Cultura™ TRANSPORT SYSTEM

INDICATIONS FOR USE
The Merit Cultura™ Transport System is intended for collection and transport of clinical specimens to the laboratory for standard diagnostic/identification techniques. The Merit Cultura™ Transport System is a culture-based media that can be used for upper respiratory viral diagnostic assays including Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), Influenza A, Influenza B, Respiratory Syncytial Virus (RSV), and Rhinovirus.

SUMMARY, EXPLANATION, AND PRINCIPLE
The Merit Cultura™ Transport System contains a vial with 3mL of Viral Transport Medium (VTM). Prior to use, vials should be stored at 2-8°C or 23-25°C. After collection, the transport tube containing the specimen can be stored for up to 120 hours at 2-8°C or 23-25°C.

REAGENTS
The VTM formulation contains Hank's Balanced Salt Solution (HBSS) enriched with proteins and sugars for virus stabilization, antibiotics and antimycotics to inhibit overgrowth of bacteria and fungi, a buffer solution to maintain a neutral pH, and a pH indicator. The Cultura VTM serves as a non-propagating transport medium.

Component	Concentration
HBSS	10 g/L
Phenol Red	< 1 g/L
Fetal Bovine Serum (FBS)	20 g/L
D-Glucose	1 g/L
Gentamicin Sulfate	< 1 g/L
Amphotericin B	< 1 g/L

STORAGE
Store product in a cool, dry place.
Storage temperature for the vial with reagent is at 2-8°C or 23-25°C. Do not overheat or freeze prior to use.
The shelf life is 12 months from the date of manufacture. Do not use beyond the expiration date on the product labeling.

LIMITATIONS
1. The Cultura VTM is intended to be used with sterile, nylon flocked collection swabs. The use of medium, tubes, or swabs from any other source has not been tested and may compromise performance.
2. Any usage of this product in conjunction with a rapid diagnostic test or instrument should be validated by the user.
3. Repeated freezing and thawing of specimens may reduce the recovery of organisms.
4. Results obtained largely depend on proper and adequate specimen collection as well as the promptness with which the specimens are transported to the laboratory and analyzed.
5. The Cultura VTM has only been evaluated with viruses listed in the performance section. All other organisms will require validation.
6. Calcium alginate fiber and wooden shaft swabs are not recommended for use with The Cultura VTM as they may affect organism viability.
7. The specimen transported in the Cultura VTM cannot be used in the laboratory to perform chlamydial, mycoplasmal or ureaplasmal testing or culture.

WARNINGS
1. This product is for single use only; reuse may cause a risk of infection and/or inaccurate results.
2. Do not re-pack.
3. Not suitable for any other application than intended use.
4. The use of this product in association with a rapid diagnostic kit or diagnostic instrumentation should be previously validated by the user.
5. Instructions for use must be followed carefully. The manufacturer cannot be held responsible for any unauthorized or unqualified use of the product.
6. To be handled by trained personnel only.
7. It must be assumed that all specimens contain infectious micro-organisms; therefore, all specimens must be handled with appropriate precautions. After use, tubes and swabs must be disposed of according to laboratory regulations for infectious waste.

CONTENTS
The Cultura™ Transport System is ready for use and requires no further preparation. The packaging includes:
1 Vial with 3mL of Viral Transport Medium

PRECAUTIONS
1. Carefully follow the instructions for use.
2. Product is sterile if package is unopened and undamaged.
3. Product cannot be reused or re-sterilized.
4. Sterile gloves and protective clothing and eyewear should be worn when collecting and handling microbiology specimens.

NOTES
The Cultura™ Viral Transport Media is provided to the end user as a sterile media per the Centers for Disease Control and Prevention's Standard Operating Procedure: "Preparation of Viral Transport Medium."

RX ONLY
Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician trained and/or experienced in the use of this device, specific therapeutic or diagnostic procedure.

INSTRUCTIONS FOR USE
1. Collect the sample. During sampling, the swab end (tip) shall only come in contact with the suspected infection, so as to reduce contamination risks.
2. After patient sampling, immediately place the tip of the swab into the tube containing the VTM.
3. Discard the stick and recap the transport tube containing the swab sample.
4. After collection, standard operating protocols for clinical specimen handling and preservation should be followed. The transport tube containing the swab sample with nucleic acids from the specimen can be stored for up to 120 hours at 2-8°C or 23-25°C, which provides convenience for transportation to the laboratory and storage.
5. After the stored sample's target RNA or DNA is extracted by commercial extraction kits, various viral diagnostic assays can be performed.
Specimens collected for clinical investigations should be collected and handled following published manuals and guidelines.
Specific requirements for the shipment and handling of specimens should be in full compliance with state and federal regulations. Shipping of specimens within medical institutions should comply with internal guidelines of the institution.

