SECTION 1: IDENTIFICATION

Product Name:	Human KIM-1 ELISA Test Kit
Catalog Number(s):	K-H-RENA-E-001
Intended Use:	The Bioassay Works®, L.L.C., Human KIM-1 ELISA test kit is intended for use in the detection and quantitation of Kidney Injury Molecule-1 (KIM-1) in human urine.
Vendor:	BioAssay Works® 10075 Tyler Place Suite 18 Ijamsville, MD 21754
Product Information:	1-301-874-8888
Emergency Phone Number:	Contact Local Poison Control Center or 1-800-222-1222
Transport Emergency:	CHEMTREC: 1-800-424-9300 (outside the U.S. 1-703-527-3887)

The product should be handled by trained laboratory personnel in a laboratory environment as indicated on the package insert/instructions. Not for consumption.

SECTION 2: HAZARD(S) IDENTIFICATION

Refer to Section 3, Composition/Information on Ingredients, to determine hazards contained in the various components.

5-Bromo-5-nitro-1,3-dioxane – Harmful if swallowed – Causes skin irritation

Methylisothiazolone – Corrosive – Causes burns – May cause sensitization by skin contact

2-Methyl-2H-isothiazol-3-one – Harmful if swallowed or if inhaled – Causes severe skin burns and eye damage – May cause an allergic skin reaction – May cause allergy or asthma symptoms or breathing difficulties if inhaled – Very toxic to aquatic life with long lasting effects

2,2'-azino-bis(3-ethylbenzothiazoline-6-sulfonic acid)-diammonium salt – May be harmful if absorbed through the skin – May cause skin irritation – May cause eye irritation – May be harmful if swallowed – May be harmful if inhaled – May cause respiratory tract irritation.

Lauryl Sulfate – Hazardous in case of skin contact (irritant), of eye contact (irritant), of ingestion, of inhalation. Slightly hazardous in case of skin contact (sensitizer). Severe over-exposure can result in death. The substance may be toxic to skin. Repeated or prolonged exposure to the substance can produce target organs damage. Repeated exposure to a highly toxic material may produce general deterioration of health by an accumulation in one or many human organs.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

- Human KIM-1 antibody coated plate, Cat. No. H-RENA-E-002. One 12 x 8well plate of microwell strips coated with anti-human KIM-1 antibody in a resealable pouch with desiccant.
- Human KIM-1 Calibrator, Cat. No. HKC-001. Two vials containing lyophilized recombinant Human KIM-1 in a buffered protein based stabilizer - 40 ng/mL after reconstitution.
- Reconstitution Solution, Cat. No. RS-002. One vial containing 1.8 mL of laboratory grade water with preservative. **Contains 5-Bromo-5-nitro-1,3-dioxane.**
- KIM-1 Negative Control, Cat. No. HKNC-001. One vial containing 200µL of a buffered protein solution.
- Sample Dilution Buffer, Cat. No. KSDB-012. One bottle containing 12 mL of phosphate buffered saline, protein stabilizer, detergent, preservative and yellow dye. **Contains 5-Bromo-5-nitro-1,3-dioxane.**
- Human KIM-1 MAb Solution, Cat. No. HKMS-006. One bottle containing 6 mL of anti-Human KIM-1 monoclonal antibody blend in phosphate buffered saline, protein stabilizer, detergent, preservative and blue dye. **Contains 5-Bromo-5-nitro-1,3-dioxane.**
- Peroxidase anti-Human KIM-1, Cat. No. HKPA-012. One bottle containing 12 mL of horseradish peroxidase labeled anti-Mouse IgG in a buffered protein solution, enzyme stabilizers and preservative. **Contains 5-Bromo-5-nitro-1,3-dioxane, Methylisothiazolone and 2-Methyl-2H-isothiazol-3-one**
- 20x Wash Solution, Cat. No. KWS-050. One bottle containing 50 mL of 20x phosphate buffered saline, detergent and preservative. **Contains 5-Bromo-5-nitro-1,3-dioxane.**
- ABTS Substrate Solution, Cat. No. KABTS-012. One bottle containing 12 mL ABTS Substrate Solution – **2,2'-azino-bis(3-ethylbenzothiazoline-6-sulfonic acid)-diammonium salt.**
- Stop Solution, Cat. No. KSS-012. One bottle containing 12 mL of 1% **Lauryl Sulfate** with preservative. **Contains 5-Bromo-5-nitro-1,3-dioxane.**

