June 17, 2024

ALB Luz
℅ Graziela Brum
Regulatory Affairs Specialist
PR Servicos Regulatorios Administrativos Ltda
Rua Alice Alem Saadi, 855/2402
Ribeirao Preto, Sao Paulo 14096-570
Brazil

Re: K233324
Trade/Device Name: Molecular Transport Media - MTM
Regulation Number: 21 CFR 866.2950
Regulation Name: Microbial Nucleic Acid Storage And Stabilization Device
Regulatory Class: Class II
Product Code: QBD
Dated: May 10, 2024
Received: May 10, 2024

Dear Graziela Brum:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Noel J. Gerald -S

Noel J. Gerald, Ph.D.
Branch Chief
Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
*See PRA Statement below.*

510(k) Number *(if known)* K233324

Device Name
Molecular Transport Media - MTM

Indications for Use *(Describe)*
The Molecular Transport Media - MTM 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 the collection transport and storage of specimens at 15-35 °C. Specimens collected and stored in a Molecular Transport Media are suitable for use with legally marketed molecular diagnostic devices.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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# Molecular Transport Media – MTM

## 510(k) Summary: K233324

### Administrative Information

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**Data Prepared** May 08, 2024

### Device name and classification

| | |
|---|---|
| **Trade Name** | Molecular Transport Media – MTM |
| **Common Name** | Specimen Collection Tube |
| **Regulation Number** | 21 CFR 866.2950 |
| **Regulatory Class** | Class II |
| **Product Code** | QBD |
| **Classification Panel** | MI -Microbiology |

## Device Description

**Predicate Device:** K212113 - MagXtract Collection Tube

### Indications For Use

The Molecular Transport Media – MTM 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 the collection transport and storage of specimens at 15-35 °C. Specimens collected and stored in a Molecular Transport Media are suitable for use with legally marketed molecular diagnostic devices.

### Subject Device Description

The MTM consists of a pre-filled plastic tube containing either 2 or 3 mL of proprietary liquid medium intended for viral nucleic acid stabilization and transportation and inactivation of nasopharyngeal swab specimens suspected of containing SARS-CoV-2. MTM is intended for use with standard diagnostic/identification techniques that have been adequately validated and found to be compatible with the MTM. The formulation of the MTM includes guanidine-free inactivation buffer, salts, a buffer to maintain a neutral pH, and distilled water.

The MTM maintains the integrity of SARS-CoV-2 viral nucleic acid when properly stored. Prior to use, vials should be stored at 15-35°C for up to 18 months. After collection, the transport tube containing the specimen can be stored at 15-35°C for up to 21 days, for transportation to the laboratory and storage.

The MTM is available in the following configurations:

- 50 vials with 3 mL of Molecular Transport Media (Catalog Number: MEI00211)
- 50 vials with 2 mL of Molecular Transport Media (Catalog Number: MEI00283)

### Technological Characteristics

The product is intended for use in the collection, inactivation, stabilization, transport, and preservation of SARS-CoV-2 viral nucleic acid from clinical samples collected from a rayon tipped nasopharyngeal swab. After sample collection, the swab is transferred into the tube of the MTM. Users then break the swab leaving the swab tip in the transport tube and screw the lid of the tube tightly.

The MTM is intended to disrupt/lyse cells and stabilize SARS-CoV-2 RNA. The preserved and stabilized SARS-CoV-2 RNA maintains its integrity for downstream molecular based detection/analysis. Samples should either be tested immediately or stored at 15-35°C for up to 21 days.

The media contains the following reagents:

- Guanidine-free inactivation buffer
- Salts
- pH buffer solution
- Distilled water

**Substantial Equivalence Information**
As with the MagXtract Collection Tube, the MTM has a formulation that inactivates viral particles and stabilizes and preserves viral nucleic acid by guanidine-free inactivation buffer, salts, pH buffer, and distilled water.

The MTM is compared with the predicate device intended use, product configuration, and packaging. Besides the subject device and the predicate device having inactivation buffers, salts, and pH buffers that differ in the formula, all of them have the same action in disrupting viral particles and stabilizing viral RNA nucleic acid.

