

HEALTH-CHEM DIAGNOSTICS LLC

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SYPHILIS (For the One-Step™ Detection of Syphilis)

1. INTENDED USE

Syphilis is a rapid, one-step test for the qualitative detection of *Syphilis antibody* in human blood, serum, and plasma.

II. SUMMARY AND EXPLANATION

The causative agent of Syphilis is *Treponema Pallidum*, discovered in 1905. The organism is a spirochete (spiral thread). Persons affected with the disease are sources of infection. The disease is transmitted via the genital organs. Syphilis may also be transmitted through the placenta to the fetus. Laboratory diagnosis is via microscopic analysis of the contents of the ulcer or papula discharge. The typical tests are the T. pallidum immobilization test, Wasserman reaction and precipitate reaction. This one-step kits is simple, specific, highly sensitive and requires no special equipment or trained personnel.

III. PRINCIPLE OF THE TEST

The Syphilis kit is a rapid membrane based screening test to detect the presence of antibodies to Syphilis. This test is the newer generation lateral immunochromatographic type assay. These are among the simplest and easiest to use POC (Point of Care Assays).

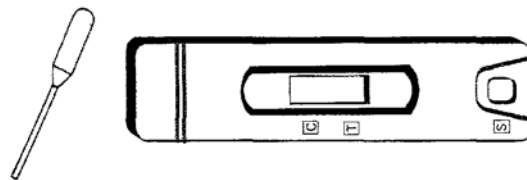
The test can be used either with serum or whole blood. The test employs the use of a recombinant antigen conjugated to a colloidal gold particle and a recombinant antigen immobilized on the membrane. Since the antigen are recombinant, these are 100 percent non-infectious.

Once the sample is added to the test cassette, the immunoglobulins in the sample react with the antigen conjugated gold as it reaches the “gold pad”. As this complex passes over the immobilized antigens on the membrane, if any antibodies to Syphilis are present the antigens capture them in turn. This produces a pink/purple in the T zone of the test card. The remaining complex continues to migrate to a control area in the test card and produces a pink/purple in the C area. This control band indicates that the test has been performed properly.

IV. MATERIALS PROVIDED

1. Test Devices.
2. Disposable pipettes.

(packaged together in foil pouch)



PIPETTE

TEST DEVICE

3. Instructions for use.

V. STORAGE AND STABILITY

Test device may be stored at ambient temperature of 20 - 30°C (50-85°F) in the original unopened foil pouches. Each Test device contains a desiccant. The test should be used without delay once the pouch has been opened. In case the temperature of the test device is considerably below room temperature and the humidity of the air is high, it is advisable to let the device reach room temperature before opening the pouch. The shelf-life of the test device is months from the date of manufacture. The expiration date is printed on the foil pouch.

VI. SAMPLE COLLECTION AND STORAGE

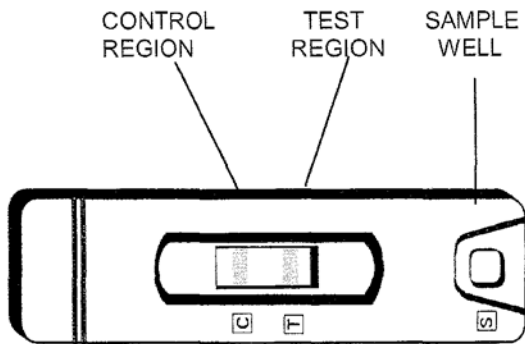
1. Fresh samples are preferred.
2. If serum/plasma specimens are not immediately tested they should be refrigerated at 2-8°C. For storage periods greater than 3 days, freezing is recommended.

WARNINGS AND PRECAUTIONS

1. Wear disposable gloves while handling Specimens.
Wash hands thoroughly afterwards.
2. Wipe up spills thoroughly using an appropriate intermediate to high level disinfectant.
3. Decontaminate and dispose of all specimens, Reaction Kits and potentially contaminated materials, as if they were infectious, in a biohazard container.
4. Avoid splashing or aerosol formation.
5. Do not use the Kit after the expiration date.
6. For in vitro diagnostic use only.

VII. TEST PROCEDURE

1. Remove the "Test Device" from its foil wrapper by tearing along the "splice" and place it on a clean level surface.

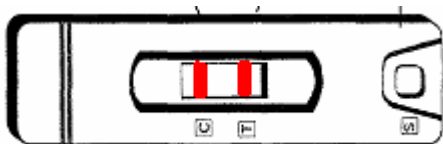


2. Fill the disposable dropper with the sample.
3. Hold the disposable dropper in a vertical position and apply 2 drops of sample into the sample well of the test device. Read the results within 10 minutes.

Warning: Discard the results after 10 minutes.

VIII. INTERPRETATION

Positive Result: If there is a dark-rose color band in the control region (marked with a 'C'), and a dark-rose color band in the test region (marked with a 'T'), Syphilis is present and the specimen is positive.



Negative Result: The absence of a color band in the test region next to the letter 'T' indicates the absence of any detectable Syphilis.



Invalid Result: If a color band does not appear in the control region "C", the test results are invalid. The sample may have been added to the wrong window, or the Test Device may have deteriorated. This specimen should be re-tested using a new Test Device.



Note: any ghost line appearing in the T-line within 10 minutes will not be considered as a positive result.

IX. LIMITATIONS OF THE TEST

1. Syphilis Kit is limited to the detection of Syphilis antibody only.
2. Although the Kit is very accurate in detecting Syphilis antibody, a very low incidence of false results might occur.
3. If negative or questionable results are obtained, and Hepatitis B infection is suspected, the test should be repeated on a fresh serum specimen.
4. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after evaluation of all clinical and laboratory findings.

External Controls:

Like any *in vitro* device, performance of the Test should be checked for accuracy and batch to batch variation by using known serum pools. These sera should be used in the same way as described in the assay procedure for serum samples. It is recommended that these control sera be used at least once with every batch or new shipment.

Internal Controls:

In addition to the external controls the test device has built-in controls. With each testing there should always be a rose-pink color band in the control region ('C'). If the color band does not appear in the control region, the result should be considered invalid. Also, after performing the test, the result window ('T') should look clear white or uniform light pink. If the result window shows large red or purple streaks at the end of 10 minutes, the test should be considered invalid. Repeat the test using a fresh test device.

Performance Characteristics

1. Precision: Inter assay and intra assay precision tests were run using five negative controls and five positive serum samples with 100% correct identification.
2. Accuracy: A study was performed using 206 serum samples assayed using the One-Step™ test and a commercially available quantitative ELISA test.

The correlation results are as follows:

Correlation between one-step and ELISA

		One Step	
		Pos.	Neg.
ELISA	Pos.	66	1
	Neg.	2	137

Sensitivity: 99.5%

Specificity: 99.5%

REFERENCES

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Manufactured in the USA by:

HEALTH-CHEM DIAGNOSTICS LLC,
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