DRG® Syphilis Rapid Test (RAP-4736)

As of 19 Feb. 2008

RUO in the USA

INTENDED USE

The Syphilis Test is a rapid chromatographic immunoassay for the qualitative detection of antibodies (IgG and IgM) to Treponema Pallidum (TP) in whole blood, serum or plasma to aid in the detection of Syphilis.

For professional in vitro use only. In the United States, this kit is intended for Research Use Only.

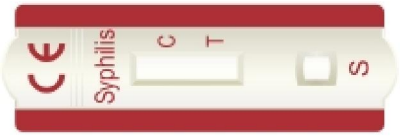
SUMMARY

Treponema Pallidum (TP) is the causative agent of the venereal disease Syphilis. TP is a spirochete bacterium with an outer envelope and a cytoplasmic membrane.[1] Relatively little is known about the organism in comparison with other bacterial pathogens. According to the Center for Disease Control (CDC), the number of cases of Syphilis infection has markedly increased since 1985.[2] Some key factors that have contributed to this rise include the crack cocaine epidemic and the high incidence of prostitution among drug users.[3] One study reported a substantial epidemiological correlation between the acquisition and transmission of the HIV virus and Syphilis.[4]

Multiple clinical stages and long periods of latent, asymptomatic infection are characteristic of Syphilis. Primary Syphilis is defined by the presence of a chancre at the site of inoculation. The antibody response to the TP bacterium can be detected within 4 to 7 days after the chancre appears. The infection remains detectable until the patient receives adequate treatment.[5]

The Syphilis Rapid Test Device (Whole Blood/Serum/Plasma) utilizes a double antigen combination of a Syphilis antigen coated particle and Syphilis antigen immobilized on membrane to detect TP antibodies (IgG and IgM) qualitatively and selectively in whole blood, serum or plasma.

PRINCIPLE



The **Syphilis Test** is a qualitative membrane device based immunoassay for the detection of TP antibodies (IgG and IgM) in whole blood, serum or plasma. In this test procedure, recombinant Syphilis antigen is immobilized in the test line region of the device. After a specimen is added to the specimen well of the device, it reacts with Syphilis antigen coated particles in the test. This mixture migrates chromatographically along the length of the test strip and interacts with the immobilized Syphilis antigen. The double antigen test format can detect both IgG and IgM in specimens. If the specimen contains TP antibodies, a coloured line will appear in the test line region, indicating a positive result. If the specimen does not contain TP antibodies, a coloured line will not appear in this region, indicating a negative result. To serve as a procedural control, a coloured line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

As of 19 Feb. 2008 **RUO in the USA**

REAGENTS

The test device contains Syphilis antigen coated particles and Syphilis antigen coated on the membrane.

PRECAUTIONS

- For professional in vitro use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use test if pouch is damaged.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use after the expiration date.

SPECIMEN COLLECTION AND PREPARATION

The Syphilis Rapid Test Device (Whole Blood/Serum/Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.

To collect fingerstick whole blood specimens:

1. Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
2. Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
3. Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
4. Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
5. Add the fingerstick whole blood specimen to the test device by using a capillary tube:
   Touch the end of the capillary tube to the blood until filled to approximately 50 µl. Avoid air bubbles.
   Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood into the specimen well (S) of the test device.
6. Add the fingerstick whole blood specimen to the test device by using hanging drops:
7. Position the patient's finger so that the drop of blood is just above the specimen well (S) of the test device.
8. Allow 2 hanging drops of fingerstick whole blood to fall into the specimen well (S) of the test device, or move the patient's finger so that the hanging drop touches the specimen well (S). Avoid touching the finger directly to the specimen well (S).

DRG International Inc., USA

Fax: (908) 233-0758 • E-mail: corp@drg-international.com • **Web:** www.drg-international.com

As of 19 Feb. 2008

RUO in the USA

Separate serum or plasma from blood as soon as possible to avoid haemolysis. Use only clear non-haemolysed specimens.

Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below 20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.

Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.

If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

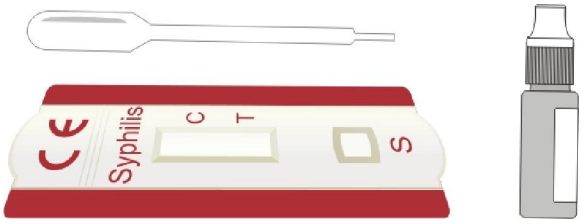
MATERIALS

MATERIALS PROVIDED

- **Syphilis Test** device
- Disposable specimen droppers
- Buffer (for whole blood only)
- Droppers
- Package insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Specimen collection containers (for venipuncture whole blood)
- Lancet (for fingerstick whole blood only)
- Disposable heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)
- Centrifuge (for plasma only / serum)
- Timer



DIRECTIONS FOR USE

1. Allow the test device, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.
2. Remove the test device from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
3. Place the device on a clean and level surface.

