ImmunoScience INDIA

ImmunoQuick

Syphilis Ab

Rapid Syphilis Antibody Test - Cassette (Device)

For *In Vitro* Diagnostic Use Only **Store at 4°C to 30°C**

OVERVIEW
Syphilis is a disease caused by a Bacterium Treponema pallidum. The disease is characterized by sores on body, skin rash, weight loss, fever etc. Syphilis is diagnosed by serological detection of antibodies to Treponema pallidum. ImmunoQuick Syphilis Antibody test is an immunochromatographic assay to detect antibodies to Treponema pallidum in human serum/plasma/whole Blood.

INTENDED USE
Rapid Syphilis Antibody test (Device) is an immunoassay for the rapid and visual detection of antibodies to Treponema pallidum in human serum or plasma or whole blood to aid in the diagnosis of Syphilis.

PRINCIPLE
After addition of the serum or plasma or whole blood 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 Treponema pallidum antigens (17, 47kDA) and rabbit IgG. If the sample contains detectable levels of the syphilis antibodies it reacts with the gold conjugated recombinant Treponema pallidum antigens (17, 47kDA) to form a complex. This complex moves further and reacts with the recombinant Treponema pallidum antigens (17, 47kDA) coated as test line on the nitrocellulose membrane area to form a colored band (Test band). The unbound complex and the rabbit IgG conjugated colloidal gold particles move further to the goat-anti rabbit 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. Control line should always appear if the test is performed as per the procedure and reagents are working properly.

CONTENTS OF KIT
1. Test Device
2. Desiccant pouch
3. Plastic Dropper
4. Package Insert

OPTIONAL MATERIAL REQUIRED
1. Stop Watch
2. Sample Container
3. Disposable gloves

PRECAUTIONS/KIT STORAGE AND STABILITY
1. Please read all the information in this package insert before performing the test. Pay particular attention to the position of the Control and Test lines.
2. Do not use after the expiration date printed on the foil pouch.
3. Store in the sealed pouch in a dry place in between temperature 4°C to 30°C. Do not freeze.
4. Do not use if pouch is torn or damaged.
5. Do not open the foil pouch until you are ready to start the test.
6. Keep out of the reach of children.

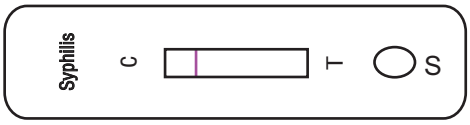
WARNINGS
1. Do not reuse the test.
2. Follow the instruction to get accurate results.
3. Use appropriate personal protective equipments.
4. Dispose off hygienically in biohazard waste.
5. Do not touch the membrane.
6. Treat used samples and tests as potentially infectious. Avoid contact with skin.
7. For in vitro diagnostic use. Not to be taken internally.
8. Do not eat the desiccant in the package.
9. Do not mix the specimen sample or interchange the different specimen.
10. The manufacturer and distributor of this product shall not be liable for any loses, liability, claims, costs or damages whether direct or consequential arising out of or related to an incorrect diagnosis, whether positive or negative, in the use of this product.

SPECIMEN COLLECTION
1. Rapid Syphilis Antibody test (device) can be performed using serum or plasma or whole blood.
2. Testing should be performed immediately after the specimens have been collected.
3. Do not leave the specimen at room temperature for prolonged periods.

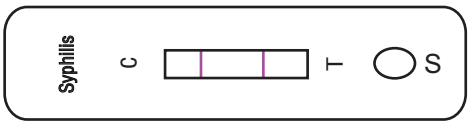
TEST PROCEDURE
1. Before opening the foil pouch allow the test device and sample to reach room temperature (20°C to 30°C).
2. Remove the test device, plastic dropper and desiccant pouch from the pouch. Check the color of desiccant it should be blue, if it has turned colorless or pink, discard the test and use another test.
3. Add 2 drops (Approx. 60 µl) of serum or plasma or 3 drops (Approx. 90 µl) whole blood sample in well 'S'.
4. Start the timer.
5. Read the result at 15 minutes. Do not read the result after 20 minutes.

