



1. Does blood contamination affect the test result?

ROM Plus test kits have been tested up to 10% blood concentration. In other words, it will function properly with trace amounts of blood in the sample, however, significant amounts of bloody discharge may cause the test to malfunction. ROM Plus is not recommended for use in these situations and it should be determined what is causing the bleeding.

2. What is ROM Plus' CLIA Classification?

ROM Plus test is not a waived test. It has been classified as Moderately Complex by CLIA (Clinical Laboratory Improvement Amendments).

3. What is sensitivity/specificity?

Sensitivity is the percentage probability that a positive test will occur in a patient who is really experiencing rupture of membranes, or the proportion of actual positives which are correctly identified as such. In a multi-site hospital study involving 285 patients, ROM Plus resulted in an overall sensitivity of 99% (see IFU for details).

Specificity is the percentage probability that a negative test will occur in a patient who is not experiencing rupture of membranes, or the proportion of actual negatives which are correctly identified as such. Specificity also refers to the ability of the test to detect the correct result in the presence of interfering components that may be present in a sample matrix (i.e., blood, urine, semen, etc.). ROM Plus resulted in an overall specificity of 85%.

4. Do you have to use the timer in the cassette to run the test?

No. The timer that is built into the cassette is included for convenience and does not need to be used while running the test.

5. Is there a time limit for reading the test?

Yes. The ROM Plus test is an immunoassay test and as with all immunoassay tests the results will diminish over time. Do not read the test results after 30 minutes have passed

6. Are there gestational age limitations for using ROM Plus?

ROM Plus does not have any gestational age limits.

7. Will semen, urine or disinfectants interfere with test?

Tylenol, aspirin, Lever Soap, Noxema cream, Pert Shampoo, human semen, urine and blood were tested as possible interference's and were shown to be negative. For additional information please see the ROM Plus IFU

8. Is there a CPT code for ROM Plus?

Yes. Please see the Reimbursement Information section of this website for additional information.

9. How often should external QC's be run?

It is the company's recommendation that external QC be completed every 30 days, or for every new lot number or shipment received, whichever comes first.