As of 19 Feb. 2008

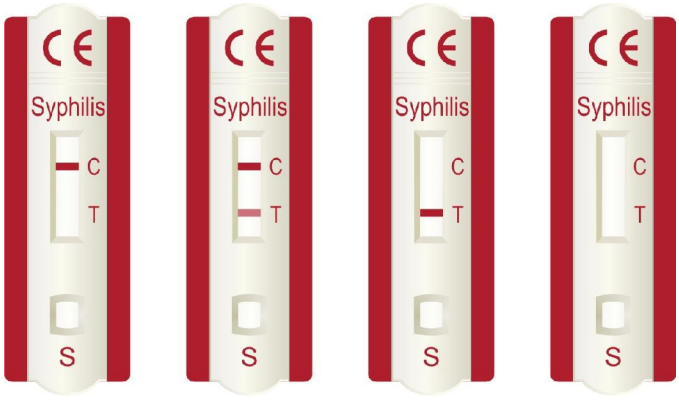
RUO in the USA

	Serum or Plasma	Venipuncture Whole Blood	Fingerstick Whole Blood
4	Hold the dropper vertically and **transfer 3 drops of serum or plasma** (approximately 75 µl) into the specimen well (S) of the test device, and start the timer. See illustration below.	Hold the dropper vertically and **transfer 2 drops of whole blood** (approximately 50 µl) to the specimen well (S) of the test device, then **add 1 drop of buffer** (approximately 40 µl) and start the timer. See illustration below.	To use a capillary tube: Fill the capillary tube and **transfer approximately 50 µl of finger-stick whole blood specimen** into the specimen well (S) of the test device, then **add 1 drop of buffer** (approximately 40 µl) and start the timer. See illustration below. To use hanging drops**:** **Allow 2 hanging drops of fingerstick whole blood specimen** (approximately 50 µl to fall into the centre of the specimen well (S) of the test device, then **add 1 drop of buffer** (approximately 40 µl) and start the timer. See illustration below. Wait for the coloured line(s) to appear. **Read results at 10 minutes.** Do not read results after 30 minutes.

As of 19 Feb. 2008

RUO in the USA

INTERPRETATION OF RESULTS



negative **positive** **invalid** **invalid**

POSITIVE*: Two distinct coloured lines appear. One coloured line should be in the control line region (C) and another apparent coloured line should be in the test line region (T).

***NOTE:** The intensity of the colour in the test line region (T) will vary depending on the concentration of TP antibodies present in the specimen. Therefore, any shade of colour in the test line region (T) should be considered positive.

NEGATIVE: One coloured line appears in the control line region (C). No line appears in the test line region (T).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A coloured 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.

As of 19 Feb. 2008

RUO in the USA

LIMITATIONS

1. The Syphilis Rapid Test Device (Whole Blood/Serum/Plasma) is for in vitro use only. The test should be used for the detection of TP antibodies in whole blood, 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 Syphilis Rapid Test Device (Whole Blood/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.

EXPECTED VALUES

The Syphilis Rapid Test Device (Whole Blood/Serum/Plasma) has been compared with a leading commercial TPHA Syphilis test, demonstrating an overall accuracy greater than or equal to 99.7%.

PERFORMANCE CHARACTERISTICS

1.1 Clinical Sensitivity, Specificity and Accuracy

The Syphilis Rapid Test Device (Whole Blood/Serum/Plasma) has correctly identified specimens of a seroconversion panel and has been compared to a leading commercial TPHA Syphilis test using clinical specimens. The results show that the relative sensitivity of the Syphilis Rapid Test Device (Whole Blood/Serum/Plasma) is 99.7%, and the relative specificity is 99.6%.

