	MARDX DIAGNOSTICS, A Trinity Biotech Company
	NAME OF PRODUCT: B. burgdorferi Marblot Strip Test Systems IgG or IgM Product Code: 40-2075G, 40-2075M, 40-2065G, 40-2065G/B, 40-2065M, and 40-2065M/B MDN: 17-0033 Page 1 of 4
MATERIAL SAFETY DATA SHEET	Effective date: Revision 2

Written By:	Approved By:
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1-Product and Company Identification

PRODUCT NAME: B. burgdorferi Marblot Strip Test System IgG or IgM

SUPPLIER:

Name:	Trinity Biotech	Emergency phone number:	National poisons unit
Address:	5919 Farnsworth Ct. Carlsbad, CA 92008		Ireland 01-837 9964 Belgium (+31) 30 2748888 France (+331) 40.37.04.04 USA 1 800 603 8076
Phone number:	(760) 929-0500		
Fax number:	(760) 929-0124		

INTENDED USE: MarDx B. burgdorferi Marblot Strip Test System is a Western Blot assay for the qualitative in vitro detection of human antibody (IgG or IgM depending on kit) to individual proteins of Borrelia burgdorferi in human serum. The MarDx B. burgdorferi Marblot Strip Test System is intended for use in testing human serum samples that have been found positive or equivocal using an EIA or IFA test procedure to provide supportive evidence of infection with B. burgdorferi.

2-Composition / Information on components

PREPARATION/ SUBSTANCE: Preparation

Components contributing to the hazard: See package insert for complete list of components.

10X Sample Diluent/Wash Solution Product Code 40-2019

Chemical	Composition	CAS #	EC Hazard symbol	R&S phrases
Sodium Azide	<1%	26628-22-8	Xn	R 22, 31 S 28,36,45

Product Codes 40-2021L, 40-2022L, 40-2023L, 40-2025G, 40-2025M, 40-2027L, and 40-2029L

Chemical	Concentration	CAS #	EC Hazard Symbol	R&S Phrases
Glycerol	20%	56-81-5	Xi	R36/38 S26,36

NOTE - The reagents found in this kit also contain the following substances at concentrations below their required reporting limits: Nitro Blue Tetrazolium, 5-bromo-4-chloro-indolyl-phosphate, magnesium chloride, thimerosal, alkaline phosphatase, and human serum. Information for these substances will not be included in this MSDS.


3-Hazard Identification

Sodium Azide (Xn) Harmful

At higher concentrations sodium azide is highly toxic (USA) and very toxic (EU). The strength of sodium azide present in the 10X Wash solution of this kit is <1% which is classified as harmful. The working strength of sodium azide after dilution is <0.1%. Sodium azide may cause heritable genetic damage. It is very toxic by inhalation, in contact with skin and if swallowed. Contact with acids liberates very toxic gas. Heating may cause an explosion. It is readily absorbed through skin. Avoid contact with metals. In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Wear suitable protective clothing, gloves and eye/face protection. Do not breath dust.

The human serum components used in the preparation of the Controls in this kit have been tested by an FDA approved method for the presence of antibodies to human immunodeficiency virus 1 & 2 (HIV 1 & 2), hepatitis C (HCV) as well as hepatitis B surface antigen and were found to be negative. Because no test method can offer complete assurance that HIV, HCV, hepatitis B virus, or other infectious agents are absent, specimens and human-based reagents should be handled as if capable of transmitting infectious agents.

This kit contains substances that are classified as **IRRITANTS**. They are irritating to the eyes, skin and respiratory system. Wear suitable protective clothing, gloves and eye and face protection.

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4-First-aid measures

The following general first aid measures apply to all components of the kit.

Inhalation:

Immediately move to fresh air and notify medical personnel. If not breathing, give artificial respiration. If breathing is difficult, give oxygen, call a physician.

Skin contact:

Immediately wash thoroughly with soap and water for at least 15 minutes and notify medical personnel. Remove and wash contaminated clothing and shoes.

Eye contact:

Immediately flush eyes thoroughly with water for at least 15 minutes and notify medical personnel.

Ingestion:

If swallowed, wash out mouth with water provided person is conscious and notify medical personnel.

Notes to a physician:

If at all possible, show all labels to physician of chemicals that you may have come into contact with.

5-Fire-fighting measures

The following general measures apply to all components of the kit.

Extinguishing media:

Dry powder, carbon dioxide, or appropriate foam. DO NOT USE WATER!

Specific hazards:

Emits toxic fumes under fire conditions. Container may be explosive under fire condition. Most materials in powder form are capable of creating a dust explosion.

Specific methods of fire fighting:

In the event of a fire, wear full protective clothing and NIOSH-approved self-contained breathing apparatus with full face-piece operated in the pressure demand or other positive pressure mode to prevent contact with skin and eyes.

6-Accidental release measures

Personal precautions:

Wear appropriate personal protective equipment as specified in Section 8. Isolate hazard area. Keep unnecessary and unprotected personnel from entering. Wear self-contained breathing apparatus, rubber boots and heavy rubber gloves.

