510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K212113

B Applicant

MagBio Genomics, Inc.

C Proprietary and Established Names

MagXtract Collection Tube

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
QBD	Class II	21 CFR 866.2950 - Microbial Nucleic Acid Storage And Stabilization Device	MI - Microbiology

II Submission/Device Overview:

A Purpose for Submission:

To make a substantial equivalence determination for the MagXtract Collection Tube for the collection, transport, and storage of viral specimens to the laboratory for downstream testing.

B Measurand:

Storage and stability of nucleic acids SARS-CoV-2 viruses.

C Type of Test:

Microbial nucleic acid storage and stabilization device.

III Intended Use/Indications for Use:

A Intended Use(s):
See Indications for Use below.

B Indication(s) for Use:
The MagXtract collection tube collection tube is intended for the stabilization, transportation, and direct lysis of infectious unprocessed nasopharyngeal samples suspected of containing SARS-COV-2 virus RNA. These devices can be used for collection transport and storage of specimens at refrigerated (2-8°C) or ambient temperatures (20-25°C). Specimens collected and stored in a MagXtract collection tube are suitable for use with legally marketed molecular diagnostic devices.

C Special Conditions for Use Statement(s):
Rx - For Prescription Use Only

D Special Instrument Requirements:

N/A

IV Device/System Characteristics:

A Device Description:
The MagXtract collection tube is intended for the collection, transportation, direct lysis, and stabilization of RNA from unprocessed nasopharyngeal (NP) swab samples suspected of containing SARS-COV-2. The MagXtract collection tube stores and transports specimens in a closed tube. Proper specimen collection and transport are essential in molecular testing and obtaining accurate test results. MagXtract collection tube allows for the stabilization and transportation of nasopharyngeal swab samples at refrigeration and ambient temperature from the collection site to the processing laboratory. The MagXtract collection tube consists of a sterile plastic, 5 ml cryogenic collection tube pre-filled with 1.2 mL of proprietary stabilization/lysis buffer (MagBio CTL Medium).

B Principle of Operation:
MagBio CTL Medium is intended to disrupt/lyse cells and stabilize SARS-COV-2 RNA. The preserved and stabilized RNA maintains its integrity for downstream molecular based detection/analysis. MagXtract collection tube may be used in conjunction with an NP swab or as a tube alone. The MagXtract collection tube is designed for storage of specimens between 34-38°F (2-4°C) and 68-77 °F (20-25 °C) for up to 5 days.

The media contains the following reagents:

- Detergents
- pH buffers
- Distilled water

V Substantial Equivalence Information:

A Predicate Device Name(s):
PrimeStore MTM

B Predicate 510(k) Number(s):

C Comparison with Predicate(s):

Device & Predicate Device(s):	Device: K212113	Predicate: DEN170029
Device Trade Name		
General Device Characteristic Similarities		
Intended Use/Indications For Use	The MagXtract collection tube collection tube is intended for the stabilization, transportation, and direct lysis of infectious unprocessed nasopharyngeal samples suspected of containing SARS-COV-2 virus RNA. These devices can be used for collection transport and storage of specimens at refrigerated (2-8°C) or ambient temperatures (20-25°C). Specimens collected and stored in a MagXtract collection tube are suitable for use with legally marketed molecular diagnostic devices.	PrimeStore MTM is intended for the stabilization, transportation and inactivation of infectious unprocessed nasal washes suspected of containing Influenza A virus RNA. PrimeStore MTM is also intended for the stabilization, transportation and inactivation of infectious unprocessed sputum samples suspected of containing *Mycobacterium tuberculosis* DNA from human samples.
Inactivation test	Inactivaes virus	same
General Device Characteristic Differences		
Specimen stability	MagXtract collection tube preserves SARS-CoV-2 RNA for up to 5 days at 2-4°C and 20-25°C.	Primestore MTM medium preserves influenza A RNA for up to 8 days at 27°C and 29 days at 4°C.
Specimen Type	Nasopharyngeal swab suspected of containing SARS-CoV-2.	Nasal wash suspected of containing Influenza A virus. Sputum samples suspected of containing MTB.

