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Frequently Asked Questions



Determine Syphilis TP

1. How sensitive is Determine Syphilis TP?

Whole Blood 92.31%
 Plasma 100%
 Serum 100%

2. How should Determine Syphilis TP be stored?

2-30° C

3. What type of patient sample do I have to use?

Human serum, plasma and whole blood
 For whole blood and plasma specimens, EDTA collection tube must be used.
 For whole blood collection by Fingerstick, EDTA capillary tube must be used.
 For testing whole blood specimens, Chase Buffer is required.

4. How critical is the timing?

The timing is critical and you cannot obtain the correct results if you do not follow the instruction exactly.

5. How long are the results stable?

The result can be read from 15 minutes to 24 hours.

6. The Test Line was fainter than the Control Line, what does this mean?

The test result is positive even if the Test Line appears lighter or darker than the Control Line.

7. No line has appeared in the Control Window, what does this mean?

The test is invalid. You will have to use a new device and run the test again.

8. What is the shelf-life of Determine Syphilis TP?

Up to a maximum of 12 months from the date of manufacture

9. If I add whole blood and forget to add chase buffer will the test still run?

You cannot obtain the correct result. It should be tested again.

10. Would a negative result conclude that a patient does not have Syphilis?

No diagnostics test provides absolute assurance that a sample does not contain either low levels of antibodies to *Treponema pallidum*, such as those present at a very early stage of infection, or antibodies with low reactivity to the *Treponema pallidum* antigens. Therefore a negative result at any time does not preclude the possibility of exposure to infection with syphilis. If the overall clinical evaluation suggests that either of the conditions described above is present, reading the test results after at least 30 minutes up to overnight as allowed in the instructions for use is recommended to maximize test sensitivity.

11. What are the storage conditions for Serum and Plasma samples?

Serum and plasma samples should be stored at 2-8°C if the test is to be run within 7 days of collection. If testing is delayed more than 7 days, the sample should be frozen (-20°C or colder).

12. What are the storage conditions for whole blood samples?

Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 7 days of collection. Do not freeze whole blood samples.

Whole blood collected by fingerstick should be tested immediately.

13. What volume does the EDTA capillary tube deliver?

50ul

Fill the tube with whole blood between the 2 marked lines and apply the sample to the sample pad.

14. Can cloudy serum or plasma samples be used with the Determine tests?

No. Specimens showing particulate matter or turbidity should be centrifuged before testing in order to avoid providing erroneous results.


 detect... diagnose... determine...

Determine HIV-1/2 Ag/ Ab Combo is currently not available in the US