



## QUICK REFERENCE INSTRUCTIONS

### Fingerstick Whole Blood Procedure

**The Syphilis Health Check test may be used at Physician Offices, Clinics, and Laboratories with Certificate of Waiver.**

Contact Diagnostic Direct Technical Services at 866-358-9282, if you are unable to produce a valid result upon repeat testing.

- These Instructions are only a Quick Reference Guide. For complete information, refer to the Syphilis Health Check Test Package Insert.
- Before you start, read the package insert and Quality Control procedures completely before using the product. Follow the instructions carefully when performing the test. Not doing so may result in inaccurate test results.
- Persons performing the test must be tested for colorblindness before performing the test.



### Materials Provided in the Kit:

Test Cassette – 20 each

- Disposable fixed volume pipettes - 20 each
- Dropper Bottle – 5 mL – containing Buffer Diluent

Make sure the materials in the kit are at room temperature before use.

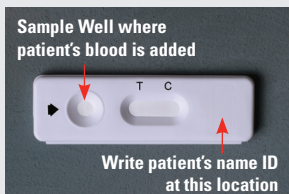
Always wear gloves when performing Syphilis Health Check.

Lay device on clean flat surface facing up.

### Test Cassette

**C** Stands for Control

**T** Stands for Test result



## STEP 1: SPECIMEN COLLECTION - Fingerstick Procedure (Wear Gloves)

### A. Wipe Finger with Alcohol Pad



### B. Prick Finger using Sterile Lancet



### C. Remove first drop of blood



## STEP 2: RUNNING TEST

### A. Draw blood from finger using fixed volume pipette (provided)

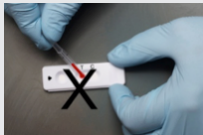


1. "MILK" pricked finger to produce blood sample
2. Hold Pipette horizontally and touch tip to the blood drop.
3. THE PIPETTE IS NOT LIKE A TURKEY BASTER, DO NOT SQUEEZE BULB AT TOP OF PIPETTE WHILE DRAWING BLOOD FROM FINGER TO PIPETTE. ALLOW THE BLOOD TO FLOW INTO THE PIPETTE ON ITS OWN.

### B. Add blood to Sample Well by pressing bulb area of pipette. The Sample Well will turn red. Allow blood to be absorbed.



### C. DO NOT ADD BLOOD SAMPLE TO OVAL REACTION WELL MARKED T + C



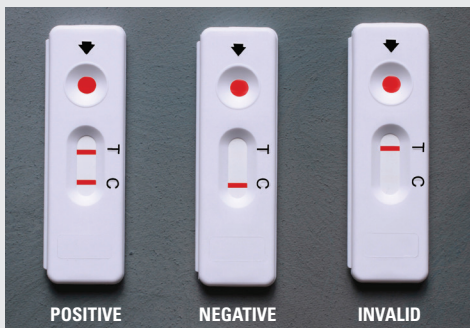
### D. Add Four (4) drops of diluent from bottle ONLY (provided).

**DO NOT USE WATER OR OTHER LIQUIDS**

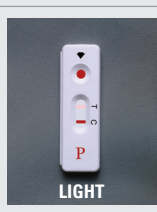
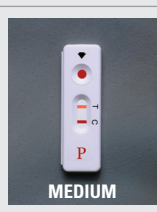


**E. Start Timer and Wait AT LEAST 10 minutes**

**F. Read results no sooner than 10 minutes and NO MORE THAN 15 minutes**



**G. POSITIVES**



**A positive SHC result is not diagnostic of syphilis without additional nontreponemal serologic testing.**

**A new venous whole blood specimen must be obtained for further testing.**

## EXTERNAL QUALITY CONTROL:

The Positive and Negative Controls, which are sold separately by the manufacturer, should be run according to laboratory requirements. These controls should be run like an unknown patient specimen, at a minimum in the following circumstances:

- Each new lot
- Each new shipment (even if from the same lot previously received)
- Each new operator (an individual who has not run the tests for at least two weeks)
- Monthly, as a continued check on storage conditions
- Whenever problems (storage, operator, or other) are identified
- Or other times as required by your laboratory's standard QC procedures.

Add ONE (1) drop (25  $\mu$ L) of the control (Positive or Negative) into the Sample Well of the cassette and proceed in the same way as for a patient's sample by adding four (4) drops of Buffer Diluent. Refer to the Syphilis Health Check Control Set package insert for complete instructions.



### **Diagnostics Direct, LLC**

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