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NADAL® Syphilis Test (test cassette)

REF 203002

IVD CE

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NADAL® Syphilis Test (Ref. 203002)

1. Intended Use

The NADAL® Syphilis Test (whole blood/serum/plasma) is a rapid visual immunoassay for the qualitative, presumptive detection of IgM and IgG antibodies against *Treponema pallidum (T. pallidum)* in human whole blood, serum or plasma specimens. The NADAL® Syphilis Test is intended for use as an aid in the diagnosis of syphilis.

2. Introduction and Clinical Significance

Treponema pallidum (T. pallidum), a spirochete bacterium with an outer cell membrane and a cytoplasmic membrane, is the causative agent of the venereal disease syphilis. Although syphilis rates are declining in the United States after an epidemic between 1986 and 1990, the incidence of syphilis in Europe has increased since 1992, especially in the states of the Russian Federation, where peaks of 263 cases per 100,000 have been reported. In addition, the positive rate of serological test results for syphilis in HIV-infected individuals has been rising recently.

The serological detection of specific antibodies to *T. pallidum* has been long recognized in the diagnosis of syphilis since the natural course of the infection is characterized by periods without clinical manifestations. The antibody response to *T. pallidum* can be detected within 4 to 7 days after the syphilis chancre appears, allowing early detection and diagnosis of syphilis infection.

A variety of antigens, such as Cardiolipin (RPR test), VDRL antigen and *T. pallidum* extracts derived from *in-vitro* culture or inoculated rabbit testes, have been used in syphilis serological tests. However, RPR and VDRL antigens are not treponemal specific and whole *T. pallidum* extracts are not reproducible and contain a certain amount of contaminating materials such as flagella, which may lead to a non-specific reaction in assays of test serum.

3. Principle of the Test

The NADAL® Syphilis Test (whole blood/serum/plasma) enables the detection of IgM and IgG antibodies against *Treponema pallidum* (*T. pallidum*) through visual interpretation of colour development on the internal strip. Specific recombinant *T. pallidum* antigens are immobilized in the test line region of the membrane. During testing, the specimen reacts with recombinant *T. pallidum* specific antigen conjugated to coloured particles and pre-coated onto the sample pad of the test. The mixture then migrates along the membrane by capillary action and interacts with reagents on the membrane. If there are sufficient antibodies against *T. pallidum* in the specimen, a coloured line will form in the test line region of the membrane. The presence of this coloured line indicates a positive result, while its absence indicates a negative result. The appearance of a coloured line in the control line region serves as a procedural control, indicating that the proper volume of specimen has been added and the membrane wicking has occurred.

4. Reagents and Materials Supplied

- 20 NADAL® Syphilis test cassettes (incl. disposable pipettes)
- 1 vial of buffer
- 1 package insert

5. Additional Required Materials

- Centrifuge
- Specimen collection container
- Timer

6. Storage & Stability

The test should be stored at 2-30°C until the expiry date printed on the sealed foil pouch. The test must remain in the sealed foil pouch until use. Do not freeze. Care should be taken to protect the components of the test kit from contamination. Do not use the test if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipments, containers or reagents can lead to false results.

7. Warnings and Precautions

- For professional *in-vitro* diagnostic use only.
- Do not use the test after the expiration date indicated on the package.
- Do not use the test if the foil pouch is damaged.
- Do not reuse tests.
- This test kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is, therefore, recommended that these products be treated as potentially infectious and handled by observing usual safety precautions (e.g., do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire package insert carefully prior to testing.
- Do not eat, drink or smoke in the area where specimens and test kits are handled.
- Handle all specimens as if they contained infectious agents. Observe established precautions against microbiological hazards throughout the test procedure and follow standard procedures for the 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 test results.
- Used testing materials should be discarded according to local regulations.

8. Specimen Collection and Preparation

The NADAL® Syphilis Test (whole blood/serum/plasma) is intended for use with human whole blood, serum or plasma specimens only.

Only clear, non-hemolyzed specimens are recommended for use with this test. Serum or plasma should be separated as soon as possible to avoid hemolysis.

Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Serum and plasma specimens can 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 specimen collection. Do not freeze whole blood specimens. Fingerstick whole blood should be tested immediately.

Containers containing anticoagulants such as EDTA, citrate or heparin should be used for whole blood storage.

Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and well mixed prior to testing. Avoid repeated freezing and thawing of specimens.

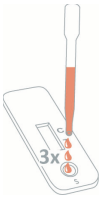
If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.

Icteric, lipemic, hemolysed, heat-treated and contaminated specimens can cause erroneous results.

9. Procedure of the Test

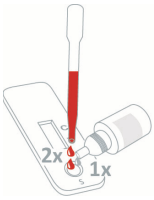
Bring tests, specimens and buffer to room temperature (15-30°C) before use.

1. Remove the test cassette from the sealed foil pouch and place it on a clean, level surface. Label the test cassette with a patient or control identification. For best results, the assay should be performed within one hour.
2. Using the provided disposable pipette, transfer 3 drops of serum/ plasma specimen (approximately 75 µL) to the specimen well (S) of the test cassette and start the timer.



OR

Transfer 2 drops of whole blood specimen (approximately 50 µL) to the specimen well (S) of the test cassette with the provided disposable pipette, then add 1 drop of buffer and start the timer.



OR

Allow 2 hanging drops of fingerstick whole blood specimen to fall into the center of the specimen well (S) of the test cassette, then add 1 drop of buffer and start the timer.

Avoid trapping air bubbles in the specimen well (S) and do not add any solution to the result area.

As the test begins to work, you will see colour move along the membrane.

3. Wait for coloured line(s) to appear. The result should be read at 10 minutes. Do not interpret the result after 20 minutes.

10. Interpretation of the Results

Positive:

Two coloured lines appear on the membrane. One line appears in the control line region (C) and the other line appears in the test line region (T).

Negative:

Only one colored line appears in the control line region (C). No coloured line appears in the test line region (T).

Invalid:

The control line fails to appear. Results from any test which has not produced a control line at the specified read time must be discarded. Please review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your distributor.

Note:

The intensity of colour in the test line region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of colour in the test line region should be considered positive. Note that this is a qualitative test only. It cannot determine the concentration of analytes in the specimen.

Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control line failure.

11. Quality Control

An internal procedural control is included in the test cassette. A coloured line developing in the control line region (C) is considered an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.

12. Limitations

- The NADAL® Syphilis Test (whole blood/serum/plasma) is for professional *in-vitro* diagnostic use only and should only be used for the qualitative detection of *T. pallidum* antibodies. No meaning should be inferred from the colour intensity or width of any apparent lines.
- The NADAL® Syphilis Test (whole blood/serum/plasma) only indicates the presence of *T. pallidum* antibodies in the specimen and should not be used as the sole criterium for the diagnosis of *T. pallidum* infection.
- If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at anytime rule out the presence of *T. pallidum* antibodies in blood, as antibodies may be present below the minimum detection level of the test.
- As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

13. Performance Characteristics

Table: The NADAL® Syphilis Test vs. TPHA

NADAL® Syphilis Test				
		+	-	Total
TPHA	+	246	1	247
	-	3	343	346
	Total	249	344	593

Relative Sensitivity: 99.6% (97.8%-99.9%)*

Relative Specificity: 99.1% (97.5%-99.8%)*

Overall Agreement: 99.3% (98.3%-99.8%)*

*95% Confidence Interval

14. References

1. Centers for Disease Control (CDC). Chlamydia trachomatis infections. Policy guidelines for prevention and control. MMWR Morb Mortal Wkly Rep. 1985 Aug 23; 34 Suppl 3: 53S-74S.
2. Tichonova L, Borisenko K, Ward H, Meheus A, Gromyko A, Renton A. Epidemics of syphilis in the Russian Federation: trends, origins, and priorities for control. Lancet. 1997 Jul 19; 350(9072): 210-3.
3. Norgard MV, Chamberlain NR, Swancutt MA, Goldberg MS. Cloning and expression of the major 47-kilodalton surface immunogen of Treponema pallidum in Escherichia coli. Infect Immun. 1986 Nov; 54(2): 500-6.