SECTION 4: FIRST-AID MEASURES

General Advice: Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area. Treat symptomatically.

Eye Contact: Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

Skin Contact: Take off contaminated clothing and shoes immediately. Wash off with soap and copious amounts of water. Consult a physician.

Inhalation: Move to fresh air. If not breathing, give artificial respiration. Consult a physician.

Ingestion: Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

Most important symptoms and effects, both acute and delayed: The most important known symptoms and effects are listed in Sections 2 and 11.

Indication of immediate medical attention and special treatment needed, if necessary: No Data Available

SECTION 5: FIRE-FIGHTING MEASURES

Suitable extinguishing media: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide

Specific hazards arising from the substance or mixture: Carbon oxides, Nitrogen oxides (NO_x), Sulfur oxides

Special protective equipment and precautions for fire-fighters: Wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Avoid contact with skin, eyes and clothing. Use personal protective equipment (refer to Section 8). Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas.

Methods and materials for containment and cleaning up: Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided. Soak up with inert absorbent material and dispose of as hazardous waste. Keep in suitable, closed/sealed containers for disposal (refer to Section 13).

SECTION 7: HANDLING AND STORAGE

Precautions for safe handling: Handle in accordance with cGMP, good industrial hygiene and safety practice. Avoid contact with skin and eyes. Avoid inhalation of vapor or mist.

Conditions for safe storage, including any incompatibilities: Keep container tightly closed in a well-ventilated place. Recommended storage temperature: 2-8°C. Containers that have been opened must be carefully resealed and kept upright to prevent leakage.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure limits: Contains no substances with occupational exposure limit values

Engineering controls: Showers, eyewash stations and ventilation systems - Handle in accordance with cGMP, good industrial hygiene and safety practice. Wash hands before breaks and at the end of the workday.

All patient samples should be considered potentially biohazardous materials. Handle at the Biosafety Level 2

Personal Protective Equipment:

Eye/face protection: Snuggly fitting safety goggles or faceshield (8 inch minimum) – Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (U.S.) or EN 166 (E.U.)

Skin protection: Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching the glove's outer surface) to avoid possible skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and cGMP. Wash hands with soap and copious amounts of water.

Body protection: Complete suit protecting against chemicals – The type of protective equipment must be chosen according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection: Where risk assessment shows air-purifying respirators are appropriate, use a full-face respirator with multipurpose combination (U.S.) or type ABEK (EN 14387) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (U.S.) or CEN (E.U.).

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Various – component dependent
Odor:	No Data Available
Odor Threshold:	No Data Available
pH:	Various – component dependent
Melting Point/Freezing Point:	No Data Available
Initial Boiling Point and Boiling Range:	Various – component dependent
Flash Point:	No Data Available
Evaporation Rate:	No Data Available
Flammability (solid, gas):	No Data Available (most components are non-flammable liquids)
Upper/Lower Flammability or Explosive Limits:	No Data Available (most components are non-flammable liquids)
Vapor Pressure:	No Data Available
Vapor Density:	No Data Available
Relative Density:	Various – component dependent
Solubility:	Various – component dependent
Partition Coefficient: n-octanol/water:	No Data Available
Auto-Ignition Temperature:	No Data Available
Decomposition Temperature:	No Data Available
Viscosity:	No Data Available
Explosive Properties:	No Data Available (Not Applicable)
Oxidizing Properties:	No Data Available

