SAFETY DATA SHEET

SECTION 1: Identification

1.1 Product Name          NeuMoDx™ HCV Calibrator Kit
Product Code            800200

1.2. Relevant identified use
For use only as an accessory to an in vitro diagnostic test.

1.3 Details of the supplier of the safety data sheet

Manufacturer          NeuMoDx Molecular Inc.
1250 Eisenhower Pl
Ann Arbor, MI 48108
www.neumodx.com
info@neumodx.com

Telephone (General)     1-734-477-0111

1.4 EMERGENCY TELEPHONE NUMBER:

24-HR Emergency Exposure 1-800-222-1222
American Association of Poison Control Centers

SECTION 2: Hazards Identification

EU/EEC
This substance is not hazardous as defined by OSHA 29CFR 1910.1200 but this product does contain live Hepatitis C Virus and should be handled according to good lab practices, with proper personal protective equipment, proper engineering controls and within the parameters of the purchaser’s safety program.

2.1. Classification of the substance or mixture
The product has not been fully tested as hazardous according to the Globally Harmonized System (GHS).

CLP
The NeuMoDx HCV External Calibrator Kit is the final finished product for use on the NeuMoDx Molecular System. The NeuMoDx HCV External Calibrator Kit contains Hepatitis C Virus (HCV) in Basematrix (Seracare Life Sciences Inc) stored in six tubes per kit at two concentrations of HCV (three tubes per concentration). The final solution is yellow-tan liquid. This product contains material derived from human plasma mixed with a potentially infectious agent and should be treated/handled as a potential biohazard. Vendors responsible for the materials going into the NeuMoDx HCV External Calibrator Kit have stated that the human source material been tested and shown by FDA approved methods to be free from antibodies to Human Immune Deficiency Virus and Hepatitis C and is non-reactive for HBsAg and anti-HIV-1/2, anti-HCV, anti-HTLV I/II, anti-HBs, and anti-HBc. Exemptions for disclosing some component information are pursuant to CLP Article 1(5)(d) and 29 CFR 1910. 1200(g)(2)(i)(C)(1) & (2). Please refer to package insert for additional information, and handle product as potentially biohazardous.
Product contains sodium azide as a preservation at a concentration below threshold amount for reporting according to OSHA hazard communication regulations (1%) but at a concentration that should be considered for disposal and other environmental considerations.

2.2 Label elements

GHS label elements:
Not required.

GHS single word:
Warning.

Hazard pictograms/statements:
Not required.

Precautionary statements:
Not required.

SECTION 3: Composition/Information on Hazardous Ingredients

3.1 Substances
Material does not meet the criteria of a substance.

3.2 Mixtures

Chemical/biological characterization:
Basematrix and Human Hepatitis C Virus are not considered hazardous based on Regulation (EC) 1272/2008 and Hazard Communication Standard No. 1910.1200. Sodium Azide is considered hazardous but is below limit of concern.

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS #</th>
<th>EINECS/ELINCS#</th>
<th>Amount</th>
<th>GHS Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basematrix</td>
<td>N/A</td>
<td>N/A</td>
<td>99%</td>
<td>Not classified</td>
</tr>
<tr>
<td>Hepatitis C Virus</td>
<td>N/A</td>
<td>N/A</td>
<td>&lt;1%</td>
<td>Not classified</td>
</tr>
<tr>
<td>Sodium Azide</td>
<td>26628-22-8</td>
<td>247-852-1</td>
<td>0.02%</td>
<td>Acute toxicity, Oral Acute toxicity, Dermal Acute aquatic toxicity Chronic aquatic toxicity</td>
</tr>
</tbody>
</table>

SECTION 4: First Aid Measures

4.1 Description of first aid measures

Immediate medical attention needed:
Yes.
After inhalation:
Immediately move exposed subject to fresh air. If not breathing, give artificial respiration. If breathing is labored, administer oxygen. Immediately notify medical personnel and supervisor.

After skin contact:
Wash exposed area with soap and water and remove contaminated clothing/shoes. Notify supervisor to determine whether further medical evaluation is necessary.

After eye contact:
If easy to do, remove contact lenses, if worn. Immediately flush eyes with copious quantities of water for at least 15 minutes. Notify supervisor to determine whether further medical evaluation is necessary.

After swallowing:
If swallowed, call a physician immediately. Do not induce vomiting unless directed by medical personnel. Do not give anything to drink unless directed by medical personnel. Never give anything by mouth to an unconscious person. Notify medical personnel and supervisor.

SECTION 5: Fire-Fighting Measures

5.1 Extinguishing media

Suitable extinguishing media:
Use alcohol resistant foam, carbon dioxide, water, or dry chemical spray. Use water spray to cool fire-exposed containers.

Unsuitable extinguishing media:
Unknown.

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products:
No data available.

5.3 Advice for firefighters
In case of fire in the surroundings: use the appropriate extinguishing agent. Wear full protective clothing and an approved, positive pressure, self-contained breathing apparatus. Decontaminate all equipment after use.

