Boditech Quick™ Syphilis

INTENDED USE

Boditech Quick™ Syphilis is a chromatographic immunoassay for the qualitative determination of antibodies to syphilis in human whole blood/serum/plasma. It is useful as an aid to diagnosis of syphilis.

For *in vitro* diagnostic use only.

INTRODUCTION

Syphilis is an infectious and sexually transmitted chronic disease caused by Treponema pallidum. The progression of syphilis is classified into early symptomatic (primary, secondary, early latent) and late asymptomatic (late latent, tertiary) stage.[1)]

These reflect the infectious period, thus early syphilis is infectious and at late stage the infection is not transmittable. Early syphilis can be divided again into primary, secondary and early latent syphilis depending on clinical presentation.[2)]

Late syphilis consists of late latent (asymptomatic) and tertiary syphilis. Approximately 30- 40% of cases untreated syphilis will develop late symptomatic disease. Tertiary syphilis is the manifestation of long term syphilis and consists of cardiovascular, neurological or gummatous involvement. syphilis can cause benign lesions in skin, bone, liver and upper respiratory tract. Cardiovascular syphilis primarily involves the aorta leading to aortitis, aortic regurgitation or aneurysm. Late neurosyphilis manifests as meningitis, stroke, cranial nerve palsies, myeopathy (including tabes dorsalis), seizures or progressive dementia (general paresis). Late latent syphilis is diagnosed in the absence of neurosyphilis and other symptoms and signs of disease. [2)]

The infection can also be passed from mother to her fetus during pregnancy. Most infected individuals have no symptoms or have transient lesions and therefore a serological test must be used to screen for infection. [2)]

The control of syphilis requires early identification and treatment of cases. This calls for tests that are easily administered and interpreted, and treatment that is fast, efficacious and side effect free.3) If syphilis patients are not diagnosed properly, it may lead to a serious public health problem. [3)]

Boditech Quick™ Syphilis is a chromatographic Immunoassay for the detection of Syphilis total anti-body in human whole blood/serum/plasma.

PRINCIPLE

The test uses a sandwich immunodetection method.

The detector antigen in conjugation pad bind to antibodies in the sample, forming antigen-antibody complexes, and migrate onto nitrocellulose matrix to be captured by the other immobilized antigens on a test strip.

More antibodies in the sample will form more antigen-antibody complexes which lead to stronger band by detector antigens, if there is no syphilis antibodies in the sample, no band is formed on the T line. "Positive" and "negative" are distinguished by the presence or absence of band formation on the T line.

COMPONENTS

Boditech Quick™ Syphilis consists of 'cartridges', 'detector diluent.

- The cartridge contains a test strip which has conjugation pad and nitrocellulose membrane. The conjugation pad has recombinant syphilis antigen-gold conjugate, chicken IgY-gold conjugate as detector for the antibodies.
- The nitrocellulose membrane has recombinant syphilis antigen at the test line, and Anti-chicken IgY at the control line. All cartridges are individually sealed in an aluminum foil pouch containing a desiccant and they are further packaged in a box.
- The detector diluent contains detergent and sodium azide as a preservative in DDW and it is pre-dispensed in dropper tubes. The detector diluent is packed in a box.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- Follow instructions and procedures described in this 'Instructions for use'.
- Use only fresh samples and avoid direct sunlight.
- Lot numbers of all the test components (cartridge, detector diluent) must match each other.
- Do not interchange test components between different lots or use test components after the expiration date, either of which might yield incorrect test result(s)
- Do not reuse cartridges. A cartridge should be used for testing one sample only.
- Do not use the test components after the expiration date.
- The cartridge should remain sealed in its original pouch until just before use. Do not use the cartridge, if pouch is damaged or has already been opened.
- Frozen sample should be thawed only once. For shipping, samples must be packed in accordance with local regulations. Sample with severe hemolysis and/or hyperlipidemia must not be used.
- If test components and/or sample are stored in refrigerator, then allow cartridge, detector diluent and sample to be at room temperature for approximately 30 minutes before use.
- Do not use the contaminated detector diluent, otherwise it might yield incorrect result.
- Used cartridges, detector diluent and micro sample collectors should be handled carefully and discarded by an appropriate measure in accordance with the relevant local regulations.
- The detector diluent contains sodium azide (NaN_3) and they may cause certain health issues like convulsions, low blood pressure and heart rate, loss of consciousness, lung injury and respiratory failure. Avoid contact with skin, eyes, and clothing. In case of contact, rinse immediately with running water.
- **Boditech Quick™ Syphilis** will provide accurate and reliable results subject to the below conditions.
  - Have to use recommended anticoagulant.