SECTION 10: STABILITY AND REACTIVITY

Reactivity: No Data Available

Chemical Stability: Stable under recommended storage conditions (refer to Section 7)

Possibility of Hazardous Reactions: No Data Available

Conditions to Avoid: No Data Available

Incompatible Materials: Strong oxidizing agents, Amines, Mercaptans, Reducing agents

Hazardous Decomposition Products: Carbon oxides, Nitrogen oxides (NO_x), Sulfur oxides

SECTION 11: TOXICOLOGICAL INFORMATION

Information on toxicological effects

Acute toxicity

LD50 **Oral** - rat - female - 1,091 mg/kg
LD50 **Oral** - rat - male - 2,834 mg/kg

Inhalation: No Data Available

LD50 **Dermal** - rabbit - > 5,000 mg/kg

Skin corrosion/irritation:
Skin – rabbit Result: Causes severe burns.

Serious eye damage/eye irritation
Eyes – rabbit Result: Corrosive

Respiratory or skin sensitization
Guinea pig – May cause allergic skin reaction.

Germ cell mutagenicity
No Data Available

Carcinogenicity

IARC: No component of this product which is present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

ACGIH: No component of this product which is present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

NTP: No component of this product which is present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

OSHA: No component of this product which is present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

Reproductive toxicity
No Data Available

Specific target organ toxicity - single exposure
Inhalation - May cause respiratory irritation.

Specific target organ toxicity - repeated exposure
No Data Available

Aspiration hazard
No Data Available

Additional Information
RTECS: Not Available

SECTION 12: ECOLOGICAL INFORMATION

Ecotoxicity: Very toxic to aquatic life

Persistence and Degradability: No Data Available

Bioaccumulative Potential: No Data Available

Mobility in Soil: No Data Available

Other Adverse Effects: No Data Available – An environmental hazard cannot be excluded in the event of unprofessional handling or disposal. Very toxic to aquatic life.

SECTION 13: DISPOSAL CONSIDERATIONS

Waste Treatment Methods

Product: Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

Contaminated Packaging: Dispose of as unused product (refer to above paragraph)

SECTION 14: TRANSPORT INFORMATION

U.S. DOT HAZARD CLASSIFICATION
Proper Shipping Name: Not Regulated
UN Number: Not Applicable
Hazard Class/Packing Group: Not Applicable
Labels Required: None
DOT Packaging Requirements: Not Applicable
Exceptions: Not Applicable

IATA/ICAO AIR TRANSPORTATION
Proper Shipping Name: Not Regulated
UN Number: Not Applicable
Hazard Class/Packing Group: Not Applicable
Labels Required: None
IATA Packaging Requirements: Not Applicable

IMDG: Not Regulated

SECTION 15: REGULATORY INFORMATION

REACH Number: A registration number is not available for this substance as the substance or its uses are exempted from registration, the annual tonnage does not require a registration or the registration is envisaged for a later registration deadline.

SARA 302 Components: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 Components: Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This material contains a chemical or chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 371.

SARA 311/312 Hazards: Acute Health Hazard

California Proposition 65: This product does not contain any substances regulated as hazardous air pollutants (HAPS) under Section 112 of the Clean Air Act Amendments of 1990. This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.

SECTION 16: OTHER INFORMATION

Prepared by: BioAssay Works®, L.L.C.
10075 Tyler Place
Suite 18
Ijamsville, MD 21754
301-874-8888
Revision -01
September 9, 2014

The information included in this Material Safety Data Sheet is believed to be accurate, complete and current but does not purport to be all inclusive and shall be used as a guide. BioAssay Works makes no representation or warranties with respect to the product described herein, including but not limited to any implied warranties or merchantability or fitness for a particular use. BioAssay Works assumes no liability or responsibility and authorizes no other person to assume any additional liability or responsibility as a result of the use of this product or the information contained in the Material Safety Data Sheet.