SECTION 6: Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures
If product is released or spilled, take proper precautions to minimize exposure by using appropriate personal protective equipment (see Section 8). Area should be adequately ventilated.

6.2 Environmental precautions
Allow aerosols to settle; wearing protective clothing, gently cover spill with paper towel and apply approved reagent for Hepatitis C Virus decontamination (ie. 1% sodium hypochlorite, Microcide, etc), starting at perimeter and working towards the center; allow sufficient contact time before cleanup. Do not empty into drains. Take Steps to avoid release into the environment, if safe to do so.

6.3 Methods and material for containment and cleaning up
DO NOT CAUSE MATERIAL TO BECOME AIRBORNE. For small spills, soak up material with absorbent, e.g., paper towels. For large spills, cordon off spill area and minimize the spreading of spilled material. Soak up material with absorbent. Collect spilled material, absorbent, and rinse water into suitable containers for proper disposal in accordance with applicable waste disposal regulations (see Section 13). Decontaminate the area with approved reagent for Hepatitis C Virus (ie 1% sodium hypochlorite, Microcide, etc).

6.4 Reference to other sections
See Sections 8 and 13 for more information.

SECTION 7: Handling and Storage

7.1 Precautions for safe handling
This material should be handled at the Biosafety Level 2 (BSL2) consistent with the U.S. Department of Health and Human Services, the U.S. Public Health Service, Centers for Disease Control (CDC), and National Institute of Health (NIH) Guidelines "Biosafety in Microbiological and Biomedical Laboratories" (December 2009, HHS Publication No. (CDC) 21-1112). Avoid contact with eyes, skin and other mucous membranes. Wash thoroughly after handling. Avoid breathing mist/spray.

7.2 Precautions for storage
Store frozen at -18°C or lower.

SECTION 8: Exposure Controls/Personal Protection

8.1 Control parameters/Occupational exposure limit values
Not applicable.

8.2 Appropriate engineering controls
Selection and use of containment devices and personal protective equipment should be based on a risk assessment of exposure potential. Use local exhaust and/ or enclosure at aerosol/mist-generating points. Emphasis is to be placed on closed material transfer systems and process containment, with limited open handling.
8.3 **Personal protective equipment (PPE)**
Personal protective equipment requirements are dependent on the user institution’s risk assessment and are specific to the risk assessment for each laboratory where this material may be used.

**Respiratory protection:**
Choice of respiratory protection is dependent on the user institution’s risk assessment.

**Hand protection:**
Impervious gloves.

**Eye protection:**
Safety glasses with side shields.

**Skin and body protection:**
Lab coat over lightweight protective clothing.

**Hygiene measures:**
Wash hands in the event of contact with this product/mixture, especially before eating, drinking or smoking. Protective equipment is not to be worn outside the work area (e.g., in common areas or out-of-doors). Decontaminate all protective equipment following use. Handle in accordance with good industrial hygiene and safety practice.

### SECTION 9: Physical and Chemical Properties

#### 9.1 General Information

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Form</strong></td>
<td>Liquid mixture in sealed plastic tube.</td>
</tr>
<tr>
<td><strong>Color</strong></td>
<td>Yellow-tan liquid in clear plastic tube with opaque plastic cap.</td>
</tr>
<tr>
<td><strong>Odor</strong></td>
<td>Odorless.</td>
</tr>
<tr>
<td><strong>Odor threshold</strong></td>
<td>Not determined.</td>
</tr>
<tr>
<td><strong>pH value at 20°C (68°F)</strong></td>
<td>7.0-8.0</td>
</tr>
<tr>
<td><strong>Melting point/melting range</strong></td>
<td>Not determined.</td>
</tr>
<tr>
<td><strong>Boiling point/boiling range</strong></td>
<td>Not determined.</td>
</tr>
<tr>
<td><strong>Freezing point</strong></td>
<td>Not determined.</td>
</tr>
<tr>
<td><strong>Flash point</strong></td>
<td>Not determined.</td>
</tr>
<tr>
<td><strong>Flammability (solid, gaseous)</strong></td>
<td>Not applicable.</td>
</tr>
<tr>
<td><strong>Auto igniting</strong></td>
<td>Product is not self-igniting.</td>
</tr>
<tr>
<td><strong>Danger of explosion</strong></td>
<td>Product does not present an explosion hazard.</td>
</tr>
<tr>
<td><strong>Explosion limits:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Lower</strong></td>
<td>Not determined.</td>
</tr>
<tr>
<td><strong>Upper</strong></td>
<td>Not determined.</td>
</tr>
<tr>
<td><strong>Density at 20°C</strong></td>
<td>Not determined.</td>
</tr>
<tr>
<td><strong>Vapor pressure</strong></td>
<td>Not determined</td>
</tr>
<tr>
<td><strong>Vapor density</strong></td>
<td>Not determined.</td>
</tr>
<tr>
<td><strong>Partition coefficient (n-octanol/water)</strong></td>
<td>Not determined.</td>
</tr>
</tbody>
</table>
**Decomposition temperature**
Not determined.

