510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K233324

B Applicant

ALB Luz

C Proprietary and Established Names

Molecular Transport Media - MTM

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 obtain substantial equivalence determination for ALB Luz Molecular Transport Media – MTM for the collection, transport and storage or nasopharyngeal specimens suspected of containing SARS-CoV-2 to the laboratory for downstream testing.

B Measurand:

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

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 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.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

D Special Instrument Requirements:

None

IV Device/System Characteristics:

A 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)

B Principle of Operation:

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

V Substantial Equivalence Information:

A Predicate Device Name(s):

MagXtract Collection Tube

B Predicate 510(k) Number(s):

K212113

C Comparison with Predicate(s):

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	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

	and stored in a Molecular Transport Media are suitable for use with legally marketed molecular diagnostic devices.	refrigerated (2-8°C) or ambient temperatures (20-25°C). Specimens collected and stored in MagXtract collection tube are suitable for use with 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 Ambient Temperatures 20-25°C
Shelf-Life	18 months	12 months

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:

   Not applicable (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):

A. 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.

B. 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.

6. Detection Limit:

The limit of detection (LoD) study, viral nucleic acid stability, and viral inactivation studies were all evaluated using the three different aged lots listed in Table 2 below.

Table 2: MTM Lot Numbers:

Lot Number	Date of Manufacture (DOM)	Expiration Date	Age at time of testing
880124MTM	1/22/2024	7/22/2025	2 months
112311150523MTM	5/15/2023	11/15/2024	10 months
02102022MTM	10/2/2022	4/2/2023	18 months

A. 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℃ and 35℃, 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°C and 35°C.

Lot	Temp (°C)	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°C and 35°C.

Lot	Temp (°C)	SARS-CoV-2 (PFU)	Replicate Number	Positive Number	Mean ± SD (Ct)		
					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.

B. 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°C						35°C					
		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.

C. Viral Inactivation:

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 112311150523MTM 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.

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.