INTERPRETATION OF RESULTS

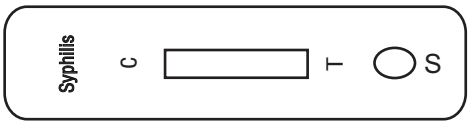
Negative: If colored line appears at the control side 'C' only.



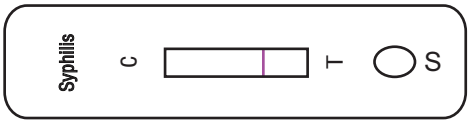
Positive: A distinct colored line appears at the control side 'C' and at the test side 'T'.



Invalid: The test should be considered invalid if,
A) No line appears at 'C' and 'T' side.



B) No line appears at 'C' side and line appear only at 'T' side.



NOTE:
The intensity of the color in the test line region (T) will vary depending on the levels of the Treponema pallidum antibodies in the specimen. However, neither the quantitative value nor the rate of increase in Treponema pallidum antibodies in the specimen can be determined by this qualitative test. Depending on the levels of Treponema pallidum antibodies in the specimen, positive results may appear as early as two minutes. Negative results must be confirmed only at the end of 15 minutes.

PERFORMANCE CHARACTERISTICS

Internal Evaluation:

In an in-house study, total 290 samples were evaluated for sensitivity and specificity. We found the relative sensitivity was 100 % (i. e. 100/100) and the relative specificity was 100 % (i. e. 190/190).

The results are summarized in the following table:

Sample	Total Number of Samples Tested	Rapid Syphilis Antibody Test - Device		Sensitivity (%)	Specificity (%)
		Positive	Negative		
Syphilis Antibody Positive Serum Samples	50	50	0	100	-
Syphilis Antibody Positive Plasma Samples	30	30	0	100	-
Syphilis Antibody Positive Whole Blood Samples	20	20	0	100	-
Syphilis Antibody Negative Serum Samples	100	0	100	-	100
Syphilis Antibody Negative Plasma Samples	40	0	40	-	100
Syphilis Antibody Negative Whole Blood Samples	50	0	50	-	100

External Evaluation:

In an external study, total 120 samples were evaluated for sensitivity and specificity. Relative sensitivity was 100 % (i. e. 20/20) and the relative specificity was 100 % (i. e. 100/100). Positive Predictive Value (PPV) and Negative Predictive Value (NPV) for the test was 100%.

The results are summarized in the following table:

Sample	Total Number of Samples Tested	Rapid Syphilis Antibody Test - Device		Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
		Positive	Negative				
Syphilis Anitibody Positive Samples	20	20	0	100	-	100	-
Syphilis Anitibody Negative Samples	100	0	100	-	100	-	100

LIMITATIONS

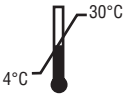
This test provides presumptive diagnosis of Syphilis. A confirmed syphilis diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

DISCLAIMER

The all precaution shall be taken to ensure the diagnostic ability and accuracy of this product. This product is utilized outside the control of manufacturer and distributors. The various factors including storage temperature, environmental conditions and procedure error may affect the results. This test provides presumptive diagnosis of syphilis.

REFERENCES

1. World Health Organization Technical Report Series. No.674 (1982) Treponemal infections.
2. Center for Disease Control. Recommendations for diagnosing and treating syphilis in HIV infected patients. MMWR Morb. Mortal Wkly Rep. 1988;37:601.
3. Marx AR. Crack, sex and STD, sexually Transmitted Disease, 1991;18:92-101.
4. Wasserheit JN. Epidemiological Synergy: Interrelationships between human immunodeficiency virus infection and other sexually transmitted diseases, Sexually Transmitted Disease 1992; 19:61:77.

IVD	In Vitro Diagnostic Use
	Manufacturer
	Manufacturing Date
	Expiry Date
LOT	Lot Number
	Store at 4°C to 30°C
	Single Use
	Number of tests in the pack
	Do not use if pouch or kit damaged
	This side Up
	Read package insert before use

MANUFACTURED BY

ImmunoScience India Private Limited
Gat No. 41, Kusgaon, Shivapur-Velhe Road,
Tal- Bhor, Pune, Maharashtra (India) -412205.

