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MATERIAL SAFETY DATA SHEET

CK-MB ELISA TEST KIT

1. IDENTIFICATION OF THE PREPARATION AND COMPANY.

1.1. **Identification of the product:**

Product name: **CREATINE KINASE (CK-MB) ELISA TEST KIT**
Product classification: In-vitro diagnostics
Product number: 1005-15

1.2. **Manufacturer identification**

Company Name: **Diagnostic Automation, Inc.**
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2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture: None
2.2 Label elements: None
2.3 Other hazards: None

3. COMPOSITION OF THE KIT COMPONENTS

3.1 Substances and/or Mixtures

All concentrations of potentially hazardous substances or mixtures are below the specific concentration limits and M-factors for hazardous identification. As preparations, the product components are not classified as hazardous. The following substance exceeds the generic cut-off value and is listed with its concentration level. At this concentration level, the substance is not hazardous. See section 16 for definitions for all risk and hazards classifications.

3.1.1 CK-MB Calibrators
N/A

3.1.2 CK-MB Enzyme Reagent
N/A

3.1.3 Streptavidin Coated Plate
N/A

3.1.4 Substrate A
N/A

3.1.5 Substrate B
N/A

3.1.6 Wash Solution Concentrate
N/A

3.1.7 Stop Solution

Chemical Name	Identification	Hazard Code Risk Phrase	Hazard Class Category Code	Hazard Statement	Concentration
Hydrochloric Acid	CAS:- EC: 231-595-7	C; R34 Xi; R37	Skin Corr. 1B STOT SE 3	H314 H335	< 5%

4. FIRST-AID MEASURES

4.1 Description of the first aid measures

General instructions: immediately rinse with soap and plenty of water. Use personal protective working aids.

If inhaled: Transport the affected person into the open air. If there are respiratory complaints, oxygen must be administered. If irritation persists, seek medical advice.

In case of skin contact: Wash contacted area with soap and water. Remove contaminated clothing. If irritation occurs, seek medical advice.

In case of contact with eyes: Rinse with a stream of water for at least 15 minutes. Thorough rinsing must be ensured by opening the eyelids. lf irritation occurs, seek medical advice.

If ingested: Do NOT induce vomiting. If conscious, rinse the mouth and administer a large amount of water to dilute the substance. In the case of unconsciousness, never administer anything orally. If irritation occurs, seek medical advice.

4.2 Most important symptoms and effects, both acute and delayed
No data available

4.3 Indication of any immediate medical attention and special treatment needed
No data available

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media
Carbon dioxide, dry powder, foam, water

5.2 Special hazards arising from the substance or mixture
None

5.3 Advice for firefighters
Wear appropriate personal protective equipment and clothing. Wear self-contained breathing apparatus, If necessary.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures
Wear rubber gloves, impermeable shoe covers and long laboratory coat.

6.2 Environmental precautions
Avoid penetration into sewerage systems, surface and ground water. Avoid soil pollution.

6.3 Methods and material for containment and cleaning up
Cover with suitable absorbing material. After removing the substance, rinse the spot of spilling thoroughly with water and soap. Dispose of waste according to all federal, state, and local regulations.

6.4 Reference to other sections
See Section 8 for personal protective equipment. See Section 13 for appropriate disposal methods.

7. HANDLING AND STORAGE

7.1 Precaution for safe handling
Avoid spills. Avoid contact with skin, eyes and clothing. Use suitable protective means to work with the substance. Use in a well-ventilated area. Follow good manufacturing practices when using product. Do not drink, smoke, or eat in work areas.

7.2 Conditions for safe storage, including any incompatibilities
Kit and unopened components: Store at temperatures between + 2 and + 8 °C in a dry and dark place until expiration date.

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Opened components: Opened reagents are stable for sixty (60) days when stored at 2-8 °C.

For prepared reagents (see product insert): Diluted wash buffer should be stored at room temperature (2-30°C) for up to 60 days. Working substrate solution should be stored at 2-8 °C and is stable for one (1) year.

7.3 Specific end uses

Product procedure should be performed by a skilled individual or trained professional for in vitro diagnostic use only.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameter

No substances with occupational exposure limits.

8.2 Exposure controls

Eye/face protection: Safety glasses or goggles with side shields recommended

Skin protection: Compatible protective gloves recommended. Wash hands after properly removing and disposing of gloves.

Other skin protection: Laboratory coats are recommended.

Respiratory protection: No respiratory protection is required. Use product in rooms enabling good ventilation. If local exhaustion is necessary, general (forced) exhaustion is recommended.

Thermal hazards: None

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical state (at 20 °C): Microtiter strips are solid; Calibrators, Enzyme Reagent, Wash Solution Concentrate, Substrate Solutions and Stop Solution are liquid.

Colour: Calibrators are straw; Enzyme Reagent is green; Stop solution, Substrates and Wash solution concentrate are clear.

