AmniSure® ROM Test Positive Control

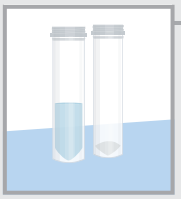
Follow these Instructions for Use with the supplied materials

CONTENTS TO BE USED FOR AMNISURE ROM TEST POSITIVE CONTROL

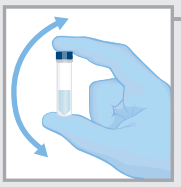
- 1 AmniSure ROM Test **Positive** Control (10 ng PAMG-1)
- 1 AmniSure Solvent Solution (1mL)

TEST PROCEDURE – AmniSure ROM Test Positive Control

Note: DO NOT USE the swab in this procedure.



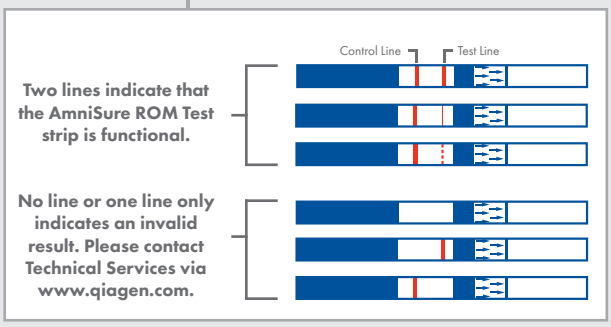
1. **Note:** Please tap the control vial before opening to ensure that no powder or pellet sticks to the cap.
Uncap the 1mL AmniSure Solvent Solution vial. Uncap the AmniSure ROM Test **Positive** Control vial containing 10 ng of freeze-dried PAMG-1 protein.



2. Add the provided AmniSure Solvent Solution (1 mL) to the AmniSure ROM Test **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 AmniSure ROM Test **Positive** Control solution vial from step 2.

4. Interpretation of results



Refer to your test's Instructions for Use to determine when to remove test strip and interpret results.

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 0.2 mL 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 10 ng 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 (36–77°F). Do not use beyond the expiration date indicated on the vial.

After the AmniSure ROM Test **Positive** Control has been reconstituted, the solution can be refrigerated for up to 24 hours at 2–8°C (36–46°F). Do not freeze.

PRECAUTIONS AND WARNINGS

- Follow all included directions.
- 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.
- Do not release components into the environment. Do not let the components enter drains. Dispose of components according to local, state, or federal/national regulations.

EXPECTED RESULTS

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

PERFORM ALL QUALITY CONTROL REQUIREMENTS IN CONFORMANCE WITH LOCAL, STATE, AND/OR FEDERAL REGULATIONS OR ACCREDITATION REQUIREMENTS.

GLOSSARY OF SYMBOLS

Symbol	Symbol Title / Number / Description	Symbol	Symbol Title / Number / Description
	Manufacturer / 5.1.1 / Indicates the medical device manufacturer**	REF	Catalog number / 5.1.6 / Indicates the manufacturer's catalogue number so that the medical device can be identified**
LOT	Batch code / 5.1.5 / Indicates the manufacturer's batch code so that the batch or lot can be identified**	IVD	In vitro diagnostic medical device / 5.5.1 / Indicates a medical device that is intended to be used as an in vitro diagnostic medical device
	Use-by date / 5.1.4 / Indicates the date after which the medical device is not to be used**		Temperature limit / 5.3.7 / Indicates the temperature limits to which the medical device can be safely exposed**
www.qiagen.com	Consult instructions for use or consult electronic instructions for use / 5.4.3 / Indicates the need for the user to consult the instructions for use**	GTIN	Global Trade Item Number / N/A / N/A
		UDI	Unique device identifier / 5.7.10 / Indicates a carrier that contains unique device identifier information**

**Regulation: ISO 15223-1: Medical devices – Symbols to be used with information to be supplied by the manufacturer

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REF ASQC-010

IVD

12/2025
HB-3295-003

AmniSure® ROM Test Negative Control

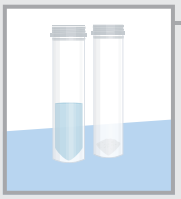
Follow these Instructions for Use with the supplied materials

CONTENTS TO BE USED FOR AMNISURE ROM TEST NEGATIVE CONTROL

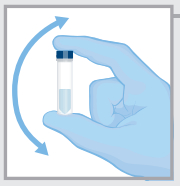
- 1 AmniSure ROM Test **Negative** Control Vial
- 1 AmniSure Solvent Solution (1 mL)

TEST PROCEDURE – AmniSure ROM Test Negative Control

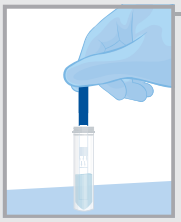
Note: DO NOT USE the swab in this procedure.



1. **Note:** Please tap the control vial before opening to ensure that no liquid sticks to the cap.
Uncap the 1 mL AmniSure Solvent Solution vial. Uncap the AmniSure ROM Test **Negative** Control vial containing the Negative control material.

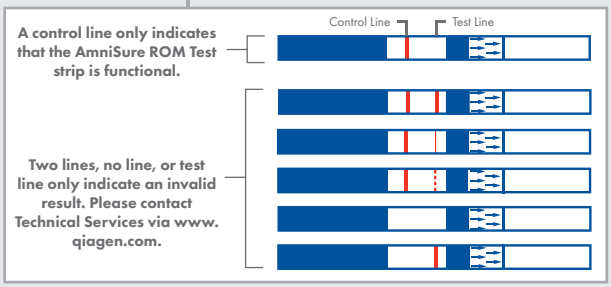


2. Add the provided AmniSure Solvent Solution (1 mL) to the AmniSure ROM Test **Negative** Control vial. Recap and mix solution for 30 seconds to ensure full reconstitution (i.e., vortex or shake vigorously.



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 AmniSure ROM Test **Negative** Control solution vial from step 2.

4. Interpretation of results



Refer to your test's Instructions for Use to determine when to remove test strip and interpret results.

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 0.2 mL 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 an 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 a diagnostic setting.

REAGENTS

The AmniSure ROM Test **Negative** Control is a sucrose solution. The 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 (36–77°F). Do not use beyond the expiration date indicated on the vial.

After the AmniSure ROM Test **Negative** Control has been reconstituted, the solution can be refrigerated for up to 24 hours at 2–8°C (36–46°F). Do not freeze.

PRECAUTIONS AND WARNINGS

- Follow all included directions.
- 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.
- Do not release components into the environment. Do not let the components enter drains. Dispose of components according to local, state, or federal/ national regulations.

EXPECTED RESULTS

The AmniSure ROM Test **Negative** Control is expected to produce only a control line on the AmniSure ROM Test Strip.

PERFORM ALL QUALITY CONTROL REQUIREMENTS IN CONFORMANCE WITH LOCAL, STATE, AND/OR FEDERAL REGULATIONS OR ACCREDITATION REQUIREMENTS.

GLOSSARY OF SYMBOLS

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www.qiagen.com	Consult instructions for use or consult electronic instructions for use / 5.4.3 / Indicates the need for the user to consult the instructions for use**	GTIN	Global Trade Item Number / N/A / N/A
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