Recommended anticoagulant

K_2 EDTA, Na_2EDTA, Lithium heparin,
Sodium heparin, Sodium citrate

LIMITATION OF THE TEST SYSTEM

- The test may yield false positive result(s) due to the cross-reactions and/or non-specific adhesion of certain sample components to the capture/detector antigens.
- The test may yield false negative result(s) due to the non-responsiveness of the antigens to the antibodies which is the most common if the epitope is masked by some unknown components, so therefore not being able to be detected or captured by the antigens. The instability or degradation of the antibodies with time and/or temperature may also cause false negative result as it makes the antibodies unrecognizable by the antigens.
- Other factors may interfere with the test and cause erroneous results, such as technical/procedural errors, degradation of the test components/reagents or presence of interfering substances in the test samples.
- Any clinical diagnosis based on the test result must be supported by a comprehensive judgment of the concerned physician in conjunction with clinical symptoms and other relevant test results.

STORAGE AND STABILITY

Storage condition			
Component	Storage Temperature	Shelf life	Note
Cartridge	2 - 30°C	20 months	Disposable
Detector diluent	2 - 30°C	20 months	Unopened
		12 months	Opened

- After the cartridge pouch is opened, the test should be performed immediately.

MATERIALS SUPPLIED

REF CFPT-36

Components of **Boditech Quick™ Syphilis**

- Cartridge box
  - Cartridge 25
  - Micro sample collector (10/20 µL) 25
  - Detector diluent 1
  - Instructions for use 1

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

Following items can be purchased separately from **Boditech Quick™ Syphilis**

- **Boditech Syphilis Control** **REF** CFPO-210

SAMPLE COLLECTION AND PROCESSING

The sample type for **Boditech Quick™ Syphilis** is human whole blood/serum/plasma.

- It is recommended to test the sample within 24 hours after collection when collected sample is stored at room temperature.
- The samples (serum, plasma) should be separated from the clot by centrifugation within 3 hours after the collection of whole blood.
- The samples (whole blood) may be stored for a day at 2-8°C prior to being tested.
- The samples (serum, plasma) may be stored for a week at 2-8°C prior to being tested. If testing will be delayed more than a week, samples should be frozen at -20°C.
- The samples (serum, plasma) stored frozen at -20°C for 2 months showed no performance difference.
- However, the whole blood sample should not be kept in a freezer in any case.
- As a repeated freeze-thaw cycle may affect the test result, do not refreeze previously frozen samples.

[Micro sample collector (10/20 µL)]

Fingertip blood sample should be collected below:

① Wear disposable gloves and the protective equipment for safety.
② Open the zipper bag which has micro sample collectors.
③ Take out the 10 µL for serum (bottom line)/plasma and 20 µL for whole blood (upper line) micro sample collector and check for damaged or contamination.
④ Hold the end of the micro sample collector and touch the surface of blood with the micro sample collector.
⑤ Fill the micro sample collector with blood up to the marked scale.
(Do not make air bubbles in the micro sample collector and careful not to get blood on the surface of the micro sample collector. If blood gets on the surface of the micro sample collector, remove it gently with gauze.)

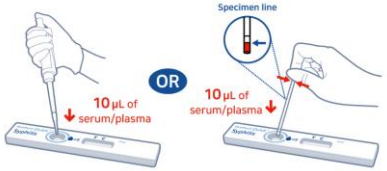
TEST SETUP

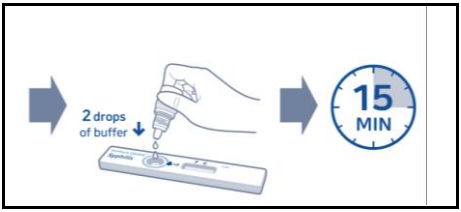
- Check the contents of **Boditech Quick™ Syphilis:** Sealed Cartridges, a detector diluent, micro sample collectors and an Instruction for use.
- Ensure that the lot number of the cartridges matches that of the detector diluent.
- If the sealed cartridge, and the detector diluent have been stored in a refrigerator, place them on a clean and flat surface at room temperature for at least 30 minutes before testing.

