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## Frequently Asked Questions

### Determine HIV 1/2

**1. How sensitive is Determine HIV-1/2?**

HIV-1 Positive 100%  
 HIV-2 Positive 100%  
 HIV-1 Subtype A-G 100%  
 HIV-1 Group O 100%

Europe 100%  
 North America 100%  
 Asia 100%  
 Africa 99.91%

**2. How should Determine HIV-1/2 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 60 minutes.

**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 HIV-1/2?**

Up to a maximum of 14 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 HIV?**

A negative result with Determine HIV does not exclude the possibility of infection with HIV. A false negative result can occur in the following circumstances;

- low levels of antibody (e.g., early seroconversion specimens) are below the detection limit of the test
- infection with a variant of the virus that is less detectable by the Determine HIV assay configuration
- HIV antibodies in the patient that do not react with specific antigens utilized in the assay configuration - in exceptional cases this may lead to observation of false negative results
- specimens handling conditions which result in loss of HIV antibody multivalency.

**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.

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