



# SAFETY DATA SHEET

REVISION DATE: 10 June 2020

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## Section 1 – PRODUCT AND COMPANY IDENTIFICATION

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**PRODUCT NAME:** INTROL® TB-XDR Panel M345  
**SYNONYMS:** N/A  
**PRODUCT CODE:** M345-5

**USE OF THE SUBSTANCE PREPARATION:** The INTROL TB-XDR Panel M345 is intended for use as an external quality control to monitor analytical performance of the extraction, amplification and detection steps of *in vitro* laboratory nucleic acid testing procedures for the qualitative detection of extensively drug resistant (XDR) *Mycobacterium tuberculosis* (MTB) complex by the Xpert® MTB/XDR Assay on Cepheid GeneXpert Instrument Systems.

**DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET AND MANUFACTURER NAME AND ADDRESS:**

<b>Maine Molecular Quality Controls, Inc (MMQCI)</b> 23 Mill Brook Road Saco, Maine 04072 (USA) E-mail: <a href="mailto:info@mmqci.com">info@mmqci.com</a> <a href="http://www.mmqci.com">www.mmqci.com</a> Emergency telephone number: 207-885-1072	<b>Manufacturer Phone Number</b> 207-885-1072	<b>Manufacturer Fax Number</b> 207-885-1079
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## Section 2 – HAZARD(S) IDENTIFICATION

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**HAZARDOUS INGREDIENTS:** None  
Classification: Void

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## Section 3 – COMPOSITION / INFORMATION ON INGREDIENTS

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**Chemical Characterization (Hazardous Chemical Ingredients):** None

**Dangerous Components According to EC Criteria:** None

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## Section 4 – FIRST AID MEASURES

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**General:** No emergency care is anticipated.

**In all cases of doubt or when symptoms occur, do the following:**

**Inhalation:** Remove affected person to fresh air. Seek medical attention if breathing becomes difficult or if cough or other symptoms develop.  
**Ingestion:** Rinse mouth with water. Seek medical attention if signs of toxicity occur.  
**Skin:** Remove contaminated clothing. Wash affected area with plenty of soap and water. Seek medical attention if irritation develops.  
**Eyes:** Rinse immediately with plenty of water. Remove contact lenses if worn. Seek medical attention if redness or irritation develops.

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## Section 5 – FIRE FIGHTING MEASURES

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**Flash Point (Method Used):** N/A  
**Extinguishing Media:** N/A  
**Auto-ignition Temperature:** N/A  
**Special Fire Hazards:** N/A  
**Explosion Hazards:** N/A



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## Section 6 – ACCIDENTAL RELEASE MEASURES

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**Personal Precautions:** Wear appropriate protective clothing.  
**Steps to be Taken in Case Material is Released or Spilled:** Wipe up with appropriate absorbent material.  
**Waste Disposal Method:** Normal disposal container

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## Section 7 – HANDLING AND STORAGE

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**Handling:** Handle per package insert instructions.  
**Storage:** Store at 2 - 8°C.

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## Section 8 – EXPOSURE CONTROLS / PERSONAL PROTECTION

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**Exposure Limit Values:** None

**Exposure Controls:** None

### PERSONAL PROTECTIVE EQUIPMENT:

<b>Respiratory Protection:</b>	None required	<b>Eye Protection:</b>	Safety glasses
<b>Skin Protection:</b>	Lab coat, gloves	<b>Work / Hygiene Practices:</b>	Standard laboratory precautions
<b>Ventilation:</b>	Normal	<b>Other Protective Equipment:</b>	None required

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## Section 9 – PHYSICAL AND CHEMICAL PROPERTIES

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<b>Component:</b>	N/A	<b>Specific Gravity (H<sub>2</sub>O = 1):</b>	N/A
<b>Boiling Point:</b>	N/A	<b>Evaporation Rate (Butyl Acetate = 1):</b>	N/A
<b>Melting Point:</b>	N/A	<b>Solubility in Water:</b>	N/A
<b>Vapor Density (AIR = 1):</b>	N/A	<b>pH:</b>	N/A
<b>Vapor Pressure (mmHg):</b>	N/A	<b>Odor:</b>	N/A
<b>Appearance:</b>	N/A		

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## Section 10 – STABILITY AND REACTIVITY

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**Stability:** N/A  
**Incompatibility (Materials to avoid):** N/A  
**Hazardous Decomposition or Byproducts:** N/A  
**Conditions to Avoid:** N/A  
**Hazardous Polymerization:** N/A

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## Section 11 – TOXICOLOGICAL INFORMATION

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**Routes of Entry:** N/A  
**Health Hazards (Acute and Chronic):** N/A  
**Carcinogenicity:** N/A  
**IARC Monographs:** N/A  
**Signs and Symptoms of Exposure:** N/A  
**Medical Conditions generally aggravated by Exposure:** N/A  
**NTP:** N/A  
**OSHA Regulated:** N/A



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## Section 12 – ECOLOGICAL INFORMATION

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**Ecotoxicity:** N/A  
**Mobility:** N/A  
**Bioaccumulation:** N/A  
**Degradability:** N/A

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## Section 13 – DISPOSAL CONSIDERATIONS

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**Appropriate Disposal / Product:** Dispose of unused product, spilled substance and waste in normal disposal container.

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## Section 14 – TRANSPORT INFORMATION

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**Land Transport:** Not restricted. Not regulated as hazardous goods.  
**Sea Transport:** Not restricted. Not regulated as hazardous goods.  
**Air Transport:** Not restricted. Not regulated as hazardous goods.

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## Section 15 – REGULATORY INFORMATION

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**California Proposition 65:** This product does not contain any substances listed on California's listing of known or potential carcinogens.  
**Chemical Safety Assessment:** Observe general laboratory safety regulations when handling chemicals.

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## Section 16 – OTHER INFORMATION

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SDS Prepared by: MMQCI  
Preparation Date: 10 June 2020

Disclaimer: The information contained in this SDS is provided only for use as a guide. The SDS was carefully prepared based on references and tests believed to be reliable; however, MMQCI makes no guarantee of the accuracy and completeness of the data. Any use of the data must be in accordance with applicable federal, state and local regulations.