AmniSure® ROM Test Positive Control

IN VITRO QUALITY CONTROL TESTING
Follow these Directions for Use with the supplied materials

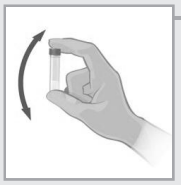
CONTENTS TO BE USED FOR AMNISURE ROM TEST POSITIVE CONTROL:

- 1 **Positive** Control vial (10ng PAMG-1)
- 1 AmniSure Solvent vial (1ml solvent)

TEST PROCEDURE – AmniSure ROM Test Positive Control

Note: The swab should NOT be used in this procedure.

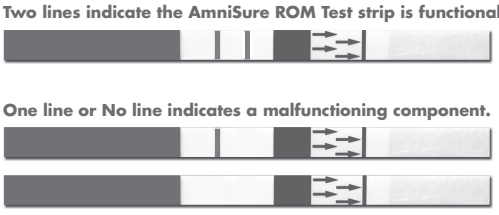
1. Uncap the AmniSure Solvent vial containing 1ml of solution. Uncap the AmniSure ROM Test **Positive** Control vial containing 10ng of freeze-dried PAMG-1 protein.



2. Add the provided Solvent (1ml) to the **Positive** Control vial. Recap and mix solution for 30 seconds to ensure full reconstitution (i.e. vortex or shake vigorously).

3. Obtain an AmniSure ROM test strip and tear open the foil pouch to remove the strip. Insert the white end of the test strip (marked with arrows) into the **positive** control solution vial from step #2.

4. Interpretation of results



Remove the test strip after exactly 5 minutes. Read the results by placing the test strip on a clean, dry, flat surface. Do not read or interpret the results after 10 minutes have passed since first dipping the test strip into the vial.

The intensity of the lines may vary. Test strip interpretation is qualitative; do not draw quantitative conclusions based on the intensity of the lines.

Note: The solution created in step #2 can be divided into aliquots, each containing at least 0.2ml of **positive** control solution. The vials for the aliquots should be similar in size to the AmniSure vials. This optional method allows for 2 to 5 test strips to be run from one AmniSure ROM Test **Positive** Control vial.

INTENDED USE

The freeze-dried human PAMG-1 (amniotic fluid protein control) is unassayed quality control material for *in vitro* qualitative testing intended to be used optionally with the AmniSure ROM Test to evaluate test strip functionality. Use of the AmniSure ROM Test **Positive** Control is not a required procedural step when running the AmniSure ROM Test in the diagnostic setting.

REAGENTS

The AmniSure ROM Test **Positive** Control is 10ng of PAMG-1 protein that has been purified from human amniotic fluid and lyophilized with a buffered saline solution (pH 7.2). The purity is greater than 92% as observed on SDS-PAGE, and the molecular weight is 32 kDa. AmniSure Solvent is a water-based solution containing distilled water, 0.9% NaCl (sodium chloride), 0.01% Triton X100, and 0.05% NaN_3 (sodium azide).

STORAGE AND STABILITY

Store the AmniSure ROM Test **Positive** Control in a dry place at 2-25°C (35-77°F). Do not use beyond the expiration date indicated on the vial labeling.

After the AmniSure ROM Test **Positive** Control has been reconstituted, the solution can be refrigerated for up to 24 hours at 4-8°C (39-46°F). Do not freeze.

PRECAUTIONS AND WARNINGS

- Follow all directions included in this Package Insert
- Test strip interpretation is qualitative. No quantitative conclusions should be made.
- The AmniSure ROM Test **Positive** Control is not meant to be used as an assay control. It is only meant for use as an optional external quality control for the AmniSure ROM test strip functionality.
- Each control is a single use disposable unit. Components cannot be reused.

EXPECTED RESULTS

The AmniSure ROM Test **Positive** Control is expected to produce two lines on the AmniSure ROM test strip.

QUALITY CONTROL REQUIREMENTS SHOULD BE PERFORMED IN CONFORMANCE WITH LOCAL, STATE, AND/OR FEDERAL REGULATIONS OR ACCREDITATION REQUIREMENTS.

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AmniSure® ROM Test Negative Control

IN VITRO QUALITY CONTROL TESTING
Follow these Directions for Use with the supplied materials

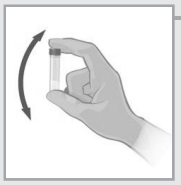
CONTENTS TO BE USED FOR AMNISURE ROM TEST NEGATIVE CONTROL:

- 1 **Negative** Control vial
- 1 AmniSure Solvent vial (1ml solvent)

TEST PROCEDURE – AmniSure ROM Test Negative Control

Note: The swab should NOT be used in this procedure.

1. Uncap the AmniSure Solvent vial containing 1ml of solution. Uncap the AmniSure ROM Test **Negative** Control vial containing the **negative** control material.



2. Add the provided Solvent (1ml) to the **Negative** Control vial. Recap and mix solution for 30 seconds to ensure full reconstitution (i.e. vortex or shake vigorously).

3. Obtain an AmniSure ROM test strip and tear open the foil pouch to remove the strip. Insert the white end of the test strip (marked with arrows) into the **negative** control solution vial from step #2.

4. Interpretation of results

One line indicates the AmniSure ROM test strip is functional.

Two lines or No line indicates a malfunctioning component.

Remove the test strip after exactly 5 minutes. Read the results by placing the test strip on a clean, dry, flat surface. Do not read or interpret the results after 10 minutes have passed since first dipping the test strip into the vial.

The intensity of the lines may vary. Test strip interpretation is qualitative; do not draw quantitative conclusions based on the intensity of the lines.

Note: The solution created in step #2 can be divided into aliquots, each containing at least 0.2ml of **negative** control solution. The vials for the aliquots should be similar in size to the AmniSure vials. This optional method allows for 2 to 5 test strips to be run from one AmniSure ROM Test **Negative** Control vial.

INTENDED USE

The AmniSure ROM Test **Negative** Control is unassayed quality control material for *in vitro* qualitative testing intended to be used optionally with the AmniSure ROM Test to evaluate test strip functionality. Use of the AmniSure ROM Test **Negative** Control is not a required procedural step when running the AmniSure ROM Test in the diagnostic setting.

REAGENTS

The AmniSure ROM Test **Negative** Control is a sucrose solution. AmniSure Solvent is a water-based solution containing distilled water, 0.9% NaCl (sodium chloride), 0.01% Triton X100, and 0.05% NaN_3 (sodium azide).

STORAGE AND STABILITY

Store the AmniSure ROM Test **Negative** Control in a dry place at 2-25°C (35-77°F). Do not use beyond the expiration date indicated on the vial labeling.

PRECAUTIONS AND WARNINGS

- Follow all directions included in this Package Insert
- Test strip interpretation is qualitative. No quantitative conclusions should be made.
- The AmniSure ROM Test **Negative** Control is not meant to be used as an assay control. It is only meant for use as an optional external quality control for the AmniSure ROM test strip functionality.
- Each control is a single use disposable unit. Components cannot be reused.

EXPECTED RESULTS

The AmniSure **Negative** Control is expected to produce one line on the AmniSure ROM test strip.

QUALITY CONTROL REQUIREMENTS SHOULD BE PERFORMED IN CONFORMANCE WITH LOCAL, STATE, AND/OR FEDERAL REGULATIONS OR ACCREDITATION REQUIREMENTS.

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