TEST PROCEDURE (Sample type: Serum/plasma)

※ Before use, read the kit instructions carefully and follow the kit instructions.

① Take out the cartridge from the aluminum pouch and place it flat.
② Please choose the procedure kind of sample type.
③ Take 10 µL of sample (serum/plasma) using a pipette or a micro sample collector and dispense it into the sample well of the cartridge.
④ Hold the detector diluent (mini plastic dropper) vertically and add 2 drops (about 60 µL) to the sample well immediately. Avoid air bubbles.
⑤ Read the test result between 15minutes after sample loading.
⑥ The results observed after 20 minutes are invalid.

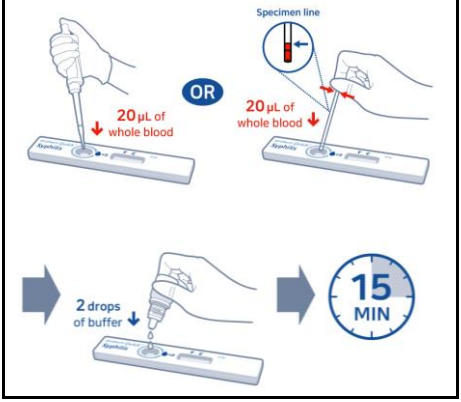




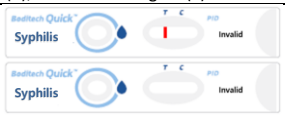
TEST PROCEDURE (Sample type: Whole blood)

※ Before use, read the kit instructions carefully and follow the kit instructions.

1) Take out the cartridge from the aluminum pouch and place it flat.
2) Take 20 µL of sample (whole blood) using a pipette or a micro sample collector and dispense it into the sample well of the cartridge.
3) Hold the detector diluent (mini plastic dropper) vertically and add 2 drops (about 60 µL) to the sample well immediately. Avoid air bubbles.
4) Read the test result between 15minutes after sample loading.
5) The results observed after 20 minutes are invalid.



INTERPRETATION OF TEST RESULT

Result	Interpretation
Negative	 One colored line should be in the control line region (C).
Positive	 Two lines appear in the control line region (C), and test line region (T).
Invalid	 No line in the control line region. Re-test with sample and new cartridge

※ Strong positive results are confirmed in 10 minutes.

※ Any line in the T line, faint or thick, should be considered positive result.

※ Do not interpret the result after 20 minutes.

QUALITY CONTROL

- Quality control tests are a part of the good testing practice to confirm the expected results and validity of the assay and should be performed at regular intervals.
- Quality control tests should also be performed whenever there is any question concerning the validity of the test results.
- Control materials are provided on demand with **Boditech Quick™ Syphilis**. For more information regarding obtaining the control materials, contact Boditech Med Inc.'s Sales Division for assistance.

(Please refer to the instruction for use of control material.)

PERFORMANCE CHARACTERISTICS

- **Analytical specificity**

- **Cross-reactivity**

Biomolecules listed in the following table were added to the test sample(s) at concentrations much higher than their normal physiological levels in the blood. **Boditech Quick™ Syphilis** test results did not show any significant cross-reactivity with these biomolecules.

No.	Name	Sample type
1	Cytomegalovirus (CMV)	Positive Serum
2	Epstein-Barr virus (EBV)	Positive Serum
3	Hepatitis A virus (HAV)	Positive Serum
4	Hepatitis C virus (HCV)	Positive Serum
5	Herpes simplex virus (HSV)	Positive Serum
6	Rubella virus	Positive Serum
7	Varicella-zoster virus (VZV)	Positive Serum
8	Human Immunodeficiency Virus (HIV)	Positive Serum
9	Anti-Nuclear antibody (ANA)	Positive Serum
10	Toxoplasma gondii	Positive Serum
11	Dengue	Positive Serum
12	HBsAg	Positive Serum
13	Rheumatoid factor (RF)	Positive Plasma
14	Early stage of pregnancy	Pregnant women sample
15	Anti-HBs	Positive Serum

- **Interference**

Interference materials listed in the following table were added to the test sample(s) the same as the below concentrations listed below. **Boditech Quick™ Syphilis** test results did not show any significant interference with these materials.