The safety and effectiveness of performance concerning the difference between shelf life and storage temperature are proven by the real-time age tests. The subject and predicate devices comparison is described in the table below:

| **Device & Predicate Device(s):** | Device: K233324 | Predicate: K212113 |
|---|---|---|
| Device Trade Name | Molecular Transport Media - MTM | MagXtract Collection Tube |
| **General Device Characteristic Similarities** | | |
| Intended Use/Indications For Use | The Molecular Transport Media - MTM 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 the collection, transport, and storage of specimens at 15-35°C. Specimens collected and stored in a Molecular Transport Media are suitable for use with legally marketed molecular | 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 MagXtract collection tube are suitable for use with |

| | | |
|---|---|---|
| | diagnostic devices. | legally marketed molecular diagnostic devices. |
| Sample Source | Same | Upper human respiratory |
| Specimen Type | Same | Nasopharyngeal swab suspected of containing SARS-CoV-2 |
| Nucleic Acid Preserved | Same | SARS-CoV-2 RNA |
| Inactivation Test | Same | Inactivates SARS-CoV-2 virus |
| **General Device Characteristic Differences** | | |
| Specimen Stability | The Molecular Transport Media - MTM collection tube preserves SARS-CoV-2 RNA for up to 21 days at 15-35°C. | MagXtract collection tube preserves SARS-CoV-2 RNA for up to 5 days at 2-4°C and 20-25°C. |
| Volume in Tube | 2 or 3 mL | 1.2 mL |
| Storage Temperature | 15-35°C | Refrigerated: 2-8°C<br>Ambient Temperatures 20-25°C |
| Shelf-Life | 18 months | 12 months |

**Sterilization**

MTM is not claimed to be sterile nor is it intended to be sterilized by the end user. These vials are single use devices. The manufacturing process includes sterilization of the polypropylene tubes prior to being filled by ethylene oxide (EO). Dispensing the MTM liquid into the tubes occurs in three steps: filtration, filling, and closing the tube.

**Shelf life**

The shelf-life for the ALB Luz Molecular Transport Media - MTM was established to be 18 months from the date of manufacture when stored in a clean, dry, ventilated environment at 15-35°C. The shelf-life study was conducted by using a real-time aging performance test for 18 months. In this study, the shelf life was evaluated for physical stability (appearance) and pH stability during the period of storage.

i. MTM Lots Tested: The lot numbers utilized for the Shelf-Life Study are summarized in Table 1 below.

**Table 1:** MTM Lot Numbers Utilized for Shelf-Life Study.

| Lot Number | Manufacture Date | Expiration Date |
|---|---|---|
| 10909040422MTM | 4/4/2022 | 10/4/2023 |
| 10910040422MTM | 4/4/2022 | 10/4/2023 |
| 02102022MTM | 10/2/2022 | 4/2/2024 |

ii. Physical Stability: To evaluate physical stability, any changes in appearance color, and turbidity of the MTM were physically or visually examined at storage time points T = 0, 3, 6, 9, 12, 15 and 18 months. Three lots with three replicates per lot at each timepoint were tested for physical stability at storage conditions of 15°C and 35°C. At each time point, the appearance of the product was inspected visually as colorless and clear liquid, without having precipitate.

iii. pH Stability: To evaluate product stability, the pH of the MTM was tested at storage time points T = 0, 3, 6, 9, 12, 15, and 18 months. Three lots with three replicates per lot at each time point were tested for pH stability at storage conditions of 15°C and 35°C. At each time point, the pH was measured by immersing the pH meter electrode into each MTM by adjusting the temperature to 25°C prior to testing. For all the tubes tested, the pH measurement was within the acceptable pH range of 8 +/- 1.

The results for physical stability and pH stability collectively support the 18-month stability claim for the MTM for 18 months.

