



Rupture of Membranes Test

INSTRUCTIONS FOR USE

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**ROM-7000, ROM-QC**



## FETAL MEMBRANES RUPTURE TEST

### QUALITY CONTROL KIT

#### INTENDED USE

The ROM Plus Quality Control Kit monitors the performance of the ROM Plus Fetal Membranes Rupture Test for the purposes of external quality control. The lyophilized human positive protein control is an assayed control material for qualitative testing.

#### REAGENTS AND COMPONENTS

Each ROM Plus Quality Control kit contains:

- One Positive Control Vial (self-contained glass ampoule of buffer)
- One Negative Control Vial (self-contained glass ampoule of buffer)
- Directions for use

The positive control is obtained from purification of human amniotic fluid, assayed to provide the appropriate concentration of insulin-like growth factor-binding protein 1 (IGFBP-1, also known as PP12) and Alpha-Fetoprotein (AFP), and then lyophilized. Buffer is mixed with the positive sample from an integrated sealed glass ampoule when performing testing.

The buffer and lyophilized control form a stabilized solvent containing normal saline, a pH of 7.4 (same as amniotic fluid). The preservatives in the buffer ampoule contain sucrose 5% BSA stabilizer and bovine serum albumin to provide 4-5 mg/ml protein concentration along with preservative 0.1% Proclin 950 at a pH of 8.1 (similar to amniotic fluid).

The negative control is a stabilized solvent containing normal saline, a pH of 7.4 (same as amniotic fluid), but does not contain IGFBP-1 or AFP.

#### STORAGE AND STABILITY

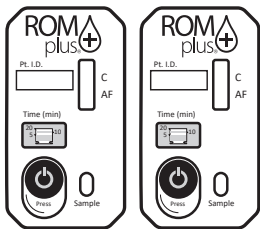
- The lyophilized positive and negative controls can be stored in a dry place at room temperature to the expiration date.

#### LIMITS OF THE TEST

- To obtain accurate results, all directions need to be followed.
- Quality control requirements should be performed in conformance with local, state and/or federal regulations or accreditation requirements.

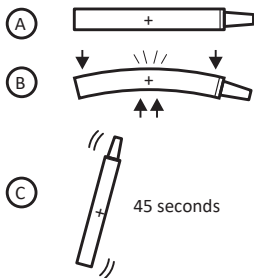
#### QUALITY CONTROL TEST PROCEDURE

Follow the test procedure steps properly to obtain an accurate quality control result. Users should treat the control material as a human specimen in terms of handling.



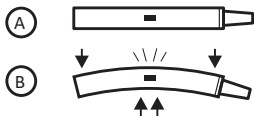
### Step 1 - Prepare Test Cassettes

Prepare two ROM Plus test cassettes, one for the Positive Control and one for the Negative Control. Since this is a quality control test and no human sample is required, the polyester vaginal swab and standard dropper vial should not be used.



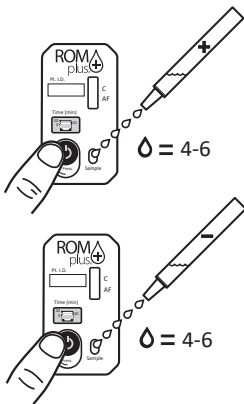
### Step 2 - Prepare Positive Control

Tear open the Positive Control Vial foil pouch and remove the vial. Gently bend or squeeze the Positive Control vial, breaking the glass ampoule inside. **Mix the buffer with the lyophilized positive sample for at least 45 seconds.** Be careful not to let the sample drip out of the vial.



### Step 3 - Prepare Negative Control

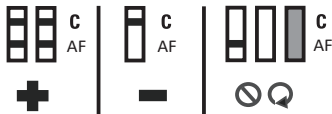
Gently bend or squeeze the Negative Control Vial, breaking the glass ampoule inside. Be careful not to let the sample drip out of the vial.



#### Step 4 - Run Tests

- Add 4-6, or more, drops of the Positive Control solution to one ROM Plus test cassette.
- Add 4-6, or more, drops of the Negative Control solution to the other ROM Plus test cassette.

Start the timers on each cassette by firmly pressing and rolling thumb over the timer button from left to right. Wait 5-20 minutes for test results to manifest in test window (C/AF).



#### Step 5 - Read Test Results

Read the test results from 5 to 20 minutes. Only a control line (C) should be visible for the negative control. Both the control line (C) and test line (AF) should be visible for the positive control. The test is positive even if the stripes are faint.

The external positive control is four times the threshold cutoff concentration prior to dilution of the patient sample with extraction buffer, and will appear at approximately 5 minutes; however, the full 20 minutes should be used before interpreting final results. Do not interpret test results based on the darkness of the stripes. It is recommended to read the strip by 20 minutes.

**CAUTION:** This product contains human sourced and/or potentially infectious components. Components sourced from human blood have been tested and found to be nonreactive for HBsAg, anti-HIV 1/2, and anti-HCV. No known test method can offer complete assurance that products derived from human sources or inactivated microorganisms will not transmit infection. Therefore, it is recommended that all human sourced materials be considered potentially infectious and handled with appropriate biosafety practices.



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