ImmunoScience INDIA

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Syphilis Ab

Rapid Syphilis Antibody Test - Dipstick

For *In Vitro* Diagnostic Use Only **Store at 4°C to 30°C**

OVERVIEW
Syphilis is a disease caused by a Bacterium Treponema pallidum. The disease is characterized by sores on body, skin rash, weight loss, fever etc. Syphilis is diagnosed by serological detection of antibodies to Treponema pallidum. ImmunoQuick Syphilis Antibody test is an immunochromatographic assay to detect antibodies to Treponema pallidum in human serum/plasma.

INTENDED USE
Rapid Syphilis Antibody test (Dipstick) is an immunoassay for the rapid and visual detection of antibodies to Treponema pallidum in human serum or plasma to aid in the diagnosis of Syphilis.

PRINCIPLE
After placing the dipstick in a container with serum or plasma, the sample moves on to the conjugate pad containing colloidal gold particles conjugated with recombinant Treponema pallidum antigens (17, 47kDA) and rabbit IgG. If the sample contains detectable levels of the syphilis antibodies it reacts with the gold conjugated recombinant Treponema pallidum antigens (17, 47kDA) to form a complex. This complex moves further and reacts with recombinant Treponema pallidum antigens (17, 47kDA) coated as test line on the nitrocellulose membrane area to form a colored band (Test band). The unbound complex and the rabbit IgG conjugated colloidal gold particles move further to the goat-anti rabbit 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. Control line should always appear if the test is performed as per the procedure and reagents are working properly.

CONTENTS OF KIT
1. Test Dipstick
2. Package Insert
3. Desiccant pouch

OPTIONAL MATERIAL REQUIRED
1. Stop Watch
2. Sample Container
3. Disposable gloves
4. Test tube (12X75) mm

PRECAUTIONS/KIT STORAGE AND STABILITY
1. Please read all the information in this package insert before performing the test. Pay particular attention to the position of the Control and Test lines.
2. Do not use after the expiration date printed on the foil pouch.
3. Store in the sealed pouch in a dry place in between temperature 4°C to 30°C. Do not freeze.
4. Do not use if pouch is torn or damaged.
5. Do not open the foil pouch until you are ready to start the test.
6. Keep out of the reach of children.

WARNINGS
1. Do not reuse the dipstick.
2. Follow the instruction to get accurate results.
3. Use appropriate personal protective equipments.
4. Dispose off hygienically in biohazard waste.
5. Do not touch the membrane.
6. Treat used samples and used dipsticks as potentially infectious. Avoid contact with skin.
7. For in vitro diagnostic use. Not to be taken internally.
8. Do not eat the desiccant in the package.
9. Do not mix the specimen sample or interchange the different specimen.
10. The manufacturer and distributor of this product shall not be liable for any loses, liability, claims, costs or damages whether direct or consequential arising out of or related to an incorrect diagnosis, whether positive or negative, in the use of this product.

SPECIMEN COLLECTION
1. Rapid Syphilis Antibody Test (dipstick) can be performed using serum or plasma.
2. Testing should be performed immediately after the specimens have been collected.
3. Do not leave the specimen at room temperature for prolonged periods.