VI Standards/Guidance Documents Referenced:

Special controls that are applicable to regulation 21 CFR 866.2950.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

   N/A

2. Linearity:

   N/A

3. Analytical Specificity/Interference:

   N/A

4. Assay Reportable Range:

   N/A

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   Shelf life: The shelf life for the MagXtract Collection Tube is 12 months after the date of manufacture. The stability of the MagXtract Collection Tube was performed using Realtime stability on a total of three (3) lots. Stability looked for bacterial and fungal growth contaminants in the media along with properties of the media, appearance, pH, and then confirmed with viral stabilization at room temperature demonstrating the stability of nucleic acids was not diminished with the age of media.

   Sterilization: The MagXtract Collection Tube with media are not sold as sterile nor are they intended to be sterilized by the user. These vials are single use devices that do not require cleaning by the operator.

6. Detection Limit:

   a) LoD testing was conducted to determine the lowest concentration of analyte that can be detected with a greater than 95% detection rate. Preliminary LoD testing for SARS-CoV-2 (USA-WA1/2020) was performed by spiking multiple concentrations of SARS-Cov-2, in triplicate, into media with negative clinical matrix. SARS-CoV-2 was spike at the following concertations $1.0x10^5$, $1.0x10^4$, $1.0x10^3$, $1.0x10^2$, $1.0x10^1$, and $1.0x10^0$ $TCID_{50}$/mL into the media with a COPAN NP FLOQSwabs. The preliminary LoD was detemined to be $1.0x10^1$ $TCID_{50}$/mL for both viruses. At a concentrarion of $1.0x10^0$ none of the SARS-CoV-2 targets were detected. The MagXtract Collection Tube contains MagBio CTL Medium that acts as both a transport medium and lysis buffer. Therefore, there was no need for viral lysis step as the virus has already been lysed in the collection tube. Paramagnetic beads were added directly to the media to capture the RNA already in the collection tube. Final RNA isolation was conducted on the KingFisher Flex using

Bindit software. Amplificaton of SARS-Cov-2 was done following Thermofischer TaqPath COVID-19 Combo Kit protocol for SARS-COV-2 detection.

Confirmatory LoD testing was provided at a concentration of $1.0x10^1$ $TCID_{50}$/mL with 20 replicates for SARS-CoV-2. The acceptance criteria of virus detection was least 95% of the replicates were recoverable within the detectabel range. At a concentration of $1.0x10^1$ $TCID_{50}$/mL, 20 of 20 replicates had recoverable concentrations. The Ct values for each virus and target are listed below in Table 1.

Table 1. Limit of detection C_t values

	C_t Value		
Replicates	SARS-CoV-2, N gene	SARS-CoV-2, ORF1ab gene	SARS-CoV-2, S gene
1	29.3	32.6	31.2
2	30.2	34.3	31.5
3	30.6	34.3	33.0
4	30.5	34.1	32.7
5	29.6	33.9	32.5
6	29.6	31.9	30.2
7	28.8	31.7	30.6
8	30.2	33.9	30.5
9	30.6	35.0	32.3
10	30.2	32.5	31.0
11	30.2	34.4	31.0
12	30.4	33.0	32.1
13	29.3	33.8	30.8
14	30.4	33.0	30.7
15	29.6	35.3	31.5
16	28.9	35.6	29.6
17	28.8	33.3	32.2
18	29.2	32.6	32.5
19	30.5	32.5	29.6
20	30.9	34.0	32.4
AVG:	29.9	33.6	32.4
SDV:	0.67	1.10	1.03

LoD testing at $1.0x10^1$ $TCID_{50}$/mL resulted in all 20 replicates for the concentration meeting the pre-defined acceptance criteria.

b) Viral Stability

The RNA stability of SARS-CoV-2 was conducted at $1x10^1$ $TCID_{50}$/mL. Samples were prepared using negative clinical matirx and tested as discribed in the LoD study above and added to collection tubes. Collection tubes were tested imeadately to establish a time point zero. Collection tubes were also stored at refigeration (2-8°C, 36-39°F) and room temperature (20-25°C, 68-77°F) for later analysis at various time points.

