

Stability:

Stability testing was performed on aged Viral Transport Medium products to support the 12month expiration date and its ability to keep the product at 2-40°C.

VTM lot number UBP042820 was manufactured on the month of April 2020. A 500ml sample of that lot was kept at room temperature for 6 months, to help support our expiration date and product stability at different temperature over time.

VTM lot number UBP042823 was manufactured on the month of August 2020. A 500ml sample of that lot was kept at in the refrigerator at temperature of 2-8°C for 2 months, to help support our expiration date and product stability at different temperature over time.

pH stability:

The pH of the test has been determined as an indicator of product stability, and was tested within 2 months, at 6 after manufacture date, on 2 representative lots of VTM stored under recommended temperature conditions of 2-40°C. At specific time intervals, 500ml of each lot were removed from storage and tested using pH meter. For all products, pH was tested within the target pH value 7.8 ± 0.15 .

Osmolarity:

The Osmolarity of the test has been determined as an indicator of product stability, and was tested within 2 months, at 6 after manufacture date, on 2 representative lots of VTM stored under recommended temperature conditions of 2-40°C. At specific time intervals, 500ml of each lot were removed from storage and tested using an Osmometer. For all products met their acceptable rage of 280 ± 14 mOsm/kg.

Conductance:

The Conductivity of the test has been determined as an indicator of product stability, and was tested within 2 months, at 6 after manufacture date, on 2 representative lots of VTM stored under recommended temperature conditions of 2-40°C. At specific time intervals, 500ml of each lot were removed from storage and tested using a conductivity meter. For all products met their acceptable rage of 15.7 ± 0.8 mS/cm.

Visual Examination:

The visual appearance was evaluated on 2 representative lots, to detect any color change, turbidity or precipitation of the medium, within 2 months, after 6 months of manufacturing date, and was acceptable for all inspected lots.

Cytotoxicity:

Cytotoxicity testing using an PC3 cell line, performed on 2 representative medium lots within 2 and at 6 months after manufacturing, resulted in the VTM testing non-toxic for all products tested at each of the time points.

Antibiotic stability:


The activity of antimicrobial agents in VTM medium was evaluated on 2 representative lots of fresh tubes (within 48 hours of manufacturing), and 2 representative lots of 6-month-old tube; all products tested gave acceptable results.

Conclusion:

The outside lab will continue testing our product for the next 6 months in real time.

The submitted information is complete and supports a substantial equivalence decision of storing the VTM at room temperature for 6 months' time. We are sure the product can be stored at room temperature for up to 12 months, however we are still collecting the Data.

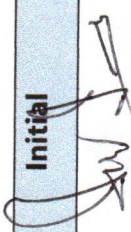

All the acceptance criteria for the stability tested after 6 months holding time at both temperatures tested, at 6- and 2-months post-manufacture date - were met for all lots tested.

	Quality Control Testing (QCT)		Revision: See QISS
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PRODUCT STABILITY DATA SUMMARY					
Product Name(s):	Virus Transport Media	Catalog No:	VTM	Lot:	UBP042820
Container/Fill:	500 mL PET Sterile Bottled	Date of Manufacturer:	4-28-20	Date of Expiration	4-28-21
Storage Temp:	2-8°C	Date Stability Study Initiated:	10-23-20	Stability Conditions:	40°C ± 2°C 65% RH ± 5%RH

No. of units for each time point	2	Total No. of units needed	30
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Test Parameter	Specification	Initial	1 month	2 months	3 months	6 months
pH	7.8 ± 0.15	7.72				
Conductance	15.7 ± 0.8 mS/cm	15.71				
Osmolarity	280 ± 14 mOsm/kg	280				

Signature	Initial	1 month	2 months	3 months	6 months
QC					
QA Approval					



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	Quality Control Testing (QCT)		Revision: See QISS
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PRODUCT STABILITY DATA SUMMARY					
Product Name(s):	Virus Transport Media	Catalog No:	VTM	Lot:	UBP042823
Container/Fill:	500 mL PET Sterile Bottled	Date of Manufacturer:	8-30-20	Date of Expiration	8-30-21
Storage Temp:	2-8°C	Date Stability Study Initiated:	10-23-20	Stability Conditions:	40°C ± 2°C 65% RH ± 5%RH

No. of units for each time point	2	Total No. of units needed	30
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Test Parameter	Specification	Initial	1 month	2 months	3 months	6 months
pH	7.8 ± 0.15	7.73				
Conductance	15.7 ± 0.8 mS/cm	15.88				
Osmolarity	280 ± 14 mOsm/kg	276				

Signature	Initial	1 month	2 months	3 months	6 months
QC					
QA Approval					

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