Syphilis Rapid Test Device vs. TPHA

Method		**TPHA**		**Total Results**
Syphilis Ultra Rapid Test Device	Results	Positive	Negative	
	Positive	384	2	386
	Negative	1	493	494
Total Results		385	495	880

Relative Sensitivity: 99.7% (98.6%-100.0%)* Relative Specificity: 99.6% (98.5%-100.0%)*

Relative Accuracy: 99.7% (99.0%-99.9%)* * 95% Confidence Interval

DRG International Inc., USA

Fax: (908) 233-0758 • E-mail: corp@drg-international.com • **Web:** www.drg-international.com

1.2 Precision

Intra-Assay

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

Inter-Assay

Between-run precision has been determined by testing 10 replicates on the same four specimens: a negative, a low positive, middle positive and a high positive. Three different lots of the Syphilis Rapid Test Device (Whole Blood/Serum/Plasma) have been tested over a 3-month period using negative, low positive, middle positive and high positive specimens. The specimens were correctly identified 99% of the time.

BIBLIOGRAPHY

1. Claire FM. Complete genome sequence of Treponema Pallidum, the Syphilis spirochete, Science 1998; 281 July: 375-381.
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 Diseases, 1991; 18:92-101.
4. Wasserheit JN. Epidemiological Synergy: Interrelationships between human immunodeficiency virus infection and other sexually transmitted diseases, Sexually Transmitted Diseases 1992; 19:61-77.
5. Johnson PC. Testing for Syphilis, Dermatologic Clinic 1994; 12 Jan: 9-17.

DRG® Syphilis Rapid Test (RAP-4736)

As of 19 Feb. 2008

RUO in the USA

SYMBOLS USED WITH DRG ASSAY´S

Symbol	English	Deutsch	Français	Español	Italiano
	Consult instructions for use	Gebrauchsanweisung beachten	Consulter les instructions d'utilisation	Consulte las instrucciones de uso	Consultare le istruzioni per l'uso
	European Conformity	CE-Konfirmitäts-kennzeichnung	Conformité aux normes européennes	Conformidad europea	Conformità europea
	In vitro diagnostic device	In-vitro-Diagnostikum	Usage Diagnostic in vitro	Para uso Diagnóstico in vitro	Per uso Diagnostica in vitro
	For research use only	Nur für Forschungszwecke	Seulement dans le cadre de recherches	Sólo para uso en investigación	Solo a scopo di ricerca
	Catalogue number	Katalog-Nr.	Numéro de catalogue	Número de catálogo	Numero di Catalogo
	Lot. No. / Batch code	Chargen-Nr.	Numéro de lot	Número de lote	Numero di lotto
	Contains sufficient for <n> tests/	Ausreichend für "n" Ansätze	Contenu suffisant pour "n" tests	Contenido suficiente para <n> ensayos	Contenuto sufficiente per "n" saggi
	Storage Temperature	Lagerungstemperatur	Température de conservation	Temperatura de conservación	Temperatura di conservazione
	Expiration Date	Mindesthaltbarkeits-datum	Date limite d'utilisation	Fecha de caducidad	Data di scadenza
	Legal Manufacturer	Hersteller	Fabricant	Fabricante	Fabbricante
Distributed by	Distributor	Vertreiber	Distributeur	Distribuidor	Distributore
Content	Content	Inhalt	Conditionnement	Contenido	Contenuto
Volume/No.	Volume / No.	Volumen/Anzahl	Volume/Quantité	Volumen/Número	Volume/Quantità

Symbol	Portugues	Dansk	Svenska	Ελληνικά
	Consulte as instruções de utilização	Se brugsanvisning	Se bruksanvisningen	Εγχειρίδιο χρήστη
	Conformidade com as normas europeias	Europaeisk overensstemmelse	Europeisk överensstämmelse	Ευρωπαϊκή Συμμόρφωση
	Diagnóstico in vitro	In vitro diagnostik	Diagnostik in vitro	in vitro διαγνωστικό
	Catálogo n.º	Katalognummer	Katalog nummer	Αριθμός καταλόγου
	No do lote	Lot nummer	Batch-nummer	Αριθμός Παρτίδος
		Indeholder tilstrækkeligt til "n" test	Innehåller tillräckligt till "n" tester	Περιεχόμενο επαρκές για «n» εξετάσεις
	Temperatura de conservação	Opbevarings-temperatur	Förvaringstempratur	Θερμοκρασία αποθήκευσης
	Prazo de validade	Udløbsdato	Bäst före datum	Ημερομηνία λήξης
	Fabricante	Producent	Tillverkare	Κατασκευαστής
Content	Conteúdo	Indhold	Innehåll	Περιεχόμενο
Volume/No.	Volume/Número	Volumen/antal	Volym/antal	Όγκος/αριθ..