



Human KIM-1 H-Rena-strip™ Lateral Flow

Catalog Number: H-RENA-LF-025

MATERIALS PROVIDED

The BioAssay Works® H-Rena-strip™ Kits contain:

- H-RENA-LF-025
 - 25 × H-RENA-LF H-Rena-strip™ cassettes in white foil pouches with desiccant

INTENDED USE

The BioAssay Works® Rena-strip™ test is a “Research Use Only” single-use, qualitative, or quantitative (with reader), lateral flow assay for the detection of KIM-1 in human urine.

BACKGROUND

KIM-1 is a type I trans-membrane structural glycoprotein located in the renal proximal tubule epithelial cells. These cells undergo regeneration after various forms of injury and shed KIM-1 antigen into the urine. Thus, urinary KIM-1 is an early and specific biomarker for tubular kidney injury. KIM-1 has become widely recognized by many organizations and agencies, including the FDA, as an excellent biomarker in pre-clinical studies to monitor acute kidney tubular toxicity by identifying adverse reactive drugs and therapeutic agents in drug development.

Kidney injury caused by therapeutic agents and drug induction is a common type of injury requiring appropriate monitoring and intervention. Current standards using blood urea nitrogen and creatinine are considered late indicators of kidney injury and are often non-specific. KIM-1 has been shown continually to outperform traditional biomarkers of kidney injury in preclinical biomarker studies.¹ Rats injected with increasing doses of gentamicin, cadmium, mercury, or chromium release into the urine proportionately increasing levels of KIM-1 antigen. The detection of KIM-1 can occur in as little as six hours post injection of an agent known to cause kidney injury.²

PRINCIPLES OF THE TEST

The BioAssay Works® Human Rena-strip™ test is a 15-minute, qualitative or quantitative (with reader) test for the detection of KIM-1 in human urine.

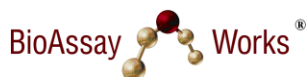
LIMITATIONS OF PROCEDURE

The Human Rena-strip™ test is intended for use with human urine only.

Please Note: Urine samples that have been heat or chemically inactivated, or have been repeatedly frozen and thawed, may not give accurate results.

The test should be performed at ambient room temperature (20–25°C).

Please Note: If the test or samples were refrigerated, please **allow all reagents to come to room temperature** before use of kit.



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TEST PROCEDURE

(Test components and urine samples should be at room temperature.)

Diluted urine

1. Remove cassette from the pouch.
2. Add 60 μ L of 1X PBS to a clean test tube. (12 mm x 75 mm polystyrene or borosilicate glass tube; DO NOT use polypropylene)
3. Add 60 μ L of human urine to the above test tube and vortex to mix.
4. Remove 100 μ L of diluted urine from test tube and transfer to the H-Rena cassette sample-well.
5. Read results at 15 minutes total time but not after 30 minutes.

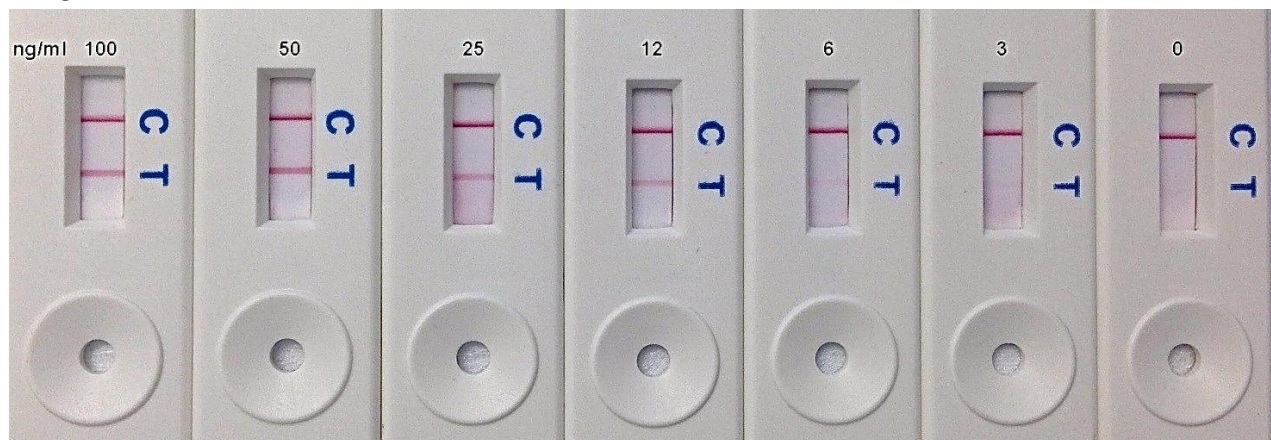
Neat urine


1. Remove cassette from the pouch.
2. Add 100 μ L of human urine to the H-Rena cassette sample-well.
3. Read results at 15 minutes total time but not after 30 minutes.

For a visual interpretation refer to the Semi-Quantitative Color Chart included below. For a quantitative result in ng/mL use the Bioassay Works® hand-held reader (LFRB-001), refer to the “instrument instructions,” and read the cassette accordingly.

For further information on the Bioassay Works® reader please contact:
sales@bioassayworks.com

Semi-Quantitative Color Chart:



BioAssay  Works®

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WARNINGS AND PRECAUTIONS

Read the package insert completely before using the product. Follow instructions carefully. Failure to follow instructions may result in inaccurate results. Practice universal precautions³ when handling urine specimens, finished assay tests, and tubes containing biological specimens.

Do not drink, eat or smoke in areas where specimens are being handled.

TEST STORAGE

Store unused pouches (unopened) at room temperature. Do not open the foil pouch containing the test cassette until you are ready to perform test.

REFERENCES

1 - Vaidya et al., *NATURE BIOTECHNOLOGY* VOLUME 28 NUMBER 5 MAY 2010, “Kidney injury molecule-1 outperforms traditional biomarkers of kidney injury in preclinical biomarker qualification studies.”

2 – Vaidya et al., *KIDNEY INTERNATIONAL* VOLUME 76 (1) 8-10, 2009. “A rapid urine test for early detection of kidney injury.”

3 – Siegel et al., CDC 2007, “Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings.”

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