**Performance testing**

**Limit of Detection Study**

LoD testing was conducted to determine the lowest concentration of SARS-CoV-2 that contains measurable nucleic acids that can be repeatedly recovered from the transport media with a greater than 95% accuracy. The LoD was determined with in both preliminary and confirmatory studies as described below.

i. Preliminary LoD Study: A preliminary LoD study was conducted using a virus stock of SARS-CoV-2 (GenBank MT126808.1, Stock: 2.70E+07 PFU/mL, initially diluted to 2.70E+06 PFU/mL, then 10-fold serially diluted) and three pooled negative clinical nasal samples in a 1:1 ratio (75 µL each) resulting in final sample SARS-CoV-2 concentrations of 1.35E+05, 1.35E+04, 1.35E+03, 1.35E+02 and 1.35E+01 PFU/mL.

Approximately 100 µL of each concentration was absorbed onto rayon swabs (Copan, CLASSIQSwabs) in triplicate to obtain virus concentrations of 1.35E+04, 1.35E+03, 1.35E+02, 1.35E+01 and 1.35 PFU. The swab was used to transfer each concentration of the virus and matrix into each lot of MTM at 15°C and 35°C, respectively, prior to RNA extraction. SARS-CoV-2 RNA was extracted using MagMAX Viral/Pathogen Nucleic Acid Isolation Kit. Detection of SARS-CoV-2 RNA was conducted using the TaqPath COVID-19 Combo Kit (EUA200010) with the Applied Biosystems 7500 instrument. All procedures for nucleic acid extraction and amplification were performed following the manufacturer's instructions. The TaqPath COVID-19 Combo Kit result interpretation per the manufacturer's instructions are summarized in Table 3 below.

**Table 3:** TaqPath COVID-19 Combo Kit Result Interpretation.

| TaqPath COVID-19 Combo Kit Targets | | | Result |
|---|---|---|---|
| ORF1ab | N gene | S gene | |
| Two or more SARS-CoV-2 targets with Ct≤37 | | | Positive |
| Only one SARS-CoV-2 targets with Ct≤37 | | | Inconclusive |
| Ct>37 | Ct>37 | Ct>37 | Negative |

Results for preliminary LoD are summarized in Table 4.

**Table 4:** Summary of Preliminary LoD Results for MTM at 15℃ and 35℃.

| Lot | Temp (℃) | SARS-CoV-2 (PFU) | Replicate Number | Positive Number | Mean ± SD (Ct) | | |
|---|---|---|---|---|---|---|---|
| | | | | | ORF1ab | N gene | S gene |
| 880124MTM | 15 | 1.35E+03 | 3 | 3 | 32.90±1.18 | 34.05±0.80 | 32.22±0.88 |
| | | 1.35E+02 | 3 | 2 | 34.13±1.07 | 34.95±0.63 | 34.61±2.60 |
| | | 1.35E+01 | 3 | 1 | 36.08±0.52 | 37.41±1.69 | Undetermined |
| | | 1.35 | 3 | 3 | 34.85±0.62 | 35.16±0.52 | Undetermined |
| | 35 | 1.35E+03 | 3 | 3 | 34.89±1.69 | 35.91±1.21 | Undetermined |
| | | 1.35E+02 | 3 | 0 | 36.46±0.31 | Undetermined | Undetermined |
| | | 1.35E+01 | 3 | 0 | 37.85±0.23 | Undetermined | Undetermined |
| | | 1.35 | 3 | 0 | Undetermined | 34.62±0 | Undetermined |
| 112311150523MTM | 15 | 1.35E+03 | 3 | 3 | 31.53±1.02 | 33.10±0.78 | 31.37±1.18 |
| | | 1.35E+02 | 3 | 0 | 36.28±0.77 | 39.14±0.32 | Undetermined |
| | | 1.35E+01 | 3 | 0 | 37.56±0.60 | Undetermined | Undetermined |
| | | 1.35 | 3 | 3 | 34.50±0.48 | 35.69±0.90 | Undetermined |
| | 35 | 1.35E+03 | 3 | 2 | 33.98±1.30 | 36.62±3.01 | Undetermined |
| | | 1.35E+02 | 3 | 1 | 37.15±1.06 | 35.21±0 | Undetermined |
| | | 1.35E+01 | 3 | 0 | 39.96±0.49 | Undetermined | Undetermined |
| | | 1.35 | 3 | 0 | Undetermined | Undetermined | Undetermined |
| 02102022MTM | 15 | 1.35E+03 | 3 | 3 | 32.37±0.26 | 33.81±0.18 | 32.43±0.80 |
| | | 1.35E+02 | 3 | 3 | 34.14±0.63 | 35.46±1.02 | 34.55±0.89 |
| | | 1.35E+01 | 3 | 1 | 36.34±0.21 | 36.47±0 | Undetermined |
| | | 1.35 | 3 | 1 | 36.69±0.53 | 37.54±0.97 | Undetermined |
| | 35 | 1.35E+03 | 3 | 2 | 34.36±0.66 | 35.46±1.45 | Undetermined |
| | | 1.35E+02 | 3 | 0 | 36.41±1.29 | 39.89±0 | Undetermined |
| | | 1.35E+01 | 3 | 0 | Undetermined | Undetermined | Undetermined |
| | | 1.35 | 3 | 0 | Undetermined | Undetermined | Undetermined |