Time zero was used as the initial C_t average for each of the two temperature ranges tested with each virus. Testing additional time points was performed. The pre-defined

acceptance criteria of (+/-) 3.0 C_t from the initial time zero value was applied to the RNA study. RNA was determined to be stabilized when the predefined acceptance criteria was met. The data suports the claimed 5 day RNA stabilization for refigeration and room tmeprature, see tables 2 and 3 below.

Table 2. SARS-CoV-2 ($1.0x10^1$ $TCID_{50}$/mL) stability at 2-8°C

	Day 0	**Day 1**	**Day 5**
SARS-CoV-2 N gene ave (C_t):	27.8	28.7	27.6
SARS-CoV-2 S gene ave (C_t):	29.4	30.3	28.7
SARS-CoV-2 ORF1ab ave (C_t):	32.3	32.5	32.5

Table 3. SARS-CoV-2 ($1.0x10^1$ $TCID_{50}$/mL) stability 20-25°C

	Day 0	**Day 1**	**Day 5**
SARS-CoV-2 N gene ave (C_t):	28.4	27.4	27.1
SARS-CoV-2 S gene ave (C_t):	29.4	30.7	28.5
SARS-CoV-2 ORF1ab ave (C_t):	33.3	33.8	33.8

Stability testing of RNA from SARS-CoV-2 when spiked into matrix resulted in a maximum change of 1.3 C_t over 5 days at 25°C and a maximum change of 0.9 C_t over 5 days at 2-8°C.

c) Inactivation

An inactivation of SARS-CoV-2 was conducted using a concentration of 1.0×10^6 $TCID_{50}$/ml of virus. The virus was incubated in the MagXtract Collection Tube with 1.2 mL of MagBio CTL Medium in MagXtract for 60 minutes. The inactivation study tested virus only, virus in the MagXtract Collection Tube media and MagXtract Collection Tube media only. These three conditions were all tested using a cell culture based viability assay. The virus only and media only serve as the controls.

Three days after cells are inoculation with virus, virus and media or media only, the cells were fixed and stained with 1.0% crystal violet in 22% formaldehyde. Cells that did not take up the stain were considered evidence of a viral cytopathic effect (CPE) and as a result were considered a measure of viral viability. The titer of the virus CPE was calcuated and recorded as plaque forming units PFUs.

Inactivation time:
The MagXtract Collection Tube media showed no cytotoxicity on Vero E6 cells at a 1:100 dilution factor and greater; therefore at least a 1:100 dilution factor is needed to avoid a direct cytotoxic effect of the the MagXtract Collection Tube media. SARS-CoV-2, was then exposed to MagXtract Collection Tube media for 60 minutes prior to serial 10 fold dilutions and inoculated onto the cells. SARS-CoV-2 samples had an initial concnetrartion of greater than 1.0×10^6 $TCID_{50}$.

SARS-CoV-2 was inacitvated when exposed to the MagXtract Collection Tube media for 60 minutes and longer. The media showed total inactivation of virus (1.0×10^6 $TCID_{50}$) when used at a concentration of undiluted to 1:100. MagXtract Collection Tube media must be used undiluted to no more than 1:100 for a minimum of 60 minutes exposure time to demonstrate inactivation of SARS-CoV-2. Measuring SARS-CoV-2 inactivation below a dilution of 1:100 was not possible because of the cytotoxic affects MagXtract Collection Tube media has on the cell culture based viability assay.

7. Assay Cut-Off:

   N/A

B Comparison Studies:

1. Method Comparison with Predicate Device:

   N/A

2. Matrix Comparison:

   N/A

C Clinical Studies:

1. Clinical Sensitivity:

   N/A

2. Clinical Specificity:

   N/A

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

   N/A

D Clinical Cut-Off:

N/A

E Expected Values/Reference Range:

N/A

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.