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## Frequently Asked Questions

### Determine® HIV-1/2 Ag/ Ab Combo

#### 1. How sensitive is Determine® HIV-1/2 Ag/Ab Combo?

A total of 1179 confirmed HIV Ab positive specimens from patients at the chronic stage of the infection were tested. The diagnostic sensitivity of Determine® HIV-1/2 Ag/Ab Combo on this population of specimens is calculated to be 100%.

Determine® HIV-1/2 Ag/Ab Combo identifies infection on average 5 days earlier (range 2-20 days) than 3<sup>rd</sup> generation antibody tests

Determine® HIV-1/2 Ag/Ab Combo identified 92.31% of the 117 pre and per seroconversion samples when compared to commercial CE marked 4<sup>th</sup> generation EIA.

See performance data section for more details.

#### 2. How should Determine® HIV-1/2 Ag/Ab Combo be stored?

2-30°C

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

Human serum, plasma and whole blood. (fingerstick and venipuncture)

For whole blood (venipuncture) and plasma specimens, EDTA collection tubes 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 instructions exactly.

#### 5. How long are results stable?

The result can be read from 20 minutes up to maximum of 30 minutes.

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

The test result is positive even if the patient bar(s) appear lighter or darker than the control bar.

#### 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 Ag/Ab Combo?

10 months

#### 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?

No test provides absolute assurance that a specimen does not contain low levels of HIV p24 antigen and/or antibodies to HIV-1 and HIV-2 such as those present at a very early stage of infection.

A negative result for both antibodies to HIV and p24 antigen does not preclude the possibility of exposure to or infection with HIV-1 or HIV-2 viruses.

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

Serum and plasma specimens 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 specimen should be frozen (at -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?

50µl

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

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

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