The preliminary LoD at SARS-CoV-2 concentration 1.35E+04 PFU the results were 3/3 for all targets, data not shown. The concentration of 1.35E+03 PFU was determined to be the preliminary LoD for MTM at both 15°C and 35°C.

ii. Confirmatory LoD: The confirmatory study was determined with 20 replicates for SARS-CoV-2 at concentrations of 1.35E+04, 1.35E+03 and 1.35E+02 PFU. Each replicate was inoculated into each lot of MTM tubes and were tested as previously described in the preliminary LoD study above. At a concentration of 1.35E+04 PFU the results were 20/20 for all targets, data not shown. Results for confirmatory LoD of MTM at 1.35E+03 and 1.35E+02 PFU are summarized in Table 5 below.

**Table 5:** Summary of Confirmatory LoD Results for MTM at 15℃ and 35℃.

| Lot | Temp | SARS-CoV-2 | | | Mean ± SD (Ct) |
|---|---|---|---|---|---|

| | (℃) | (PFU) | Replicate Number | Positive Number | ORF1ab | N gene | S gene |
|---|---|---|---|---|---|---|---|
| 880124MTM | 15 | 1.35E+03 | 20 | 20 | 30.70±1.44 | 31.10±1.46 | 29.92±0.78 |
| | | 1.35E+02 | 20 | 11 | 35.55±1.34 | 37.01±1.73 | 35.10±0.74 |
| | 35 | 1.35E+03 | 20 | 20 | 30.22±0.53 | 30.40±0.65 | 29.55±0.57 |
| | | 1.35E+02 | 20 | 1 | 37.61±1.13 | 36.80±1.16 | 37.25±0.66 |
| 112311150523MTM | 15 | 1.35E+03 | 20 | 19 | 29.78±0.52 | 30.04±0.62 | 29.54±0.57 |
| | | 1.35E+02 | 20 | 15 | 35.48±0.97 | 36.34±1.71 | 35.50±0.91 |
| | 35 | 1.35E+03 | 20 | 20 | 30.39±0.71 | 30.15±0.74 | 29.70±0.53 |
| | | 1.35E+02 | 20 | 14 | 35.56±1.19 | 35.37±0.81 | 34.73±1.90 |
| 02102022MTM | 15 | 1.35E+03 | 20 | 20 | 30.31±0.50 | 26.32±1.18 | 29.50±0.45 |
| | | 1.35E+02 | 20 | 19 | 35.27±0.90 | 35.90±1.13 | 35.15±0.70 |
| | 35 | 1.35E+03 | 20 | 20 | 29.72±0.67 | 29.88±0.77 | 29.06±0.58 |
| | | 1.35E+02 | 20 | 12 | 35.66±0.97 | 36.66±1.41 | 35.84±1.71 |

Based on the results, the confirmatory LoD for MTM is 1.35E+03 PFU.