No.	Interference material	Concentration
1	Li-Heparin	100,000 U/L
2	Na-Heparin	100,000 U/L
3	Na_2EDTA	2 mg/mL (5 μM)
4	K_2EDTA	2 mg/mL (5 μM)
5	Sodium citrate	25 mg/mL (0.085 μM)
6	Hemoglobin	2 mg/mL
7	BSA	60 mg/mL
8	Bilirubin	0.24 mg/mL (400 μM)
9	Triglycerides	1.5 mg/mL
10	Cholesterol	7.7 mg/mL (20 mM)

- **Precision**

- Between days

One person tested 1 lot of **Boditech Quick™ Syphilis** for 5 days. Each standard material was tested 2 times per day. For each test, each material was triplicated.

No	sample	Concordance rate /Total test no.					Total concordance rate
		Day 1	Day 2	Day 3	Day 4	Day 5	
1	High Positive	6/6	6/6	6/6	6/6	6/6	100% (30/30)
2	Mid Positive	6/6	6/6	6/6	6/6	6/6	100% (30/30)
3	Low positive	6/6	6/6	6/6	6/6	6/6	100% (30/30)
4	Negative	0/6	0/6	0/6	0/6	0/6	0% (0/30)

- Between lots

One person tested three different lots of **Boditech Quick™ Syphilis** at 1 site, 2 times a day, 2 replicates per trial, at each concentration of the control standard for 5 days.

No	sample	Concordance rate /Total test no.			Total concordance rate
		Lot 1	Lot 2	Lot3	
1	High Positive	20/20	20/20	20/20	100% (60/60)
2	Mid Positive	20/20	20/20	20/20	100% (60/60)
3	Low positive	20/20	20/20	20/20	100% (60/60)
4	Negative	0/20	0/20	0/20	0% (0/60)

- Between person

Three testers tested 1 lot of **Boditech Quick™ Syphilis** at 1 site, 2 times a day, 2 replicates per trial at each concentration of the control standard for 5 days.

No	sample	Concordance rate /Total test no.			Total concordance rate
		Tester 1	Tester 2	Tester 3	
1	High Positive	20/20	20/20	20/20	100% (60/60)
2	Mid Positive	20/20	20/20	20/20	100% (60/60)
3	Low positive	20/20	20/20	20/20	100% (60/60)
4	Negative	0/20	0/20	0/20	0% (0/60)

- Between sites

One person tested **Boditech Quick™ Syphilis** at three different site, 2 times a day, 2 replicates per trial at each concentration of the control standard for 5 days.

No	sample	Concordance rate /Total test no.			Total concordance rate
		Site 1	Site 2	Site 3	
1	High Positive	20/20	20/20	20/20	100% (60/60)
2	Mid Positive	20/20	20/20	20/20	100% (60/60)
3	Low positive	20/20	20/20	20/20	100% (60/60)
4	Negative	0/20	0/20	0/20	0% (0/60)

- **Clinical evaluation**

		Reference product		
		Positive	Negative	Total
Boditech Quick™ Syphilis	Positive	99	1	100
	Negative	1	199	200
	Total	100	200	300
Percent positive agreement		99% (95% CI: 94.55-99.82%)		
Percent negative agreement		99.5% (95% CI: 97.24-99.91%)		

REFERENCES

1. Recent Trends in Clinical Observation of Syphilis and Consideration for Laboratory Tests. Choi et al., J Korean Med Assocl. 2009; 52(11): 1100 – 1106
2. Syphilis: A Review of the Diagnosis and Treatment. CR. Emerson et al., The Open Infectious Diseases Journal. 2009, 3, 143-147
3. Syphilis - Recognition, Description and Diagnosis. NS Sato et al., InTech. 87-88 pp. ISBN 978-953-307-554-9, 2011

Note: Please refer to the table below to identify various symbols.

Σ	Sufficient for <n> tests
	Read instruction for use
	Use by Date
LOT	Batch code
REF	Catalog number
	Caution
	Manufacturer
EC REP	Authorized representative of the European Community
IVD	In vitro diagnostic medical device
	Temperature limit
	Do not reuse
CE	This product fulfills the requirements of the Directive 98/79/EC on in vitro diagnostic medical devices

For technical assistance, please contact:
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