Methods of cleaning up:

Contain liquid when possible. Use non-sparking tools and equipment. Absorb with an inert material (e.g., vermiculite, dry sand, earth), and place in a chemical waste container. Do not use combustible materials, such as sawdust. Powders should be swept up, placed in a bag and held for waste disposal. Ventilate area and wash spill site after material pickup is complete.

Environmental precautions:

Collect spilled material, absorbent, and rinse water into suitable containers for proper disposal in accordance with applicable waste disposal regulations. Do not flush to sewers, storm drains, surface waters, or soil.

Decontamination:

Decontaminate all surface areas with a 10% sodium hypochlorite or equivalent solution when a control containing human serum is spilled.


7-Handling and storage

Avoid contact with skin, eyes or clothing. Wear appropriate personal protective equipment (see section 8). Use adequate ventilation or minimize exposure to mists, dust, or aerosols. Wash hands thoroughly after handling. DO NOT permit contact with acids and other incompatible substances. Keep containers tightly closed. Store at 2-8° C.

8-Exposure control / Personal protection

Occupational Exposure Limits:

There are not established exposure limits for this product. However, the following exposure limits exist for the following hazardous ingredients:

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Ingredients:	OSHA PEL	ACGIH TLV
Glycerol	15 mg/m ³	10 mg/m ³
Sodium Azide	0.3 mg(hg)/m ³	0.29 mg/m ³

Personal protective equipment:

Eye and Face Protection:

Wear safety glasses with side shield, or full-face shield if eye contact is likely. The choice of protection should be based on the job activity and potential for exposure to eyes and face. Have safety shower and eye bath.

Respiratory protection:

When handling bulk quantities or for long durations where aerosol of material is likely, wear a NIOSH—approved air-purifying respirator or use Chemical fume hood.

Skin and body protection:

Wear gloves, lab coat, or other protective over-garment if skin contact is likely. The choice of skin protection should be based on the job activity and potential for exposure to the skin.

Hygiene measures:

Wash hands immediately after handling materials (especially before eating, drinking, or smoking). Decontaminate or discard protective equipment after each use.

Remove personal protective equipment when leaving work area.

9-Physical and chemical properties

Data is not currently available for the chemical properties of the preparations found in this kit. Potentially hazardous components are present in buffered aqueous solution. Refer to the package insert for information on the physical properties of the individual components of this kit.

10-Stability and reactivity

Glycerol is incompatible with strong oxidizing agents, and strong bases.

Sodium Azide:

Stability: Stable

Incompatibilities: Acid Chlorides and halogenated solvents. Avoid contact with metals and acid. Explodes when heated.

Hazardous Combustion and Decomposition Products: Nitrogen Oxides

The kit should only be used as instructed in the package insert. See package insert for further information of kit stability.

11-Toxicological information

The preparations contained in this kit may be harmful or fatal by inhalation, ingestion, or skin absorption. They may cause eye and skin irritation and may be irritating the mucous membranes and upper respiratory tract. Prolonged exposure can cause nausea, headache and vomiting. The human serum components used in the preparation of the Controls may contain infectious agents. The chemical, physical, and toxicological properties of these preparations have not been thoroughly investigated.

In laboratory experiments in animals, sodium azide has shown to produce a profound hypotensive effect, demyelination of myelinated nerve fibers in the central nervous system, testicular damage, blindness, attacks of rigidity, and hepatic and cerebral effects.

12-Ecological information



Data not available.

13-Disposal considerations

Dispose of materials in this kit according to Federal, State and Local Requirements.

14-Transport information

Land transport ARD / RID:	Not Regulated
- Description of goods:	<i>In vitro</i> diagnostic test kit
Inland waterways ADN / ADNR:	Not Regulated
Sea IMDG:	Not Regulated
Air CAO / IATA:	Not Regulated

  <p>MARDX[®] A TRINITY BIOTECH COMPANY</p> <p>Trinity biotech</p> <p>Diagnostics, Inc.</p>	<p>MARDX DIAGNOSTICS, A Trinity Biotech Company</p> <p>NAME OF PRODUCT: B. burgdorferi Marblot Strip Test Systems IgG or IgM Product Code: 40-2075G, 40-2075M, 40-2065G, 40-2065G/B, 40-2065M, and 40-2065M/B</p> <p>MDN: 17-0033 Page 4 of 4</p>
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15-Regulatory information

Labeling according to EU guidelines:

-Code letter and hazard designation:

Xn (Harmful)

- R-Phrases: 22 Harmful if swallowed.
31 Contact with acids liberates toxic gas.
- S-Phrases: 28 After contact with skin, wash immediately with plenty of water.
36 Wear suitable protective clothing, gloves and eye/face protection.
45 In case of accident or if you feel unwell, seek medical advice, immediately (show label where possible).

Xi (Irritant)

- R-Phrases: 36/38 Irritating to eyes and skin.
- S-Phrases: 26 In case of contact with eyes rinse immediately with plenty of water.
36 See above

16-Other information

The above information is based on data available at Trinity Biotech and is believed to be correct. Since the information may be applied under conditions beyond the control of Trinity Biotech and with which the company may be unfamiliar, Trinity Biotech does not assume any responsibility for the results of its use and all persons receiving it shall make their own determination of the effects, properties, and protections, which pertain to their particular conditions.

No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the material, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material.