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SECTION 1 – IDENTIFICATION

Product Identifier	Reference Number	[WHMIS Classification]
IB10 sphingotest® Troponin-99	IVR-IB50	No information available
IB10 sphingotest® 3-in-1 Cardiac	IVR-IB51	
IB10 sphingotest® D-Dimer	IVR-IB52	
IB10 sphingotest® SOB	IVR-IB53	
IB10 sphingotest® beta-hCG	IVR-IB54	
IB10 sphingotest® TSH	IVR-IB55	
IB10 sphingotest® NT-proBNP	IVR-IB56	
IB10 sphingotest® DPP3	IVR-IB58	
Nexus IB10 EQC	IVR-IB60	
IB10 sphingotest® bio-ADM®	IVR-IB61	
IB10 sphingotest® penKid®	IVR-IB62	
IB10 sphingotest® PCT	IVR-IB65	

Product Use

A medical diagnosis test device composed of hard plastic parts and substrates coated/containing minute quantities of immunochemistry reagents. Used to measure concentrations of analytes in human source blood specimens supplied by a patient. Exception to Nexus IB10 EQC Tests which does not contain immunochemistry reagents and is only used for testing the performance check of the Nexus IB10 analyzer. Refer to the specific EQC Test SDS for detailed information.

Manufacturer's Name Nexus Dx, Inc.		Supplier's Name	
Street Address 6759 Mesa Ridge Rd		Street Address	
City San Diego	State CA	City	State
Postal Code 92121	Phone Number (858) 410 4600	Postal Code	Emergency Telephone
Emergency Telephone (858) 410-4600			

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SECTION 2 – HAZARD(S) IDENTIFICATION

Route of Entry
When unused: Skin Contact
Potential Health Effects
<p>Test device is not classified as dangerous as per EC Regulation 1272/2008.</p> <p>Test devices is exempt from OSHA's Hazard Communication Standard 29 CFR 1910.1200, however: Based upon Code of Federal Regulations, Title 29, Section 1910, 1200 and the California Code of Regulations, Title 8 Section 5194, Hazard Communication: Nexus Dx, Inc., has determined that these products are not considered to be hazardous or to contain hazardous chemicals at levels required to be listed in this Safety Data Sheet. No mercury is contained in these products.</p> <p>Each test devices contains sodium azide at concentration of <0.01% and is below the acceptable limit of LD50 27mg/kg. For DPP3, penKid, bio-ADM refer to the respective SDS for information.</p>

SECTION 3 – COMPOSITION/INFORMATION ON INGREDIENTS


No additional information available

SECTION 4 – FIRST AID MEASURES

Skin Contact: Wash affected area with soap and water. Seek medical attention as required.
Eye Contact: Flush eyes with fresh water for at least 15 minutes. Seek medical attention as required.
Inhalation: Remove to fresh air. Seek medical attention as required.
Ingestion: Rinse mouth out with water. Seek medical attention as required.

SECTION 5 – FIRE-FIGHTING MEASURES

Flammable <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	If yes, under which conditions? Exposure to direct flame	
Means of Extinction Use water spray, alcohol-resistant foam, dry chemical, or carbon dioxide		
Flashpoint (° C): 304°C (580°F)	Upper Flammable Limit (% by volume): No information available	Lower Flammable Limit (% by volume): No information available
Autoignition Temperature (°C): No information available	Explosion Data — Sensitivity to Impact: None	Explosion Data — Sensitivity to Static Discharge: None

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<p>Hazardous Combustion Products:</p> <p>Nitrocellulose (<1.0%)</p> <p>DMSO, Dimethyl Sulfoxide (<1.0%)</p> <p>Acrylic test housing: when heated to decomposition, acrid emits acrid smoke and irritating fumes. Irritation to eyes, respiratory system, and skin.</p> <p>[NFPA]</p> <p>No information available.</p>

SECTION 6 – ACCIDENTAL RELEASE MEASURES


<p>Leak and Spill Procedures:</p> <p>Used Test Devices</p> <p>Spills or leaks from used test devices are potentially infectious, and should be treated as biohazardous. Spills or leaks should be cleaned up immediately using Good Laboratory Practices, and disposed of in accordance with the facility’s solid waste and/or biological safety program disposal procedures. Immunochemical reagents are contained within the test in a manner which precludes separation.</p> <p>Unused Test Devices</p> <p>Unused tests are not hazardous. Immunochemical reagents are contained within the test in a manner which precludes separation.</p>

SECTION 7 – HANDLING AND STORAGE

<p>Handling Procedures and Equipment:</p> <p>This product is utilized with other components to test human blood specimens. When these fluids are used in the test, follow universal precautions: Bloodborne Pathogen Standard applies.</p> <p>Storage Requirements:</p> <p>Do not remove from pouch until ready for use. Refer to Instructions for Use for special storage instructions before use.</p>

