DIALAB Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.
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DIAQUICK Syphilis Cassette

for whole blood, serum and plasma samples

(en) English

REF	Content
Z06903CE	- 30 tests individually packed, disposable pipette (30x REF Z03903B) - 2 vials buffer, sufficient for 30 tests - 1 package insert

For professional in vitro diagnostic use only.

INTENDED USE

The DIAQUICK Syphilis Cassette is a rapid chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to *Treponema pallidum* in human whole blood, serum and plasma specimens. Intended as an aid in the diagnosis of a *Treponema pallidum* infection and for manual and professional laboratory use.

DIAGNOSTIC SIGNIFICANCE

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 antibodies 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 DIAQUICK Syphilis Cassette 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.

TEST PRINCIPLE

The DIAQUICK Syphilis Cassette (whole blood/serum/plasma) is a qualitative membrane 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 test. After specimen is added to the specimen well of the cassette, it reacts with Syphilis antigen coated particles in the test. This mixture migrates chromatographically along the length of the test and interacts with the immobilized Syphilis antigens. 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.

REAGENT COMPOSITION

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

MATERIAL REQUIRED BUT NOT PROVIDED

- specimen collection container
- centrifuge
- timer
  For fingerstick whole blood
- heparinised capillary tubes and dispensing bulb
- lancets

REAGENT PREPARATION

The test is ready to use.

STORAGE AND STABILITY

Conditions: The cassette must remain in the sealed aluminium pouch until use.
Storage: at 2-30 °C; DO NOT FREEZE!
Stability: up to the expiration date

WARNINGS AND PRECAUTIONS

- For in vitro diagnostic use only. Do not use kit beyond the 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 the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

SPECIMEN COLLECTION AND STORAGE

- The DIAQUICK Syphilis Cassette (whole blood/serum/plasma) can be performed using whole blood (from venipuncture or fingerstick), serum, or plasma.
- To collect **Venipuncture Whole Blood specimens**:
  - Collect anti-coagulated blood specimens (sodium or lithium heparin, potassium or sodium EDTA, sodium oxalate, sodium citrate) following standard laboratory procedures.
- To collect **Fingerstick Whole Blood specimens:**
  - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
  - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
  - Puncture the skin with a sterile lancet. Wipe away the first sign of blood
  - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
  - Add the Fingerstick Whole Blood specimen to the test by using **a capillary tube**:
    Touch the end of the capillary tube to the blood until filled to approx. 80 µL.
    Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen well (S) of the test cassette.
- 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 specimen collection. 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.
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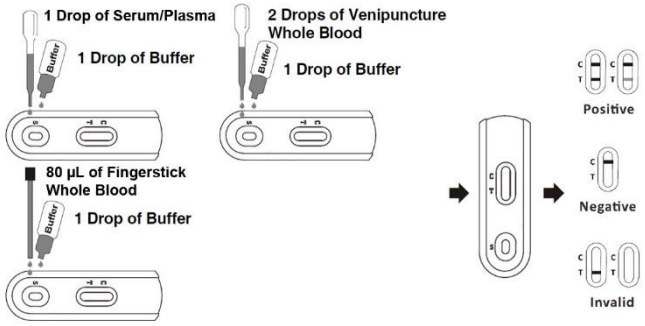
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

TEST PROCEDURE

Allow the test cassette, specimen, buffer, and/or controls to equilibrate to room temperature (15 – 30 °C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it within one hour.
2. Place the test cassette on a clean and level surface.
   For **Serum or Plasma** specimens:
   Hold the dropper vertically and **transfer 1 drop of serum or plasma** (approx. 40 µL) to the specimen well (S), then **add 1 drop of buffer** (approx. 40 µL) and start the timer.
   For Venipuncture Whole Blood specimen:
   Hold the dropper vertically and transfer **2 drops of whole blood** (approx. 80 µL) to the specimen well (S), then **add 1 drop of buffer** (approx. 40 µL) and start the timer. For **Fingerstick Whole Blood** specimen:
   Fill the capillary tube and **transfer approx. 80 µL of fingerstick whole blood specimen** to the specimen well (S) of the test cassette, then **add 1 drop of buffer** (approx. 40 µL) and start the timer. See illustration below.
3. Wait for the coloured line(s) to appear. The result should be read at 5 minutes. Do not interpret results after 20 minutes.