CAUTIONS
1. In the laboratory, wear protective gloves and other protection commensurate with universal precautions when handling clinical specimens. Observe biosafety recommendations when handling or analyzing patient samples.
2. Condition, timing, and volume of specimen collected for clinical investigation are significant variables in obtaining reliable results. Follow recommended guidelines for specimen collection.
3. Check the package before using it. If damaged, do not use.
4. Vial container may become brittle at cold temperatures and may crack if dropped. Handle with care.

WASTE DISPOSAL
VTM must be disposed of in accordance with applicable regulations.
Dispose of any used or contaminated disposable materials following procedures for infectious or potentially infectious products. It is the responsibility of each laboratory to handle waste and effluents produced according to their nature and degree of hazardousness and to treat and dispose of them (or have them treated and disposed of) in accordance with applicable regulations.

PERFORMANCE CHARACTERISTICS
Culture-Based Studies
Performance of the Cultura Transport System was evaluated for virus viability using commercial strains of Influenza A, Influenza B, RSV, and Rhinovirus. 600 µL of organism suspension was used to inoculate the Cultura VTM in quadruplicate and stored for 0, 48 hrs., 72 hrs., and 120 hrs. at 2-8°C and at controlled room temperature (23-25°C). At each timepoint, an aliquot of the Cultura VTM and organism suspension was inoculated into the appropriate host cell line. All the cultures were processed using the standard laboratory culture technique. Organism viability was determined by the Reed-Muench method calculation of TCID50.

Merit Cultura™ Transport System preserved the samples of all the organisms tested for up to 120 hours at both controlled room temperature and refrigerated. The organisms evaluated and the results obtained are given in Table 1 below. The table below represents the titer of virus inoculated at T-0. The word "present" confirms the viability of the virus.

Table 1. Viral recovery results for viruses at T0 and T120 hours at 2-8°C and 23-25°C.

Organism	ATCC#	Host cell line	ATCC#	Virus recovered at T-0 (TCID50)	T-0 Hours		T-120 Hours	
					2-8°C	23-25°C	2-8°C	23-25°C
RSV	VR-26	Hep-2	CCL-23	101.5	Present	Present	Present	Present
Influenza A Virus	VR-1496-TC	MDCK	CCL-34	101	Present	Present	Present	Present
Influenza B Virus	VR-284	MDCK	CCL-34	101.5	Present	Present	Present	Present
Rhinovirus	VR-1535	H1- Hela	CRL-1958	101.5	Present	Present	Present	Present

Amplification-Based Studies
Performance of the Cultura Transport System was evaluated by Real-Time PCR amplification studies using 12 unique, SARS-CoV-2 positive clinical specimens in 3 lots of Cultura VTM. Samples were selected to span the range of Ct values (low, mid-range and high). Testing has been performed in triplicate to show the suitability of the Cultura VTM for the preservation of nucleic acids (RNA and DNA) for down-stream nucleic acid extraction and molecular testing when VTM and collection samples are stored per the instructions provided.

Nucleic acid was detected using the CDC 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel (catalog No. 2019-nCoVEUA-01), which detects SARS-CoV-2 (N1 and N2 nucleoprotein) markers. The rRT-PCR enzyme used in the master mix was the Thermofisher TaqPath™ 1-Step RT-qPCR Master Mix (catalog No. A15299). RNA was extracted using the Qiagen QIAcube using the QIAmp Viral RNA Mini Kit (catalog No. 52906) per the manufacturer's instructions. Samples were run on the Applied Biosystems 7500 Fast Dx PCR System with SDS version 1.4 software (catalog No. 4406985). T=0 hours, T=72 hours, T=120 hours, and T=216 hours samples were stored in temperature-controlled environments of 2-8°C and 23-25°C.

