercial Syphilis test, demonstrating an overall accuracy greater than or equal to 99%

PRECISION

Intra - Assay. Within-run precision has been determined by using 10 replicates of four specimens: a negative, a low positive, a medium positive and a high positive. The negative, low positive, medium positive and high positive values were correctly identified >99% of the time.

Inter - Assay. Between-run precision has been determined by 10 independent assays on the same four specimens: a negative, a low positive, a medium positive and a high positive. Three different lots of First View Syphilis Rapid Test Card (Serum/Plasma)have been tested using negative, low positive, medium positive and high positive specimens. The specimens were correctly identified >99% of the time.

REFERENCES

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4. J.N. Wasserheit. *Epidemiological Synergy: Interrelationships between human immunodeficiency virus infection and other sexually transmitted diseases*, Sexually Transmitted Diseases 1992; 19:61-77
5. Johnson Phillip C.*Testing for Syphilis*, Dermatologic Clinic 1994; 12 Jan: 9-17

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