SECTION 8 – EXPOSURE CONTROL / PERSONAL PROTECTION

<p>Exposure Limits</p> <p><input type="checkbox"/> ACGIH TLV <input type="checkbox"/> OSHA PEL <input type="checkbox"/> Other (specify)</p>
<p>Specific Engineering Controls (such as ventilation, enclosed process)</p>
<p>Not Applicable</p>

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Personal Protective Equipment <input checked="" type="checkbox"/> Gloves <input type="checkbox"/> Respirator <input checked="" type="checkbox"/> Eye <input type="checkbox"/> Footwear <input checked="" type="checkbox"/> Clothing
If checked, please specify type
Personal Protection Equipment as per facility guidelines, Good Laboratory Practices, and Bloodborne Pathogen Standard

SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Solid	Odor and Appearance: In vitro diagnostics test devices. Containing solid components impregnated on a test paper and plastic frit, within a plastic disc. Odorless Refer to Instructions-for-use for additional description.	Odor Threshold (ppm): No information available.
Specific Gravity: No information available.	Vapor Density (air = 1): No information available.	Vapor Pressure (mmHg): No information available.
Evaporation Rate: No information available.	Boiling Point (° C): No information available.	Freezing Point (° C): No information available.
pH: No information available.	Coefficient of Water/Oil Distribution: No information available.	[Solubility in Water]: No information available.

SECTION 10 – STABILITY AND REACTIVITY

Chemical Stability <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	If no, under which conditions? Test device is stable under the stated conditions of use until the expiration date indicated on the corresponding labels.
Incompatibility with Other Substances <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	If yes, which ones? None known
Reactivity and under what conditions? High temperatures or pressures may cause deformation of the test device, rendering the test device unusable.	
Hazardous Decomposition Products: No hazardous decomposition products expected.	

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SECTION 11 – TOXICOLOGICAL INFORMATION


Effects of Acute Exposure: No information available.	
Effects of chronic exposure: No information available.	
Irritancy of Product: No information available.	
Skin sensitization: No information available.	Respiratory sensitization: No information available.
Carcinogenicity-IARC: No information available.	Carcinogenicity – ACGIH: No information available.
Reproductive toxicity: No information available.	Teratogenicity: No information available.
Embryotoxicity: No information available.	Mutagenicity: No information available.
Name of synergistic products/effects: No information available.	

SECTION 12 – ECOLOGICAL INFORMATION

No information available.

SECTION 13 – DISPOSAL CONSIDERATIONS

<p>Unused: Dispose of in accordance with your facility's solid waste disposal practices.</p> <p>Used: Used test devices potentially containing Bloodborne pathogens and other waste containing biological materials should be decontaminated and disposed of using an autoclave or by incineration as per your facility's biological safety program which is consistent with applicable Federal, State/Provincial, and local regulations. Refer to the relevant local authorities and/or approved waste-disposal companies for information to ensure compliance with anti-pollution and other laws.</p>

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SECTION 14 – TRANSPORT INFORMATION

<p>Unused:</p> <p>TDG/DOT CLASSIFICATION: Not regulated by ground transport.</p> <p>ICAO/IATA CLASSIFICATION: Not regulated by air transport.</p>
<p>Used: Refer to applicable Federal, State/Provincial, and local regulations.</p> <p>TDG/DOT CLASSIFICATION: Regulated as UN3373 by ground transport.</p> <p>ICAO/IATA CLASSIFICATION: Regulated as UN 3373 by air transport.</p>

SECTION 15 – REGULATORY INFORMATION

Special Shipping Information: No information available.	
	PIN: N/A
TGD: Not regulated as a hazardous material.	[DOT]: Not regulated as a hazardous material.
[IMO]: Not regulated as a hazardous material.	[CAO]: Not regulated as a hazardous material.
[WHIMS Classification]: Not regulated as a hazardous material.	[OSHA]: Not regulated as a hazardous material.
[SARA]: Not regulated as a hazardous material.	[TSCA]: Not regulated as a hazardous material.
<p><i>This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by CPR.</i></p>	

SECTION 16 – OTHER INFORMATION

<p>All individuals using the test devices should follow general good laboratory safety procedures as established and implemented by your institution, in compliance with any federal, state, and local requirements. When used with human specimen, the Bloodborne Pathogen Standard applies.</p>

Notice to reader: The information above is believed to be accurate and represents the best information available to us. However neither the above named supplier nor any of its subsidiaries assume any liability for the accuracy or completeness of the information. Users should make their own investigations to determine the suitability of the information for their particular purposes. In no event shall Nexus Dx be liable for any claims, losses or damages of any third party for loss of profits or any special, indirect, incidental, consequential or exemplary damages.