The tables below show mean Ct values of replicates for each sample at each timepoint and the difference in Ct (Δ Ct) between time 0 and 120 hours. Results are presented in separate tables according to storage temperature. Results show 100% concordance of the qualitative result (Ct < 40 is a positive result). Ct values were stable for all samples according to lot number, incubation time, or storage condition. See below for details.

Table 2. Test results (Ct, Δ Ct) for samples at storage times (hours) and temperature of 2-8°C

	Storage Time (T, hours) and Detected Markers (N1, N2)								Δ Ct T_0 vs. T_{120}	
	T_0		T_{72}		T_{120}		T_{216}			
Sample	N1	N2	N1	N2	N1	N2	N1	N2	N1	N2
A	18.56	18.39	18.83	18.48	18.36	18.33	18.14	18.73	-0.20	-0.06
B	18.45	18.55	18.36	18.98	18.47	18.64	18.86	19.13	0.02	0.09
C	25.22	24.66	24.36	24.85	25.57	25.05	24.74	24.34	0.36	0.39
D	31.20	31.40	31.02	30.98	30.51	31.40	30.64	31.56	-0.69	0.00
E	25.72	24.65	24.95	24.79	25.02	24.57	24.99	25.08	-0.69	-0.09
F	38.01	38.58	38.04	39.19	37.95	38.08	38.91	38.60	-0.06	-0.50
G	37.51	37.21	38.13	37.82	38.54	37.90	37.77	38.64	1.03	0.70
H	33.85	34.45	33.81	34.58	33.75	33.86	33.84	34.29	-0.10	-0.59
I	22.05	22.91	22.74	22.98	23.15	23.52	21.91	21.82	1.11	0.61
J	32.40	31.78	31.09	31.32	31.70	31.16	31.19	31.63	-0.70	-0.61
K	20.00	19.38	20.95	19.87	19.68	20.12	19.88	19.63	-0.32	0.74
L	32.08	32.71	32.12	32.70	32.60	32.15	33.75	32.28	0.52	-0.57

Table 3. Test results (Ct, Δ Ct) for samples at storage times (hours) and temperature of 23-25°C

	Storage Time (T, hours) and Detected Markers (N1, N2)								Δ Ct T_0 vs. T_{120}	
	T_0		T_{72}		T_{120}		T_{216}			
Sample	N1	N2	N1	N2	N1	N2	N1	N2	N1	N2
A	18.40	18.50	18.57	18.67	17.94	18.84	18.00	18.27	-0.46	0.34
B	18.73	18.59	18.49	18.52	19.10	18.21	18.07	18.41	0.37	-0.38
C	24.80	24.88	24.89	24.58	24.91	25.17	25.10	25.82	0.11	0.29
D	31.29	30.10	30.85	30.21	30.76	30.45	30.81	30.87	-0.53	0.35
E	25.43	25.53	24.34	24.79	24.98	24.84	24.88	25.00	-0.45	-0.69
F	38.03	39.08	38.82	38.06	38.13	38.86	37.92	39.66	0.10	-0.22
G	37.91	38.29	37.81	38.13	38.93	38.33	37.57	38.01	1.02	0.04
H	34.51	33.89	34.41	33.36	33.59	34.82	33.74	33.70	-0.92	0.93
I	21.82	23.18	22.43	22.75	21.88	22.61	22.76	23.00	0.06	-0.57
J	31.71	31.70	31.03	31.36	31.86	31.01	31.61	31.58	0.15	-0.69
K	20.14	19.61	19.95	19.86	19.92	19.34	20.64	19.75	-0.23	-0.28
L	33.04	32.15	32.40	33.10	32.46	32.16	32.28	32.70	-0.58	0.01

All viral diagnostic testing was performed following Clinical Laboratory Improvement Amendments (CLIA) procedures and protocols used for the clinical detection of upper respiratory viruses.

Single Use	Single Use		Date of Manufacture
STERILE A	Sterilized Using Aseptic Processing Techniques	IVD	For In Vitro Diagnostic Use
STERILIZE	Do Not Resterilize		Do not use if package is damaged and consult instructions for use
25°C 2°C	Storage Temperature, (2-25°C)		Use by Date

MERITMEDICAL®

Made in U.S.A

For technical information or questions please contact Customer Service at (801) 208-4300.

To access Merit's step-by-step guide or to watch our video tutorial, please scan the QR code above

Merit Medical
1600 West Merit Parkway
South Jordan, Utah 84095

www.merit.com

406947006_001 ID 2021-09-14