Odour: Odourless

Odour threshold: Not applicable

pH value: Stop solution: < 3; Others: 6.8-7.4

Melting point/freezing point: Not determined

Initial boiling point boiling range: Not determined

Flash point: Not applicable

Evaporation rate: Not determined

Flammability (solid, gas): Not flammable

Upper/lower flammability or explosive limits: Not applicable

Vapour pressure: Not determined

Vapour density: Not determined

Relative density: Not determined

Solubility: Water soluble

Partition coefficient: n-octanol/water: Not determined

Auto-ignition temperature: Not applicable
Decomposition temperature: Not determined
Viscosity: Not determined
Explosive properties: None
Oxidising properties: Not determined

9.2 Other Information
None

10. STABILITY AND REACTIVITY

10.1 Reactivity: No known reactivity hazards associated with product
10.2 Chemical Stability: Stable under recommended storage conditions
10.3 Possibility of hazardous reactions: No hazardous polymerization
10.4 Conditions to avoid: Excessive heat and light
10.5 Incompatible materials: Acids
10.6 Hazardous decomposition products: Not determined

11. TOXICOLOGIAL INFORMATION

11.1 Acute toxicity: Not determined
11.2 Skin corrosion/ irritation: Not determined
11.3 Serious eye damage/ irritation: Not determined
11.4 Respiratory or skin sensitisation: Not determined
11.5 Germ cell mutagenicity: Not determined
11.6 Carcinogenicity: No component of this product present at levels > 0.1% is identified as probable, possible or confirmed human carcinogen by NTP (National Toxicology Program), IARC (International Agency for Research on Cancer), or OSHA (Occupational Safety & Health Administration)
11.7 Reproductive toxicity: Not determined
11.8 STOT-single exposure: Not determined
11.9 STOT-repeated exposure: Not determined
11.10 Aspiration hazard: Not determined
11.11 Information on likely routes of exposure:
If ingested: No known health effects
If inhaled: No known health effects
If contact with skin: No known health effects
If contact with eyes: No known health effects
11.12 Symptoms related to the physical, chemical, and toxicological characteristics:
None after short or long-term exposure

12. ECOLOGICAL INFORMATION

12.1 Toxicity: Not determined.
12.2 Persistence and degradability: Not determined
12.3 Bioaccumulative potential: Not determined

12.4 Mobility in soil: Not determined
12.5 Results of PBT and vPvB assessment: Not determined
12.6 Other adverse affects: Not determined

13. DISPOSAL CONSIDENRATIONS

All waste disposals must be carried out in accordance with federal, state, and local legislation and administrative regulations. A licensed professional waste disposal service should be utilized to dispose of material and packaging.

14. TRANPORT INFORMATION

14.1 UN number: Not available
14.2 UN proper shipping name: Not available
14.3 Transport hazard class(es): Not available
14.4 Packing group: Not available
14.5 Environmental hazards:
Overland transport (ADR/RID): None
Water transport (ADN/IMDG): None
Air transport (ICAO/IATA): None
14.6 Special precautions for user: None
14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code:
Not applicable

15. REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/ legislation specific for the substance or mixture:
SARA Reporting Requirements: None
TSCA: All components in product preparations are lifted on the US Toxic Substances Control Act inventory of chemicals or are exempt from listing.

This safety data sheet has been prepared to comply with the requirements of Annex II, European Community Regulation No. 190712006 REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) and OSHA (Occupational Safety & Health Administration) 1910.1200, Appendix D.
15.2 Chemical safety assessment: None

16. OTHER INFORMATION

Revision 2 (2015-MAY-05): updated to comply with requirements of Annex ll, European Community Regulation No. 1907/2006 (REACH) and OSHA 1910.1200, Appendix D
Revision I (2010-DEC-01): updated to 16 point format

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Revision 0 (2OO5-DEC-22): Initial creation

Hazard Statements		Hazard Class and Category Codes	
H314	Cause severe skin burn and eye damage	Skin Corr.	Skin Corrosion/Irritation
H335	May Cause respiratory irritation	STOT SE 3	Specific Target Organ toxicity-Single Exposure
Hazard Codes		Risk Phrases	
C	Corrosive	R34	Cause burns
Xi	Irritant	R37	Irritating to respiratory system

The material safety data sheet contains data necessary to ensure safety and health and environmental protection in working with chemical substances. This product is a chemical substance and can be solely used by persons with chemical education at their own risk. Diagnostics Automation, Inc. kits are designed for biomedical research. The manufacturer has no responsibility for damage caused by unsuitable use and by disrespecting the enclosed working instructions. The above-stated information cannot be considered as complete and must be understood to be only a methodical instruction.

Date Adopted	**2017-02-07**
REF **1005-15**	**CK-MB ELISA TEST KIT**

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