

Human PAMG-I (amniotic fluid protein control)

NDIA-P0104B

One vial containing 10 ng of the freeze-dried PAMG-1 protein
(10 ng/ml PAMG-1 concentration is obtained after reconstitution with saline solution)

DIRECTIONS FOR *IN VITRO* DIAGNOSTIC USE

INTENDED USE

The Human freeze-dried PAMG-I (amniotic fluid protein control) is an assayed quality control material for the in vitro qualitative testing (positive control) intended to monitor the performance of the AmniSure® ROM Test.

REAGENTS

PAMG-1 protein is a native protein purified from human amniotic fluid. It is lyophilized from buffered saline solution, pH 7.2 and has a molecular weight of 32 kDa and a purity of > 92% as observed on SDS-PAGE. A 10 ng/ml solution of PAMG-1 is used for qualitative positive control of the AmniSure® ROM Test. The 10 ng/ml PAMG-1 solution is obtained by dissolving the freeze-dried PAMG-1 with saline solution.

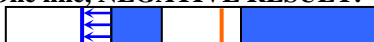
TEST PROCEDURE

*** Since no human sample is collected, the use of Polyester vaginal swab and vial should not be used to perform this procedure.**

1. Take the vial containing 10 ng of freeze-dried Human PAMG-1 protein and add 1 ml of saline solution to it. Shake the resulting solution for few seconds.
2. This solution from step #1 may be aliquoted out into 5 separate vials (similar to the original vial), each containing 0.2 ml of the solution, so that 5 positive controls may be run from 1 vial of PAMG-1 amniotic fluid protein control.
3. Use the solution from step #1 for positive quality control of the AmniSure® ROM (Rupture Of fetal Membranes) Test by following the two steps below:
 - a. Dip the white end of the test strip (marked with arrows) into the positive control solution from step #2 **for 10 minutes sharp.**
 - b. Remove the test strip after 10 minutes sharp. Read the results by placing the test on a clean, dry, flat surface. Do not read or interpret the results after 15 minutes have passed since dipping the test strip into the vial.

INTERPRETATION OF RESULTS

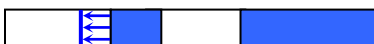
One line, NEGATIVE RESULT:



Two lines, POSITIVE RESULT:



No lines, TEST IS INVALID, take another test:



If only a control line is visible, the test result is negative. If both control and test lines are visible, the test result is positive. If no lines are visible, the test result is invalid.

The darkness of the lines may vary. The test is valid even if the lines are faint or uneven. Do not try to interpret the test result based on line coloration.

Quality control requirements should be performed in conformance with local, state, and/or federal regulations or accreditation requirements.



STORAGE AND STABILITY

Freeze-dried purified PAMG-1 can be stored in a dry place at -18 to -12°C (0 to 10°F) for up to 18 months. When stored at the recommended temperature, the test is stable until the “Exp.” date indicated on the vial packaging.

After dissolving the freeze-dried PAMG-1 with the saline solution, the obtained solution can be stored under refrigeration at $+4$ to $+8^{\circ}\text{C}$ (39 to 46°F) for up to 24 hours.

LIMITS OF THE TEST

- You must follow all directions carefully to obtain an accurate reading of the results.
- When used as a positive quality control for the AmniSure® ROM (Rupture Of [fetal] Membranes) Test, the human PAMG-I (Native protein) produces qualitative results. No quantitative interpretation should be made based on the test results.
- This product is for use as a positive quality control only. It is not intended for clinical diagnostic purposes. Not for use *in vivo*.

EXPECTED VALUES

A PAMG-1 concentration of 10.0 ng/ml or higher produces a positive result in the Test Region of AmniSure® ROM Test when used as a positive quality control for such a test.

For technical assistance please contact:

AmniSure® International LLC
30 JFK Street, 4th Floor
Cambridge, MA 02138
USA
617-234-4441
info@amnisure.com

June 2009