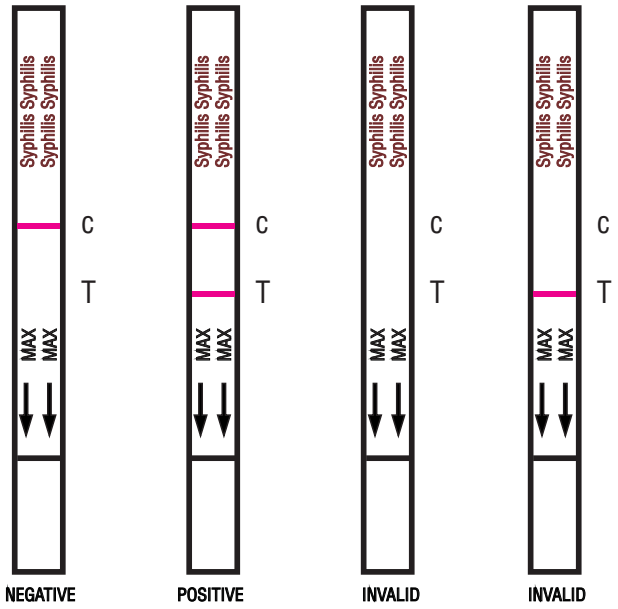
TEST PROCEDURE
1. Before opening the foil pouch allow the test strip and sample to reach room temperature (20°C to 30°C)
2. Remove the test dipstick and desiccant pouch from the pouch. Check the color of desiccant it should be blue, if it has turned colorless or pink, discard the strip and use another test.
3. Take approximately 1 ml of serum or plasma sample in the (12X75) mm test tube.
4. With arrows pointing toward the sample, immerse the test strip vertically in sample.
5. Start the timer.
6. Read the result at 15 minutes. Do not read the result after 20 minutes.

INTERPRETATION OF RESULTS

Negative: If colored line appears at the control region 'C' only.

Positive: A distinct colored line appears at the control region 'C' and at the test region 'T'.

Invalid: The test should be considered invalid if,
A) No line appears at control region 'C' and at test region 'T'.
B) No line appears at control region 'C' and line appear only at test region 'T'.



NOTE:
The intensity of the color in the test line region (T) will vary depending on the levels of the Treponema pallidum antibodies in the specimen. However, neither the quantitative value nor the rate of increase in Treponema pallidum antibodies in the specimen can be determined by this qualitative test. Depending on the levels of Treponema pallidum antibodies in the specimen, positive results may appear as early as two minutes. Negative results must be confirmed only at the end of 15 minutes.

PERFORMANCE CHARACTERISTICS

Internal Evaluation:
In an in-house study, total 220 samples were evaluated for sensitivity and specificity. We found the relative sensitivity was 100 % (i. e. 80/80) and the relative specificity was 100 % (i. e. 140/140).

The results are summarized in the following table:

Sample	Total Number of Samples Tested	Rapid Syphilis Antibody Test - Dipstick		Sensitivity (%)	Specificity (%)
		Positive	Negative		
Syphilis Antibody Positive Serum Samples	50	50	0	100	-
Syphilis Antibody Positive Plasma Samples	30	30	0	100	-
Syphilis Antibody Negative Serum Samples	100	0	100	-	100
Syphilis Antibody Negative Plasma Samples	40	0	40	-	100

External Evaluation:
In an external study, total 120 samples were evaluated for sensitivity and specificity. Relative sensitivity was 100 % (i. e. 20/20) and the relative specificity was 100 % (i. e. 100/100). Positive Predictive Value (PPV) and Negative Predictive Value (NPV) for the test was 100%.

The results are summarized in the following table:

Sample	Total Number of Samples Tested	Rapid Syphilis Antibody Test - Dipstick		Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
		Positive	Negative				
Syphilis Anitibody Positive Samples	20	20	0	100	-	100	-
Syphilis Anitibody Negative Samples	100	0	100	-	100	-	100

LIMITATIONS
This test provides presumptive diagnosis of Syphilis. A confirmed syphilis diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

DISCLAIMER
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3. Marx AR. Crack, sex and STD, sexually Transmitted Disease, 1991;18:92-101.
4. Wasserheit JN. Epidemiological Synergy: Interrelationships between human immunodeficiency virus infection and other sexually transmitted diseases, Sexually Transmitted Disease 1992; 19:61:77.

IVD	In Vitro Diagnostic Use
	Manufacturer
	Manufacturing Date
	Expiry Date
LOT	Lot Number
30°C 4°C	Store at 4°C to 30°C
	Single Use
Σ	Number of tests in the pack
	Do not use if pouch or kit damaged
	This side Up
i	Read package insert before use

MANUFACTURED BY
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