



**H-Rena-strip™ Lateral-flow Kit for the detection of KIM-1 in Human urine**  
**Cat. #: H-RENA-025**  
**H-RENA-050**

## **MATERIALS PROVIDED**

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

### **H-RENA-025**

- 25 H-Rena-strip cassettes in foil pouches
- 5 mL Sample Diluent Buffer

### **H-RENA-050**

- 50 H-Rena-strip cassettes in foil pouches
- 5 mL Sample Diluent Buffer

## **INTENDED USE**

The BioAssay Works® H-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 FDA, as an excellent tool 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 time and again to outperform traditional biomarkers of kidney injury in preclinical biomarker studies.<sup>1</sup> The detection of KIM-1 can occur in as little as six hours post injection of an agent known to cause kidney injury.<sup>2</sup>

## **PRINCIPLES OF THE TEST**

The BioAssay Works H-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 H-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 temperature (18° – 30° C).

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

## TEST PROCEDURE

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

1. Remove cassette from the pouch.
2. Add 75 µl of Sample Diluent Buffer to clean test tube. (12 mm x 75 mm polystyrene or borosilicate glass tube; DO NOT use polypropylene)
3. Add 75 µl of human urine to the above test tube and vortex to mix.
4. Remove 100 µl of diluted urine from test tube and transfer to R-Rena cassette sample-well.
5. Set a timer for 15 minutes, or note the time the sample was added.
6. Read results at 15 minutes, but not after 20 minutes.
7. To read visually, refer to the included color chart for a semi-quantitative interpretation of the result.
8. For a quantitative result in ng/mL use the Bioassay Works hand-held reader, refer to the “instrument instruction,” and read the cassette accordingly. Use the “multiplier” located below the lot number of each KIM-1 test lot to obtain a quantitative result. (The multiplier is colored orange.) For example, if the reader LED display reads 155, and the multiplier is 0.04, the KIM-1 result is 6.2 ng/mL. Sample reading less than 0.9 are negative for KIM-1.

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

## 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 precautions 10-13 when handling urine specimens, used assay tests and tubes.

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

## TEST STORAGE

Store unused pouches (unopened) and Sample Diluent Buffer 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”

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