**Viral Nucleic Acid Stability Study**

The SARS-CoV-2 virus stock (diluted to 6.00E+04 PFU/mL) were combined with pooled negative clinical nasal matrix in a 1:1 ratio (75 µL each) resulting in a final concentration of 3.00E+04 PFU. Approximately 100 µL of this mixture was absorbed onto rayon swabs in triplicate at a final virus concentration of 3.00E+03 PFU. Each swab was transferred into three MTM tubes of each lot and incubated at 15°C or 35°C for the following time points: 0, 7, 14 and 21 days post-inoculation. At the end of each time point, SARS-CoV-2 RNA was extracted using MagMAX Viral/Pathogen Nucleic Acid Isolation Kit, analyzed using TaqPath COVID-19 Combo Kit and Applied Biosystems 7500 instrument. All procedures for nucleic acid extraction and amplification were performed following the manufacturer's instructions. The results of the viral nucleic acid stability study summarized in Table 6 below.

**Table 6:** Summary of SARS-CoV-2 Viral Nucleic Acid Stability Results.

| Lot | Days | 15℃ | | | | | | 35℃ | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | ORF1ab | | N gene | | S gene | | ORF1ab | | N gene | | S gene | |
| | | Mean Ct | ΔCt | Mean Ct | ΔCt | Mean Ct | ΔCt | Mean Ct | ΔCt | Mean Ct | ΔCt | Mean Ct | ΔCt |
| 880124MTM | 0 | 25.89 | 0 | 30.28 | 0 | 26.26 | 0 | 25.94 | 0 | 27.62 | 0 | 26.50 | 0 |
| | 7 | 25.41 | 0.48 | 25.87 | 4.41 | 26.00 | 0.26 | 25.50 | 0.44 | 25.33 | 2.29 | 26.22 | 0.28 |
| | 14 | 25.45 | 0.44 | 25.57 | 4.71 | 26.35 | -0.09 | 25.78 | 0.16 | 25.62 | 2.00 | 26.45 | 0.04 |
| | 21 | 26.75 | -0.86 | 26.62 | 3.66 | 27.94 | -1.68 | 27.02 | -1.08 | 26.42 | 1.20 | 28.47 | -1.98 |
| 112311150523MTM | 0 | 25.62 | 0 | 31.40 | 0 | 26.14 | 0 | 26.53 | 0 | 27.64 | 0 | 27.16 | 0 |
| | 7 | 24.67 | 0.95 | 25.26 | 6.14 | 25.25 | 0.89 | 25.80 | 0.73 | 25.75 | 1.89 | 26.55 | 0.61 |
| | 14 | 24.96 | 0.66 | 25.10 | 6.30 | 25.71 | 0.43 | 27.16 | -0.63 | 26.14 | 1.50 | 27.09 | 0.07 |
| | 21 | 26.39 | -0.77 | 26.21 | 5.19 | 27.65 | -1.51 | 27.71 | -1.18 | 27.22 | 0.42 | 28.64 | -1.48 |
| 02102022MTM | 0 | 25.34 | 0 | 27.71 | 0 | 25.90 | 0 | 26.46 | 0 | 27.19 | 0 | 27.25 | 0 |
| | 7 | 25.58 | -0.24 | 25.83 | 1.88 | 26.36 | -0.46 | 24.50 | 1.96 | 24.48 | 2.71 | 25.25 | 2.00 |
| | 14 | 24.75 | 0.59 | 24.75 | 2.96 | 25.54 | 0.36 | 26.46 | 0.00 | 26.17 | 1.02 | 27.07 | 0.18 |
| | 21 | 26.03 | -0.69 | 25.88 | 1.83 | 26.94 | -1.04 | 27.00 | -0.54 | 26.33 | 0.86 | 28.30 | -1.05 |
| ΔCT calculation (Mean Ct Day 0 minus Mean Ct Day 7, 14 and 21) | | | | | | | | | | | | | |

The MTM provided positive detection for all samples tested with Ct variation (ΔCt) less than ±3 Ct values for at least two of the three viral targets (ORF1ab, N gene and S gene) at time points 7, 14 and 21 days post-inoculation comparing to time point 0 for both 15°C and 35°C.

Based on these study results, MTM is able to provide stability to the SARS-CoV-2 viral nucleic acid (i.e., RNA) for 21 days at both 15 and 35°C.

