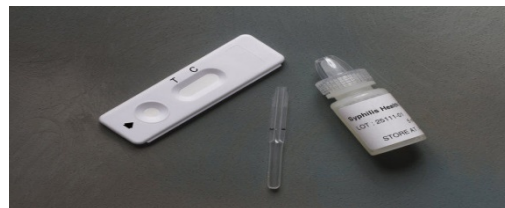


SYPHILIS HEALTH CHECK™  
RAPID POINT-OF-CARE SYPHILIS TESTING  
Fact Sheet and Frequently Asked Questions (FAQ)



**Syphilis Health Check™ (SHC) Facts**

- Manufacturer: Diagnostics Direct
- Qualitative rapid assay for detection of *Treponema pallidum* (syphilis) antibodies in human whole blood (fingerstick sample), serum or plasma
- 3<sup>rd</sup> generation enzyme immunoassay (EIA) format detecting both immunoglobulin G (IgG) and immunoglobulin M (IgM) antibodies
- Results available in 10 minutes
- 97-98% agreement with other reference treponemal assays, sensitivity may be reduced in primary disease
- Food and Drug Administration (FDA) cleared and Clinical Laboratory Improvement Amendments (CLIA) waived (may be performed in traditional clinical/laboratory settings and non-traditional settings such as mobile vans, health fairs, and other venues)
- Test kit contains: 20 test devices, pipettes, and 1 bottle of diluent. Shelf-stable at room temperature for 2 years from manufacture date.
- Control kit contains: 1 bottle each of positive/negative control. Controls must be refrigerated.
- Additional supplies needed: gloves, lancets, timer
- Pricing for test kit and controls:
  - Diagnostic Direct's (manufacturer) price: \$200/kit (\$10/test), \$49/controls
  - Trinity Biotech's (authorized seller) price: \$200/kit, \$27/controls

**How should SHC be used? Who can be tested with SHC?**

SHC can be used for initial screening of asymptomatic patients, or SHC can be used conjunction with a non-treponemal test (e.g. rapid plasma reagin [RPR]) and clinical findings to aid in diagnosis of symptomatic patients. Specific populations to target for screening include men who have sex with men, commercial sex workers and their clients, pregnant patients (especially with poor prenatal care), people experiencing homelessness, people who are incarcerated, and people who inject drugs.

**Who should NOT be tested with SHC?**

**Patients with a known prior history of syphilis should NOT receive testing with the SHC.**

Treponemal antibodies often remain positive for life after previous infection, therefore the SHC cannot distinguish an old infection versus a new, current infection. For patients with a prior history of syphilis, a non-treponemal test (e.g. RPR or venereal disease research laboratory [VDRL]) should be performed instead of SHC.

### Who can perform SHC in California?

In California, [Business and Professions Code 1206.5](#) dictates which individuals can perform CLIA waived tests. Please refer to the code for a complete listing. As of July 2018, a [letter from the State Public Health Laboratory Director](#) indicates that the **SHC can be performed by disease intervention specialists (DIS) or other non-licensed staff** in California under the following conditions:

- Non-licensed staff conducting rapid syphilis tests are operating **under the authority of the Public Health Laboratory Director** for the local health department.
- CLIA-waived rapid syphilis tests must be FDA-cleared, approved as waived tests, and used according to the manufacturer's instructions.
- Blood collection is performed by skin puncture only.
- Testing is performed on-site and reported directly to the person requesting the test.
- A minimum of 20 hours of [basic phlebotomy didactic training](#) approved by the California Department of Public Health (CDPH) Laboratory Field Services (LFS) is completed. DIS with phlebotomy certifications from LFS-approved programs have already met that training requirement. HIV/HCV test counselor training or training by test distributors do not count toward the didactic training requirement.

### What settings should be targeted for use of SHC?

SHC may be useful in 1) clinical settings such as emergency departments or urgent cares, sexually transmitted diseases (STD) clinics, HIV clinics, family planning clinics, practices providing prenatal care; 2) non-clinical settings offering limited services: corrections, homeless shelters, drug treatment facilities; 3) community/outreach settings: mobile vans, homeless encampments, commercial sex venues, needle exchange sites, health fairs.

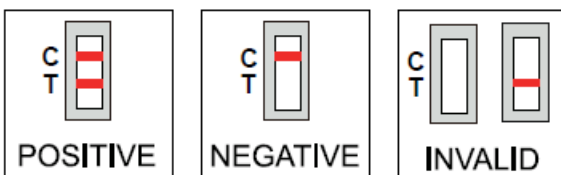
### How is the test performed?

Please refer to the [package insert](#) for step by step instructions for how to perform SHC.

### How are results interpreted?

Results are positive, negative, or invalid.

- **Positive:** Colored bands in the test area AND control area
- **Negative:** 1 colored band in the control area
- **Invalid:** No distinct color bands in either area OR 1 colored band in test area and no band in control area.



### What if I find a patient with a positive SHC result in a non-clinical setting?

Draw blood for further testing and treat empirically in the field, if possible. Regardless, refer the patient to a local clinic for further testing and possible treatment.

**What are reporting requirements for SHC results?**

Positive SHC results should be reported to the health department similarly to other positive syphilis serology tests.

**What if I have questions about interpretation of test results and/or treatment of patients with positive SHC results?**

The CDPH STD Control Branch and the California STD-HIV Prevention Training Center (PTC) warmline clinical staff can answer questions regarding clinical management of patients with syphilis or other STDs. Clinicians can access [STD consultation online](#) though and current [syphilis treatment recommendations](#).