Rev.1, 2014-12-19 OM/UJ

Symbol	Deutsch	English	Français	Español	Italiano	Polski
CE	CE Konformitätszeichen	CE marking of conformity	Conformité aux normes européennes	Conformidad europea	Conformità europea	Znak zgodności CE
	Gebrauchsanweisung beachten	Consult instructions for use	Consulter la notice d'utilisation	Consúltense las instrucciones de uso	Consultare le istruzioni per l'uso	Przestrzegać instrukcji obsługi
IVD	In-vitro-Diagnostika	In-vitro diagnostic medical device	Dispositif médical de diagnostic in vitro	Producto sanitario para diagnóstico in vitro	Dispositivo medico-diagnostico in vitro	Tylko do diagnostyki in vitro
	Temperaturbegrenzung	Temperature limitation	Limites de température	Límite de temperatura	Limiti di temperatura	Temperatura przechowywania
LOT	Chargenbezeichnung	Batch code	Code du lot	Código de lote	Codice lotto	Numer serii
	Nicht zur Wiederverwendung	Do not reuse	Ne pas réutiliser	No reutilizar	Non riutilizzare	Tylko do jednorazowego użytku
	Verwendbar bis	Use by	Utiliser jusqu'au	Fecha de caducidad	Utilizzare entro	Data ważności
REF	Bestellnummer	Catalogue Number	Référence du catalogue	Número de catálogo	Riferimento di Catalogo	Numer katalogowy
	Hersteller	Manufacturer	Fabricant	Fabricante	Fabbricante	Producent
	Ausreichend für <n> Ansätze	Sufficient for <n> tests	Suffisant pour "n" tests	Suficiente para <n> utilizaciones	Sufficiente per "n" saggi	Wystarczający na <n> Powtórzeń

Symbol	Português	Český	Suomi	Svenskt	Nederlands	Dansk	Norsk
CE	Conformidade com as normas europeias	CE certifikát	CE-merkitty	CE-märkning	CE-markering	CE-mærkning	CE standardisert
	Consultar as instruções de utilização	Viz návod k použití	Katso käyttöohjetta	Läs bruksanvisningen	Raadpleeg de gebruiksaanwijzing	Se brugsanvisningen	Les bruksanvisning nøye
IVD	Dispositivo médico para diagnóstico in vitro	Diagnostický zdravotnický prostředek in vitro	In vitro - diagnostiikkaan tarkoitettu lääkinnällinen laite	Medicinteknisk produkt avsedd för in vitro-diagnostik	Medisch hulpmiddel voor in-vitrodiagnostiek	Medicinsk udstyr til in vitro-diagnostik	In-vitro diagnostic medisinsk enhet
	Limites de temperatura	Teplotní omezení	Lämpötilarajat	Temperatur-begränsning	Temperatuurlimiet	Temperatur-begrænsning	Temperatur begrensning
LOT	Código do lote	Kód šarže	Eräkoodi	Satsnummer	Code van de partij	Batchkode	Merking
	Não reutilizar	Pro jednorázové použití	Kertakäyttöinen	Får inte återanvändas	Niet opnieuw gebruiken	Må ikke genbruges	Må ikke brukes om igjen
	Prazo de validade	Spotřebujte do	Käytettävä viimeistään	Används före	Houdbaar tot	Udløbsdato	Tidtaking
REF	Número de catálogo	Katalogov éčíslo	Luettelonumero	Listnummer	Catalogus nummer	Best il l ingsnummer	Katalog nummer
	Fabricante	Výrobce	Valmistaja	Tillverkare	Fabrikant	Fabrikant	Produsent
	Suficiente para <n> test	Dostačuje pro <n> testů	Lukumäärä <n> test	Räcker till <n> test	Voldoende voor <n> test	Tilstrækkeligt til <n> test	Tilstrekkelig for<n> tester

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