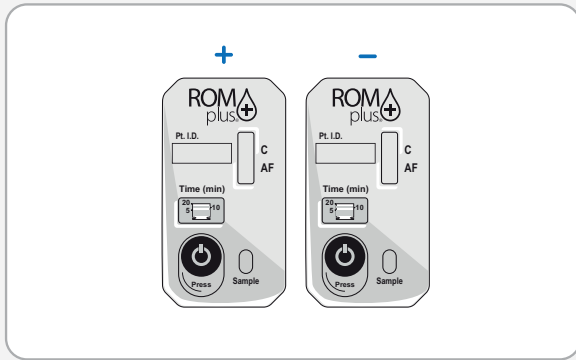


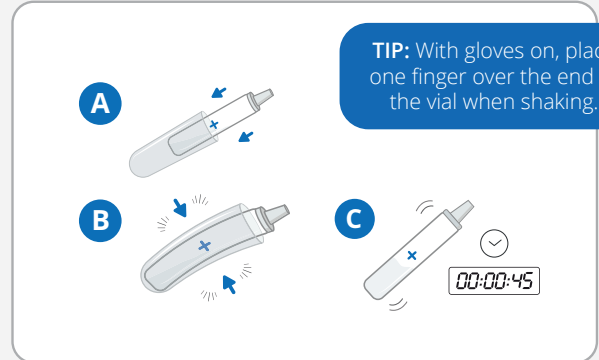


1 Prepare Test Cassettes



Prepare two ROM Plus test cassettes, one for the Positive Control and one for the Negative Control. Since this is a quality control test, the polyester vaginal swab and standard dropper vial should not be used.

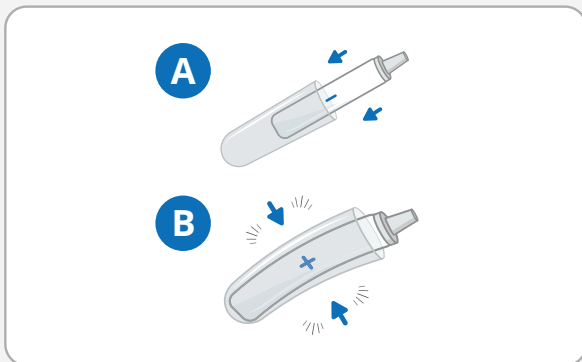
2 Prepare Positive Control



TIP: With gloves on, place one finger over the end of the vial when shaking.

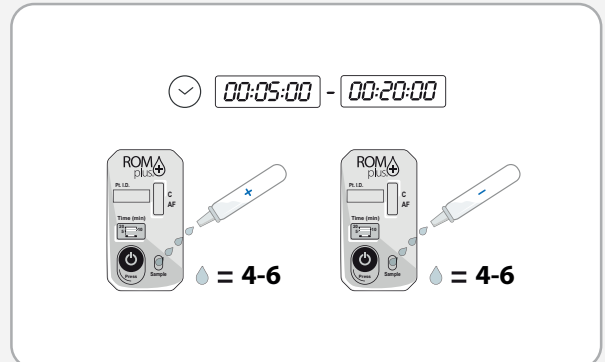
Remove the Positive Control vial from the foil pouch. Place the vial in the safety sleeve, gently squeeze and bend to break the glass ampoule inside. **Mix the buffer with the lyophilized positive sample for at least 45 seconds.** Be careful not to let the sample drip out of the vial.

3 Prepare Negative Control



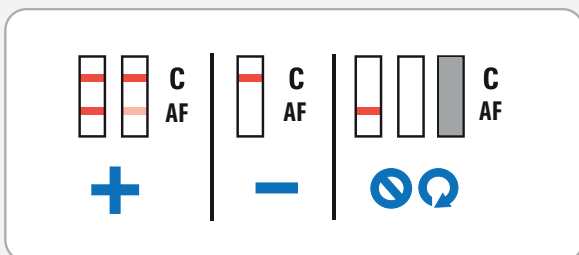
Place the Negative Control vial in the safety sleeve, gently squeeze and bend to break the glass ampoule inside. Be careful not to let the sample drip out of the vial.

4 Run Tests



Add 4-6 drops of the Negative Control solution to the cassette, do the same for the Positive Control solution cassette. Start the timers on each cassette by firmly pressing and rolling thumb over the timer button from left to right.

5 Interpret Test Results



Wait 5-20 minutes for test results to manifest in test window (C/AF). Only **C** should be visible for the negative control. Both the **C** and **AF** should be visible for the positive control. The test is positive even if the stripes are faint.

See Instructions for Use for full instructions, warnings, precautions & contraindications

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Sign-off for ART-0149

REV	ECN NO.	DESCRIPTION	DRWN BY	DATE	APRV. BY	DATE
01	...	Initial Release	K. English	11.22.19		