**Viral Inactivation Study**

A viral inactivation study was conducted to test the ability of MTM to inactivate SARS-CoV-2 virus.

i. Cytotoxicity: A volume of 30 µL of each lot of MTM was transferred to a 24-well microplate containing 270 µL of Dulbecco's Modified Eagle Medium with 10% fetal bovine serum cell culture media (DMEM with 10% FBS) and serially diluted (10-fold) to obtain dilutions of 1:10E+01 to 1:10E+08 in triplicate (i.e., three tubes per lot of MTM). Next, 300 µL of each dilution was added onto confluent Vero cells (ATCC, Cat: CCL-81) and incubated at 37°C at 5% CO2 for 48 hours. Cytotoxicity was determined visually using an inverted microscope looking for Cytopathic Effect (CPE). Results of the cytotoxicity study are summarized in Table 7 below.

**Table 7:** Summarized of Cytotoxicity Study Results of MTM.

| Lots* | Temp (°C) | MTM Dilution | Replicate (MTM tubes) | Cytotoxicity (CPE) |
|---|---|---|---|---|
| 880124MTM<br>112311150523MTM<br>02102022MTM | 15 | 1:10E+01 | 3 | Cytotoxic |
| | | 1:10E+02 | 3 | |
| | | 1:10E+03 | 3 | Non-cytotoxic |
| | 35 | 1:10E+01 | 3 | Cytotoxic |
| | | 1:10E+02 | 3 | |
| | | 1:10E+03 | 3 | Non-cytotoxic |
| *Each MTM lot was tested individually and obtained identical results. | | | | |

The lowest dilution to indicate normal cell growth (i.e., no cytotoxicity) was determined to be the 1:10E+03 dilution in all lots at 15°C and 35°C of temperature storage. No cytotoxicity was observed for any of the dilutions from 1:10E+04 to 1:10E+08, data not shown.

ii. Viral Inactivation: A volume of 75 µL of SARS-CoV-2 virus stock was mixed with 75 µL of pooled clinical negative nasal matrix in a 1:1 ratio to obtain a virus concentration of 1.35E+07 PFU/mL. Approximately 100 µL of this mixture was absorbed onto a rayon swab at a virus concentration of 1.35E+06 PFU and transferred into three tubes of each MTM lot number stored at 15°C and 35°C at time pointes of 0, 5 and 15-minutes post inoculation.

At the end of each time point, 30 µL of each sample was added into 270 µL of DMEM with 10% FBS cell culture media and serially diluted (10-fold) to 1:10E+01 to 1:10E+08 in triplicate (i.e., three tubes per lot of MTM). Next, 300 µL of each dilution was added onto confluent Vero cells and incubated at 37°C with 5% CO2 for virus absorption for one hour. Semisolid media containing DMEM with 10% FBS, 1% carboxymethylcellulose, and 1% penicillin/streptomycin antibiotics were added to each well and incubated at 37°C with 5% CO2 for up to 6 days. After the incubation period, the microplate wells containing the Vero cells were fixed with 10% paraformaldehyde, washed and stained with 1% crystal violet. Plaque-forming units (PFUs) were counted visually.

No PFUs were obtained after the exposure times of 0, 5 and 15 minutes for all MTM lot numbers at 15°C and 35°C. All the results appear to be acceptable and support SARS-CoV-2 inactivation at 5 minutes exposure with MTM at 15°C and 35°C.

**Non-Clinical Performance Data**

Non-clinical data submitted, referenced, or relied upon to demonstrate substantial equivalence included:

- CLSI M40-A2{2014) Quality Control of Microbiological Transport Systems; Approved Standard Second Edition.
- ASTM O4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems
- USP-NF M98810_01_01 <71> Sterility Tests
- ISO 13408-1:2015 Aseptic processing of health care products -Part 1: General requirements
- ISO/CO 10993-7: 2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
- ISO 11135:2014/Amd 1:2018 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation, and routine control of a sterilization process for medical devices – Amendment 1: Revision of Annex F. Single batch release.

**Clinical performance Data**

No clinical data were included in this submission.

**Conclusion**

The documentation submitted in this premarket notification demonstrates that the subject device K233324 has comparable features and performance and is substantially equivalent to the predicate device.