SAFETY DATA SHEET

According to Regulation (EC) No. 1907/2006 (REACH), Annex II

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Trade name	NEPHROCHECK® Liquid Control Kit NEPHROCHECK® Calibration Verification Kit

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified use(s)	*In vitro diagnostic reagent.* For professional use only.

1.3 Details of the supplier of the safety data sheet

Company Identification	Astute Medical, Inc. 3550 General Atomics Ct. Building 2 San Diego, CA 92121 USA
Telephone	+1 (858) 500-7000
E-Mail (competent person)	info@astutemedical.com

1.4 Emergency telephone number

Emergency Phone No.	+1(855) 807-2783

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Regulation (EC) No. 1272/2008 (CLP)	Not classified as hazardous.
OSHA Hazard Communication Standard 29 CFR 1910.1200 (HazCom 2012) / GHS	Not classified as hazardous.

2.2 Label elements — No measures required.

2.3 Other hazards — Significant health effects are not anticipated from routine use of these materials when following the precautions listed within this SDS. None of the Research Reagents listed within this SDS are considered hazardous as defined by the Occupational Safety and Health Administration (OSHA), the Canadian Workplace Materials Information System (WHMIS), and the European Union. Handle as if potentially infectious.

Urine donors have been screened to be negative for HIV, Hepatitis B, Hepatitis C, and Syphilis. May still contain other potentially infectious components.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures

Description:	*In vitro diagnostic reagent.* Lyophilised human urine.
Dangerous components:	The product does not contain reportable quantities of dangerous components.
Additional information	Urine donors have been screened to be negative for HIV, Hepatitis B, Hepatitis C, and Syphilis. May still contain other potentially infectious components.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

Inhalation	Supply fresh air. Consult a physician if any symptoms develop.
Skin Contact	Wash skin with soap and water. Consult a physician if any symptoms develop.
Eye Contact	Rinse with water for several minutes. Consult a physician.
Ingestion	Induce vomiting. Wash out mouth with water. Consult a physician if symptoms develop.

4.2 Most important symptoms and effects, both acute and delayed — None known.

4.3 Indication of the immediate medical attention and special treatment needed — None.

SECTION 5: FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable Extinguishing Media — CO_2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

5.2 Special hazards arising from the substance or mixture — In case of fire, the following can be released: Carbon oxides (COx), nitrogen oxides (NOx),

5.3 Advice for fire-fighters — Use fire-extinguishing methods suitable to surrounding conditions. Wear full protective suit and self-contained breathing aparatus (SCBA) when extinguishing fires.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures — Isolate spillage and clean up immediately.
Refer to Section 8 for protective measures when handling the spillage.

6.2 Environmental precautions — No special requirements.

6.3 Methods and material for containment and cleaning up — Collect material and dispose of as waste according to Section 13.
Swab down area with disinfecting agent.

6.4 Reference to other sections — 8, 13

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling — This product should be handled as a potentially infectious material, as no known test method procedure can offer complete assurance that products derived from materials of human origin will not transmit infectious agents.
Refer to EU directive 2000/54EC or US regulation 29 CFR 1910.1030 for information on handling biohazardous materials. Follow universal precautions.
Avoid contact with skin and eyes.
Keep out of reach of children.
Wash hands before breaks and after work.
Clean work areas with hypochlorite or other disinfecting agent.
If aerosolization potential exists, handle under local exhaust ventilation such as a biological safety cabinet or fume hood.

