



DIAGNOSTIC AUTOMATION, INC.

21250 Califa Street, Suite 102 and 116, Woodland Hills, CA 91367

Tel: (818) 591-3030 Fax: (818) 591-8383

onestep@rapidtest.com

technicalsupport@rapidtest.com

www.rapidtest.com

MATERIAL SAFETY DATA SHEET

CA19-9

1. IDENTIFICATION OF THE PREPARATION AND COMPANY.

1.1. Identification of the product:

Product name: **GASTROINTESTINAL CANCER ANTIGEN (CA19-9)
ENZYME IMMUNOASSAY TEST KIT**

Product classification: In-vitro diagnostics

Product number: 6909-16

1.2. Manufacturer identification

Company Name: **Diagnostic Automation, Inc.**

Address: 21250 Califa Street, Suite 102 and 116, Woodland Hills,
California 91367

Phone: (818) 591-3030 Fax: (818) 591-8383

E-mail: onestep@rapidtest.com

Website: <http://www.rapidtest.com>

Emergency Telephone number: Please contact the local hospitals.

2. COMPOSITION of the kit COMPONENTS

2.1. Microwell Strips, Microwell coated with CA 19-9 MAb, (96 wells)

2.2. CA 19-9 Reference Standard set, CA 19-9 Calibrators, 6 vials (1.0 ml)

2.3. Assay Buffer, Chemical Buffers, 1 bottle, 12 ml.

2.4. CA 19-9 Enzyme Conjugate, CA 19-9 Enzyme Conjugate, 1 bottle (12 ml),

- 2.5. TMB Chromogenic Substrate, TMB Substrate, 1 bottle (12 ml),
- 2.6. Stop Solution Stop Solution, 2N HCl, 1 bottle (12 ml),
- 2.7. Wash Concentrate 50X, Detergent Concentrate, 1 bottle (15 ml)
- 2.8. Package Insert Package Insert, paper, 1 piece.

3. **HAZARDS IDENTIFICATION**

3.1. **Potential Biohazard:**

The Calibrators and Controls are formulated with a buffer base, animal serum, and human serum. The human serums are tested by a United States Food and Drug Administration (USFDA) licensed method and found to be non-reactive for HIV-1, HIV-2, Hepatitis B surface antigen and HCV. Because no test method can offer absolute assurance that these agents are absent, reagents should be handled at the Biosafety Level 2, as recommended for any potentially infectious human blood product, in the United States Center for Disease Control (USCDC) and National Institute of Health (USNIH) manual "Biosafety in Microbiological Laboratories", 1988. All bovine products and goat sera have been derived from animals of US origin and processed in USDA licensed facilities.

3.2. **Chemical Hazard:**

The Calibrators and Controls are formulated with sodium azide. Concentrated Sodium Azide may react with copper and lead plumbing to form explosive metal azides. May react with acids to form explosive hydrazoic acid. If drain disposed, flush with large amounts of water to prevent azide build-up.

The TMB Chromogenic Substrate containing TMB, is formulated with DMSO, an irritant and mucous membranes. In case of contact with any of these reagents, wash thoroughly with water. TMB is a suspected carcinogen. Stop Solution is an acidic and corrosive agent. Avoid contact with skin.

4. **FIRST AID**

- 4.1. Skin Contact: Remove contaminated clothing and wash the exposed skin area thoroughly with soap and water.
- 4.2. Eye Contact: Flush with copious amounts of water for at least 15 minutes. Seek medical attention.
- 4.3. Inhalation: Remove to fresh air, give oxygen if breathing becomes difficult and seek medical attention.
- 4.4 Ingestion: Flush mouth with copious amounts of water, provided that the person is conscious and seek medical attention.

5. **MEASURES IN CASE OF FIRE**

- 5.1. Suitable Extinguishing Media: Chemical or water fire extinguisher.
- 5.2. Extinguishing Media Not to be Used: None known.
- 5.3. Special Fire Fighting Procedures: None Known.
- 5.4. Unusual Fire and Explosion Hazards: N/A
- 5.5. NFPA Rating: Health: 2, Flammability: 0, Reactivity: 1

Chemical safety assessment not completed for the components contained

NFPA Kit Classification:

Health Hazard (blue): 1
Fire Hazard (red): 0
Reactivity (yellow): 0
Special Hazards (white): None



6. MEASURES IN CASE OF ACCIDENTAL SPILL

- 6.1. **Body Precautions:** Wear rubber gloves, impermeable shoe covers and long laboratory coat.
- 6.2. **Environmental Precautions:** Contain the spill to the smallest area possible.
- 6.3. **Cleaning Measures:** Take care not to contaminate body. Absorb the material with disposable towels. Soak area with a 10% bleach solution and wipe up with disposable towels. Dispose of all contaminated trash in accordance with local regulations.

7. MANIPULATION AND STORAGE

- 7.1. **Manipulation:** Wear suitable personal protective equipment. Take care not to splash spill or splatter reagents. Do not eat, drink, smoke or apply cosmetics in laboratory areas. Do not pipette samples or reagents by mouth.
- 7.2. **Storage:** Store the test kits in 2 - 8° C refrigerators designated and labeled to contain human blood products.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

- 8.1. **Body Protection:** Wear long laboratory coat.
- 8.2. **Respiratory protection:** In case of fire, wear self-contained breathing apparatus.
- 8.3. **Hand Protection:** Wear non-permeable rubber, neoprene, latex or nitrile disposable gloves. Change gloves when they become contaminated.
- 8.4. **Eyes Protection:** Wear safety glasses or goggles when a splash hazard exists.

9. ECOLOGICAL EFFECTS None known.

10. DISPOSAL REQUIREMENTS

- 10.1. **Disposal of Preparation Left:** Dispose according to current regional and national rules.
- 10.2. **Contaminated Containers:** Dispose of following current regulations.


11. INFORMATION ON REGULATION

- 11.1. **Classification:** This preparation is classified and labeled in accordance with applicable national and international regulations.
- 11.2. **Symbols of Danger:** N/A
- 11.3. **"R" Phrases Indicating Specific Risks:** Irritant R36/37/38, Irritating to the eyes, respiratory system and skin.
- 11.4. **"S" Phrases Indicating Caution:** S26, In case of contact with any reagents rinse with copious amounts of water for at least 15 minutes. If irritation persists, seek medical attention. S36, Wear suitable protective clothing.


12. OTHER INFORMATION

Recommended Use: For research or clinical investigational use only. Not for use on or in human and animals. Information contained in this MSDS relies upon our best knowledge of the product upon issue of this document to describe the use, storage, transport and disposal under safe and secure measures. Such information is not a guarantee of the characteristics and specific quality of the product. This MSDS concerns the stated preparation and cannot apply to the product if used with other materials or in a process other than those specifically stated.

Date Adopted	2016-05-13
REF 6909-16	DA-CA19-9



DIAGNOSTIC AUTOMATION, INC.
 21250 Califa Street, Suite 102 and 116, Woodland Hills, CA 91367
 Tel: (818) 591-3030 Fax: (818) 591-8383
ISO 13485-2003



Revision Date: 2008-07-15