


AmniSure® ROM Test Training Panel

 QIAGEN
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USA

REF FMRT-1-15-TP

1133495 Rev. 02

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Intended Use

For laboratory training purposes only.

Not for use in diagnostic procedures.

The AmniSure® ROM Test Training Panel is intended to provide blinded positive and negative samples for laboratory training.

Summary and Explanation

The AmniSure ROM Test Training Panel consists of 30 total blinded positive and blinded negative samples, along with 30 vials of AmniSure Solution. These samples are to be tested as specimens simulating the AmniSure ROM Test.

Because each sample is blinded, the AmniSure ROM Test Training Panel can be used to help assure proper training for those using the AmniSure ROM Test.

Refer to AmniSure ROM Test instructions for use for detailed instructions on assay performance and procedures.

Kit Contents

AmniSure ROM Test Positive Samples:
Blinded Amount

10 ng of PAMG-1 protein that has been purified from human amniotic fluid. Contents of vial might not be visible.

AmniSure ROM Test Negative Samples: Blinded Amount

Lyophilized sucrose. Contents of vial might not be visible.

AmniSure Solution (500- μ l Vial): 30 Vials

A water-based solution containing distilled water, 0.9% NaCl (sodium chloride), 0.01% Triton X100, and 0.05% NaN₃ (sodium azide).

Materials Required, but not Provided

AmniSure ROM Test Strip from the AmniSure ROM Test: 30 test strips

Precautions and Warnings

Follow all directions included in these instructions for use.

The AmniSure ROM Test Training Panel is for laboratory training purposes only and **NOT** for use in diagnostic procedures.

Each sample is a single-use disposable unit. Do not reuse components.

See Safety Data Sheets at www.qiagen.com/safety for more information regarding components.

Storage and Stability

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

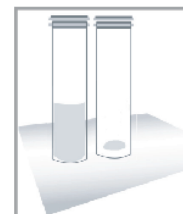
Limitations

1. For Laboratory Use Only. Not for use in diagnostic procedures.
2. The AmniSure ROM Test Training Panel Test Procedure and Interpretation of Results must be followed closely to obtain reliable sample results.

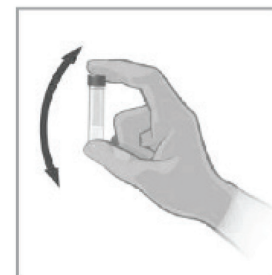
Test Procedure

Note: DO NOT USE the swab in this procedure.

1. Uncap one of the 500- μ l AmniSure Solution vials, and then uncap a training panel sample (e.g., ROM-01).



2. Add 500 μ l of AmniSure Solution to the training panel sample, recap, and mix solution for 30 seconds to ensure full reconstitution (i.e., vortex or shake vigorously).



3. Obtain an AmniSure ROM Test Strip. Tear open the foil pouch and remove the strip. Insert the white end of the test strip (marked with arrows) into the corresponding training panel sample (e.g., ROM-01).



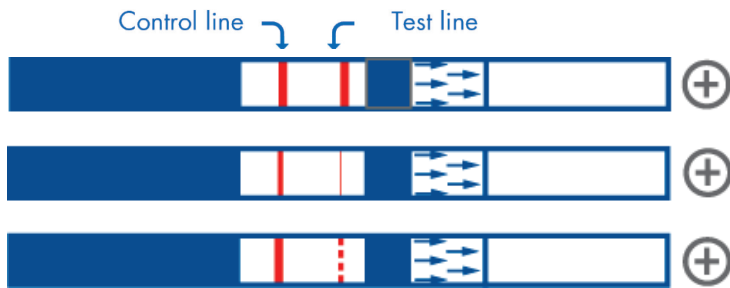
Remove the test strip after exactly 10 minutes. Read the results by placing the test strip on a clean, dry, flat surface. Do not read or interpret the results after 15 minutes have

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. See the Interpretation of Results section in these Instructions for Use to aid in determining results.

4. Use the ROM Panel Key provided by your local sales representative for the list of the desired results.
5. Repeat Test Procedure steps 1-4 for each of the remaining Training Panel samples; record results for each sample.

Interpretation of Results

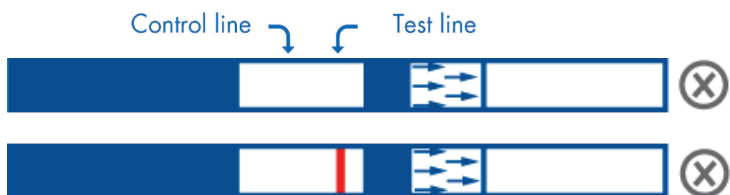
Two lines indicate the AmniSure ROM Test Strip has returned a positive result.













A Control Line only indicates a negative test result.



No line or only Test line only indicates an invalid test result.



Glossary of Symbols

-  Legal Manufacturer
-  Batch Number
-  Expiration Date
-  Catalog Number
-  Temperature Range
-  Global Trade Item Number
-  Components
-  Number
-  Sufficient for "X" amount of tests
-  Consult Instructions for Use

Ordering Information

For technical and ordering information, consult www.qiagen.com

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