
Section 1 – Identification

PRODUCT NAME: CONSULT Mononucleosis Cassette Test
MFR #: 5012

DISTRIBUTED BY:

McKesson Medical-Surgical Inc.
 9954 Mayland Drive, Suite 4000
 Richmond, Virginia 23233

INFORMATION LINE: 1-800-777-4908
 Monday – Friday 8:00 a.m. – 6:00 p.m. EST

EMERGENCY PHONE: 1-800-451-8346 (3E Company) Day or Night
 Poison Control (US): 1-800-222-1222

INTENDED USE: Mono test qualitatively detects infectious mononucleosis antibodies in human whole blood, serum or plasma specimens. This test is intended for use as an aid in the diagnosis of infectious mononucleosis

Section 2 – Hazard Identification

For *in vitro* diagnostic use only. Each test strip/device is for single use only.

- 2.1** Avoid direct contact with chemical components. Any component containing biological material should be handled as being potentially hazardous.
 - 2.2** All patient specimens and samples used for this test should be handled as potential infectious materials. Follow **Universal Precautions** as necessary.
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Section 3 – Composition / Component Information

3.1 Test Kit Components: Test strip/device, Developer Solution, Positive Control, Negative Control, Sample Pipettes.

3.2 Hazardous Substances: This product does not contain any hazardous substances above 1% or above 0.1% levels required, depending on the hazard.

Chemical	CAS#	EC#	Kit Component	Concentration	Classification	Risk Phrases
N/A	N/A	N/A	N/A	N/A	N/A	N/A

Section 4 – First Aid Measures

- 4.1 Skin Contact:** Immediately wash affected area with soap and water for 15 minutes. Remove and wash any contaminated clothing. If pain, irritation, or a rash occur, seek medical attention.
- 4.2 Eye Contact:** Immediately flush eyes with water for at least 15 minutes. If pain or irritation occur, seek medical attention.
- 4.3 Ingestion:** If swallowed, rinse mouth with copious amount of water. Do not induce vomiting. If irritation or discomfort occur, seek medical attention.
- 4.4 Inhalation:** Move to fresh air if inhaled. If breathing becomes difficult or stops, seek medical attention immediately.

Section 5 – Fire Fighting Measures

- 5.1 Suitable Extinguishing Media:** Dry chemical, carbon dioxide, water, or foam.
- 5.2 Specific Hazards:** Fire may cause material to produce noxious fumes or gases.
- 5.3 Fire Fighting Procedure:** Wear self-contained breathing apparatus and protective equipment. Remove containers from fire area if possible. Cool fire-exposed containers with water.
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Section 6 – Accidental Release Measures

- 6.1 Personal Precautions:** Kit contains material of biological origin, avoid direct contact with material. Wear protective clothing as outlined in Section 8.
- 6.2 Environmental Precaution:** Keep away from drains, surface and ground water, and soil. Collect spilled and contaminated material in appropriate containers and dispose according to waste regulations.
- 6.3 Methods and Materials for Clean up:** Isolate spill area to prevent further spreading of spilled material. Use absorbent so soak up spilled material. Use 10% sodium hypochlorite, 70% ethanol, or equivalent solution to clean contaminated surfaces when spilled material is of biological origin
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Section 7 – Handling and Storage

- 7.1 Handling:** Avoid direct contact with contents. Wear personal protective equipment (Section 8). Wash thoroughly after handling.
- 7.2 Storage:** Store according to directions listed in the package insert. Keep away from combustible materials and ignition sources.
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Section 8 – Exposure Controls / Personal Protection

- 8.1 Exposure Limits:** Not Available
- 8.2 Occupational Exposure Controls:**
- 8.2.1 Engineering Controls:** No special engineering controls are required.
- 8.2.2 Personal Protective Equipment:**
- Respiratory Protection:* None needed under normal circumstances.
- Hand Protection:* Medical gloves (latex, nitrile, or equivalent), should be worn to avoid direct contact
- Eye Protection:* Wear suitable lab safety glasses.
- Skin Protection:* Wear lab coat or other protective clothing.
- 8.2.3 Environmental Controls:** No special environmental controls required.

Section 9 – Physical and Chemical Properties

9.1 General Information and Important health, safety and environmental information:

Properties:	Test Strip	Developer Solution	Positive Control	Negative Control
Appearance	White strip in plastic housing	Clear, colorless liquid	Clear, colorless liquid	Clear, colorless liquid
Odor	Odorless	Odorless	Odorless	Odorless
pH	N/A	7.2	7.0	7.0
Boiling Point (°C)	N/A	N/A	N/A	N/A
Flash Point	N/A	N/A	N/A	N/A
Flammability	N/A	N/A	N/A	N/A
Explosive Properties	N/A	N/A	N/A	N/A
Oxidizing Properties	N/A	N/A	N/A	N/A
Vapor Pressure	N/A	N/A	N/A	N/A
Relative Density	N/A	N/A	N/A	N/A
Solubilit(ies)	Insoluble	Soluble	Soluble	Soluble
Partition coefficient: n-octanol/water	N/A	N/A	N/A	N/A
Viscosity	N/A	N/A	N/A	N/A
Vapor Density	N/A	N/A	N/A	N/A
Evaporation Rate	N/A	N/A	N/A	N/A

Section 10 – Stability and Reactivity

Stability: Stable under normal conditions. Hazardous reactions are not expected to occur.

10.1 Conditions to Avoid: None identified.

10.2 Materials to avoid: None Identified.

10.3 Hazardous decomposition products: Decomposition as a result of high heat/fire may result in noxious fumes, CO and CO₂.

Section 11 – Toxicological Information

Presently no toxicological data available for this kit or its components.

Routes of Exposure:

Inhalation: May cause irritation of the respiratory tract.

Ingestion: May cause irritation of mouth, throat, and gastrointestinal system.

Skin Contact: May cause irritation of the skin.

Eye Contact: May cause irritation of the eyes.

Effects of Short and Long Term Exposure: No data available.

Section 12 – Ecological Information

12.1 Ecotoxicity: No data available.

12.2 Mobility: No data available.

12.3 Persistence and degradability: No data available.

12.4 Bioaccumulative potential: No data available.

Section 13 – Disposal Considerations

Dispose according to local, state, and national regulations.

Section 14 – Transportation Information

This product is not regulated for transport.

UN Number: N/A

Class: N/A

Proper Shipping Name: N/A

Packing Group: N/A

Environmental Hazards: N/A

Section 15 – Regulatory Information

15.1 Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture: This product and its contents are not classified as dangerous under any regulation.

15.2 Chemical Safety Assessment: No Chemical Safety Assessment has been carried out on the components of this product.

Section 16 – Other Information

This product is intended for *in vitro* medical diagnostic use. The tests should only be used according to the instructions provided within the kit.

DISCLAIMER: This information relates onto to the specific material designated and may not be valid for such material used in combination with any other materials or in any process. The information and recommendations contained herein are to the best of the manufacturer's knowledge and belief accurate and reliable as of the date indicated. No representation warranty or guarantee, however, is made with regards to accuracy, reliability or completeness. Conditions of use of the material are under the control of the user; therefore, it is the user's responsibility to satisfy itself as to the suitability and completeness of such information for its own particular use. Appropriate warnings and safe-handling procedures should be provided to handlers and users.