**Solubility in/miscibility with:**
- **Water**: Miscible.
- **Dynamic**: Not determined.

### 9.2 Other information
No additional physical and chemical parameters noted.

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**SECTION 10: Stability and Reactivity**

#### 10.1 Reactivity
No dangerous reaction known under conditions of normal use.

#### 10.2 Chemical stability
Stable.

#### 10.3 Possibility of hazardous reactions
Contact of sodium azide with heavy metals may form explosive azides. Contact of sodium azide with acids may liberate toxic gas.

#### 10.4 Conditions to avoid
Avoid buildup of sodium azide in copper or lead plumbing. Thorough flushing of plumbing with water is recommended. Avoid temperature greater than 25°C.

#### 10.5 Incompatible materials
Contact of sodium azide with heavy metals may form explosive azides. Contact of sodium azide with acids may liberate toxic gas.

#### 10.6 Hazardous decomposition products
Hazardous decomposition products formed under fire conditions: carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride gas.

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**SECTION 11: Toxicological Information**

#### 11.1 Principal routes of exposure/potential health effects

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>LD50 (oral, rat/mouse)</th>
<th>LD50 (dermal, rat/rabbit)</th>
<th>LC50 (inhalation, rat/mouse)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium azide</td>
<td>27 mg/kg (rat)</td>
<td>20 mg/kg</td>
<td>No data available</td>
</tr>
</tbody>
</table>

- **Eyes**: May be absorbed.
- **Skin**: May be absorbed.
- **Inhalation**: May be absorbed.
- **Ingestion**: May be absorbed.
- **Carcinogenic effects**: No studies identified.
This mixture is not listed by NTP, IARC, ACGIH or OSHA as a carcinogen.

- **Mutagenic effects**: None.
- **Reproductive toxicity**: None.
- **Sensitization**: None.
- **Target organ effects**: Unknown.
- **Human health data**: See Section 2.

### SECTION 12: Ecological Information

#### 12.1 Information on ecological effects

- **Ecotoxicity effects**: No information available.
- **Acute aquatic toxicity**: Category 1.
- **Chronic aquatic toxicity**: Category 1.
- **Mobility**: No information available.
- **Biodegradation**: No information available.
- **Bioaccumulation**: No information available.
- **Additional toxicity information**: The toxicological properties of this mixture have not been fully characterized.

**Note**: The environmental characteristics of this product/mixture have not been fully investigated. The above data are for the active ingredient and/or any other ingredient(s) where applicable.

### SECTION 13: Disposal Considerations

#### 13.1 Waste Treatment Methods

Used product should be disposed as biohazard material according to local, state, and federal regulations. Do not send down the drain or flush down the toilet. All wastes containing the material should be properly labelled. Dispose of wastes in accordance to prescribed federal, state, and local guidelines, e.g., appropriately permitted biohazard waste incinerator. Rinse waters resulting from spill clean-ups should be discharged in an environmentally safe manner, e.g., appropriately permitted municipal or on-site wastewater treatment facility.

### SECTION 14: Transport Information

- **Proper shipping name**: Not classified as dangerous in the meaning of transport regulations.
- **Transport**: Land Transport (ADR/RID): Not a dangerous good in sense of this transport regulation. Inland waterways
transport (AND): Not a dangerous good in sense of this transport regulation.
Sea Transport (IMDG): Not a dangerous good in sense of this transport regulation.
Air Transport (ICAO-TP/IATA-DGR): Shipped as a Biological Substance Category B, UN3373.
DOT Classification: Not a DOT controlled material (United States).

Special precautions
Mixture not fully tested – avoid exposure.

Environmental class
Based on the available data, this product/mixture is not regulated as an environmental hazard or a marine pollutant.

Hazard class
Not available.

Subsidiary class
Not available.

Packing group
Not available.

UN-No
Not available.

SECTION 15: Regulatory Information

15.1 U.S. Federal Regulations

| Safety, health and environmental regulations/legislation specific for the substance or mixture | This SDS generally complies with the requirements listed under current guidelines in the US, EU and Canada. Consult your local or regional authorities for more information. |
| Chemical safety assessment | Not conducted. |
| WHMIS classification | This product/mixture has been classified in accordance with the hazard criteria of the Controlled Products Regulations and the SDS contains all of the information required by those regulations. |
| TSCA status | Not listed |
| SARA section 313 | Not listed. |
| California proposition 65 | Not listed. |
| Additional information | No other information identified. |
This product has been classified according to the hazard criteria of the CPR and the SDS contains all of the information required by the CPR.

SECTION 16: Other Information

Disclaimer/Statement of Liability
The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons received it must make their own determination of the effects, properties, protections and disposal which pertain to their particular conditions. Caution should be used in the handling and use of the material. No representation, warranty, or guarantee, express or implied including a warranty of fitness or merchantability for a particular purpose is constituted by the information in this SDS.