

## MagCTL Collection Tube

### Instructions For Use

**Device Classification Name:** Microbial Nucleic Acid Storage and Stabilization Device

**Type of Device:** Device for microbial cell lysis and stabilization of nucleic acids

**Device Name:** MagCTL Collection Tube Containing MagBio CTL Medium™

**Intended Use:** It is designed for the collection, transportation, direct lysis, and stabilization of RNA from unprocessed nasopharyngeal swab samples suspected of containing SARS-COV-2.

**Background:** The MagCTL Collection Tube stores and transports specimens in a closed tube. Performance characteristics for The MagCTL Collection Tube have been established with SARS COV-2 using Applied Biosystems 7500 Real Time Instrument. The user is responsible for establishing additional MagCTL Collection Tube performance.

**Summary and Explanation:** Proper specimen collection and transport are essential in molecular testing and obtaining accurate test results. MagCTL Collection Tube allows for the stabilization and transportation of nasopharyngeal swab samples at ambient temperature from the collection site to the processing laboratory.

**Device Description:** The MagCTL Collection tube consists of a sterile, plastic, 5 ml cryogenic tube containing 1.2 mL of proprietary stabilization/lysis buffer (MagBio CTL Medium™). MagBio CTL Medium™ is intended to disrupt/lyse cells and stabilize SARS-COV-2. The preserved and stabilized RNA maintains its integrity for downstream molecular based detection/analysis.

### Materials Provided

**MagCTL Collection Tube (Cat. No. MXCT-100)**

**Materials Required: To be supplied by the Customer:** Nasopharyngeal swabs

### **Warnings and Precautions**

Special precautions must be taken when handling MagCTL Collection Tube.

- Do not ingest or apply the transport medium directly to skin or mucous membranes. For Information on transport medium components and product safety, refer to the Safety Data Sheet at [www.magbiogenomics.com](http://www.magbiogenomics.com).
- Do not insert swab into solution before collecting patient specimen.
- Do not leave tubes uncapped for extended periods.
- Specimens may be infectious. Follow Universal Precautions when handling specimens. To be used by trained and qualified professionals trained in handling infectious materials.

### **Storage Requirements**

MagCTL Collection Tube can be stored at room temperature 15°C to 25°C temperature before use. The shelf life prior to use is 12 months.

Specimen containing SARS COV-2 can be stored in MagCTL Collection Tube for up to 8 days at room temperature (15°C to 25°C) or at refrigeration temperature (2°C to 8°C).

**Acceptable Specimen Types to be Used with MagCTL Collection Tube:** The acceptable specimen for use with MagCTL Collection Tube is Nasopharyngeal swabs (NP swabs).

### **Specimen Handling**

**Specimens** - NP swabs

**Samples** – This refers to any specimen collected in MagCTL Collection Tube.

*Note:* Treat every sample as if it is infectious and handle clinical samples carefully to avoid cross-contamination. Maintain standard infection contamination control practices to avoid healthcare personnel exposure to clinical specimen. Avoid contamination of the outside of the tube and the tube cap especially during sample transfer. Ensure that the tubes lids are secured tightly to avoid any leakage.

### **Specimen Collection**

The accuracy of laboratory results depends on proper sample collection and transportation.

#### **NP swab -Sample Collection**

Specimen collection using NP swabs should be done following the standard technique. Preferably use a polyester, rayon, or flocked nylon swab for collection of NP swab specimen. After collecting the specimen, insert the swab into 1.2 mL of MagBio CTL Medium™ in MagCTL Collection Tube.

### **Specimen processing**

When using MagCTL Collection Tube for sample collection, use 200 uL of the sample aliquot for RNA capture from respiratory samples.

### **Specimen stability in MagCTL Collection Tube**

1. Specimen containing SARS COV-2 or Influenza A can be stored in MagCTL Collection Tubes for up to 8 days at room temperature (15°C to 25°C) or refrigeration temperature.
2. When the specimen is not processed within 8 days after collection it needs to be frozen at -80°C. Frozen samples must thaw to room temperature before processing. Freeze thawing of samples can be done 3 times without affecting sample stability.
3. Store MagCTL Collection Tube upright in a rack to ensure that RNA is immersed in the buffer and to avoid any sample leakage.

### **Limitations:**

- Performance characteristics of MagCTL Collection Tube have been demonstrated for SARS COV-2 and Influenza A respiratory pathogens only using MagBio paramagnetic beads for RNA capture, KingFisher Flex purification system and 7500 Real Time PCR Instrument (Applied Biosystems). The users are responsible for validating MagCTL Collection Tube for use in their laboratory.
- The user is responsible for establishing appropriate system performance characteristics for other specimen types and validating additional nucleic acid capture systems (other paramagnetic beads) for extraction-less protocols on other nucleic acid purification platforms and detection systems.
- MagCTL Collection Tube is a collection, lysis, preservation, transport, and storage system for nucleic acids only. It is a non-propagating transport system and complies with 21 CFR 809.10(a) and 21 CFR 809.10(b).

**Quality Control:** Each lot of MagCTL Collection Tube undergoes quality control to ensure efficient RNA extraction, stabilization and reproducible performance.

**Results:** The molecular testing results' accuracy depends on proper specimen collection, sample quality, integrity of nucleic acids extracted, and PCR amplification/ detection kit.



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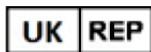
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## SYMBOLS



European  
Conformity



In vitro  
diagnostic  
medical  
device



Consult  
instructions  
for use



UK Conformity  
Assessed



Contains  
sufficient  
for <n>  
tests



Temperature  
limit



Manufacturer



Medicines and  
Healthcare  
products  
Regulatory  
Agency



Use-by  
date



Catalogue  
Number



Lot Number



For use by  
trained personnel  
only