7.2 Conditions for safe storage, including any incompatibilities — Store in the original container at -20 to 4°C.

7.3 Specific end use(s) — Use as per instructions for use.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1	**Control parameters**	
8.1.1	**Occupational Exposure Limits**	The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
8.2	**Exposure controls**	
8.2.1	**Appropriate engineering controls**	If aerosolization potential exists, handle under local exhaust ventilation such as biological safety cabinet or fume hood.
8.2.2	**Personal protection equipment**	
	Eye/face protection	Safety glasses. When in solution, use safety goggles if splash potential exists.
	Hand protection	Disposable gloves.
	Material of gloves:	Latex / natural rubber, Nitrile rubber
	Penetration time of glove material:	Gloves resistance is not critical when the product is handled according to the instructions for use.
	Body protection	Laboratory coat.
	Respiratory protection	Not required under recommended use. Avoid aerosolization. Handle under local exhaust ventilation if aerosolization potential exists.
8.2.3	**Environmental Exposure Controls**	No special measures are required.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1	**Information on basic physical and chemical properties**	
	Appearance	Solid.
	Colour	Pale yellow.
	Odour	No odour.
	Odour Threshold (ppm)	No data available.
	pH (Value)	No data available.
	Melting Point (°C) / Freezing Point (°C)	No data available.
	Boiling point/boiling range (°C):	No data available.
	Flash Point (°C)	No data available.
	Evaporation rate (BA = 1)	No data available.
	Flammability (solid, gas)	No data available.
	Explosive limit ranges	No data available.
	Vapour Pressure (Pascal)	No data available.
	Vapour Density (Air=1)	No data available.
	Density (g/ml)	No data available.
	Solubility (Water)	Soluble.
	Solubility (Other)	No data available.
	Partition Coefficient (n-Octanol/water)	No data available.
	Auto Ignition Temperature (°C)	No data available.
	Decomposition Temperature (°C)	No data available.
	Viscosity (mPa.s)	No data available.
	Explosive properties	Not explosive.
	Oxidising properties	Not oxidising
9.2	**Other information**	No data available

SECTION 10: STABILITY AND REACTIVITY

10.1	**Reactivity**	No data available.
10.2	**Chemical stability**	The product is stable in accordance with the recommended storage conditions.
10.3	**Possibility of hazardous reactions**	None known. Hazardous polymerisation will not occur.
10.4	**Conditions to avoid**	None
10.5	**Incompatible materials**	No data available.
10.6	**Hazardous Decomposition Product(s)**	No data available

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

11.1.2 Mixtures

Acute toxicity	No data available
Skin corrosion/irritation	No data available
Serious eye damage/irritation	No data available
Respiratory/skin sensitization	No data available
Germ cell mutagenicity	No data available
Carcinogenicity	No data available
Reproductive toxicity	No data available
STOT-single exposure	No data available
STOT-repeated exposure	No data available
Aspiration hazard	No data available

Health Effects and Symptoms

Skin Contact	No significant harmful effects anticipated.
Eye Contact	No significant harmful effects anticipated.
Ingestion	No significant harmful effects anticipated.

11.2 Other information

The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations. When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

The product does not contain significant quantities of ingredients that are environmentally toxic.

12.2 Persistence and degradability

The organic part of the product is biodegradable.

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

No data available

12.6 Other adverse effects

No data available

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product:

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

European waste catalogue:

18 01 03.

Packaging:

Disposal should be in accordance with local, state or national legislation. Contaminated packaging must be disposed of in the same manner as the product. Packaging materials may be recycled. Contact your local service providers for further information.

SECTION 14: TRANSPORT INFORMATION

14.1	**UN number**	Not applicable.
14.2	**UN Proper Shipping Name**	Not applicable.
14.3	**Transport hazard class(es)**	Not classified as dangerous for transport.
14.4	**Packing Group**	Not applicable.
14.5	**Environmental hazards**	Not applicable.
14.6	**Special precautions for user**	Not applicable.
14.7	**Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**	Not applicable.

SECTION 15: REGULATORY INFORMATION

15.1	**Safety, health and environmental regulations/legislation specific for the substance or mixture**	In Vitro diagnostics medical devices directive 98/79/EC. OSHA Hazard Communication Standard 29 CFR 1910.1200 Consumer Product Safety Regulations 16 CFR 1600 IVD Product Labelling 21 CFR 809
	Carcinogen listings	
	IARC:	None of the ingredients is listed.
	NTP:	None of the ingredients is listed.
	ACGIH:	None of the ingredients is listed.
	OSHA:	None of the ingredients is listed.
	EPA:	None of the ingredients is listed.
	Californian Proposition 65	
	Chemicals known to cause cancer:	None of the ingredients is listed.
	Chemicals known to cause reproductive toxicity:	None of the ingredients is listed.
	SARA	
	Section 355 (extremely hazardous substances):	None of the ingredients is listed.
	Section 313 (specific toxic chemical listings):	None of the ingredients is listed.
15.2	**Chemical Safety Assessment**	Not applicable.

SECTION 16: OTHER INFORMATION

References:

Raw safety data sheets.

Additional Information

Reason for update:	SDS Compliance
Supersedes:	PN: 300127 Rev E

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