INTERPRETATION OF RESULTS

POSITIVE:* Two distinctly coloured lines appear. One line should be in the control line region (C) and another apparent 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 antibody present in the specimen. Therefore, any shade of colour in the test 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. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL AND CALIBRATION

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.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity
The DIAQUICK Syphilis Cassette (whole blood/serum/plasma) has correctly identified specimens of a seroconversion panel and has been compared to a leading commercial TPPA Syphilis test using clinical specimens. The results show that the relative sensitivity of the DIAQUICK Syphilis Cassette (whole blood/serum/plasma) is > 99.9 %, and the relative specificity is 99.7 %.

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Method		TPPA		Total Results
DIAQUICK Syphilis Cassette	Results	Positive	Negative	
	Positive	130	1	131
	Negative	0	299	299
Total Results		130	300	430

Relative Sensitivity: > 99.9 % (97.7 % - 100.0 %) *
Relative Specificity: 99.7 % (98.2 - 100.0 %) *
Accuracy: 99.8% (98.2 % - 100.0 %) *
* 95 % Confidence Interval

Precision

Intra-Assay
Within-run precision has been determined by testing 15 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 15 independent assays on the same four specimens: a negative, a low positive, a medium positive and a high positive. Three different lots of the DIAQUICK Syphilis Cassette (whole blood/serum/plasma) have been tested over a 3-day period using negative, low positive, medium positive and high positive specimens. The specimens were correctly identified > 99 % of the time.

Cross-reactivity
The DIAQUICK Syphilis Cassette (whole blood/serum/plasma) has been tested by HAMA, RF, HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, HCV, HIV, H. pylori, MONO, CMV, Rubella and TOXO positive specimens. The results showed no cross-reactivity.

Interfering Substances
The following potentially interfering substances were added to Syphilis negative and positive specimens.

Acetaminophen	20 mg/dL	Caffeine	20 mg/dL
Acetylsalicylic Acid	20 mg/dL	Gentisic Acid	20 mg/dL
Ascorbic Acid	2 g/dL	Albumin	2 g/dL
Creatin	200 mg/dL	Haemoglobin	1.1 mg/dL
Bilirubin	1 g/dL	Oxalic Acid	600 mg/dL

None of the substances at the concentration tested interfered in the assay.

TRACEABILITY

As a reference, the DIAQUICK Syphilis Cassette was compared to a leading commercial TPPA Syphilis test. The results show that the relative accuracy of the DIAQUICK Syphilis Cassette (whole blood/serum/plasma) is > 99.9 %.

EXPECTED VALUES

The DIAQUICK Syphilis Cassette (whole blood/serum/plasma) has been compared with a leading commercial TPPA Syphilis test, demonstrating an overall accuracy of 99.8 %

LIMITATIONS

- The DIAQUICK Syphilis Cassette (whole blood/serum/plasma) is for in vitro diagnostic 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.
- The DIAQUICK Syphilis Cassette (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.
- As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
- 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.

WASTE MANAGEMENT

Please refer to local legal regulations

LITERATURE

1. Claire M. Fraser. Complete genome sequence of Treponema Pallidium, 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. Aral R. Marx. Crack, sex and STD, Sexually Transmitted Diseases, 1991; 18:92- 101
4. L.N. Wasserheit. Epidemiological Synergy: Interrelationships between human immunodeficiency virus infection and other sexually transmitted diseases, Sexually Transmitted Diseases 1992; 19:61-77
5. Phillip C. Johnson. Testing for Syphilis, Dermatologic Clinic (1994); 12 Jan: 9- 17.

USED SYMBOLS

Symbol	Description
Cont.	Content