OmniTrans™ Transport System

[Intended Use]

OmniTrans™ Transport System is intended for use in the collection of clinical specimens (i.e., sputum, throat/oropharyngeal swab, whole blood, urine, skin lesion material or exudate) potentially containing viruses, chlamydiae, mycoplasma, or ureaplasma and in their transport from the collection site to the testing laboratory. The system can be processed using standard clinical laboratory operating procedures for culture of clinical specimens.

[Summary]

OmniTrans™ Transport System is provided with two different types – transport medium with or without swab(s). Type with swab(s) is supplied in several customer convenient pre-packaged collection sets for routine procedures in the diagnosis of infections caused by viruses, chlamydiae, mycoplasma or ureaplasma. Each set comprises of a package containing one labeled screw-cap tube of Transport Medium and a peel pouch incorporating one or two specimen collection swabs for the collection and safe transportation of biological specimen. Type without swab (Model OM) contains labeled screw-cap tube with transport medium only. For details, please see Model & Specification.

[Model & Specification]

REF	Model	Description	
		Tube	Swab
6992111	ON	1 mL of Transport Medium in screw-cap tube	One minitip flocking swab with 8 cm breaking point
6992311		3 mL of Transport Medium in screw-cap tube	
6992121	OO	1 mL of Transport Medium in screw-cap tube	One regular flocking swab with 3 cm breaking point
6992321		3 mL of Transport Medium in screw-cap tube	
6992191	ONO	1 mL of Transport Medium in screw-cap tube	One minitip flocking swab with 8 cm breaking point and one regular flocking swab with 3 cm breaking point
6992391		3 mL of Transport Medium in screw-cap tube	
6992014	OM	3 mL of Transport Medium in screw-cap tube	Swab not included
6992024		2 mL of Transport Medium in screw-cap tube	
6992034		1 mL of Transport Medium in screw-cap tube	
6992074		1.5 mL of Transport Medium in screw-cap tube	

[Reagents]

Hank's Balanced Salt Solution
HEPES Buffer
Bovine Serum Albumin
Sucrose
Antimicrobials
Amino Acid
Gelatin
Phenol Red
pH 7.3±0.2 @ 25°C

[Principle of Procedure]

Swabs are comprised of an applicator with a solid molded plastic shaft and a flocked tip of either a regular size or a mini size. Each swab is used for specimen collection and placed into a tube of the OmniTrans™ Transport Medium. The swab shaft is snapped off at the pre-scored line (breaking point), and the medium tube is recapped and closed tightly for storage, transportation, and subsequent testing [1].

The OmniTrans™ Transport Medium is mainly composed of modified Hank's balanced salt solution, bovine serum albumin, gelatin, sucrose, and amino acid, with HEPES buffer to maintain the pH and phenol red as pH indicator. Antimicrobials are incorporated into the medium to inhibit competing bacteria and fungi. The medium is non-toxic to mammalian host cells or cell lines commonly used for culturing the virus and chlamydiae tested [2, 3].

[Materials Provided]

Transport Medium:

- One screw-cap tube containing specified volume of Transport Medium, for non-propagating transportation.

Swabs:

- One minitip flocking swab with 8 cm breaking point
- One regular flocking swab with 3 cm breaking point
- One minitip flocking swab with 8 cm breaking point and one regular flocking swab with 3 cm breaking point

NOTE: Model OM only provides Transport Medium (without swab).

[Materials Required but Not Provided]

Appropriate materials for isolating, differentiating, and culturing the pathogens in specimens using standard clinical laboratory operating procedures. These materials include culture cell lines, culture medium, incubation systems and reading equipment.

[Storage Conditions and Expiry Date]

The product must be stored in the original packaging at a temperature of 2°C to 25°C before use, and the shelf life is 18 months. See table below for component storage conditions:

Transport Medium	Store at 2°C to 25°C
Swab	Store at 2°C to 30°C

NOTE: Do not use after expiration date, which is clearly printed on the outer box and on each individual sterile pouch unit, the specimen transport tube label and swab pouch label.

[Specimen Storage]

Specimens for investigation should be collected and handled following published manuals and guidelines [4, 5]. After collection, the specimen should be stored at 2–25°C and processed within 48 hours. To maintain optimum viability of the pathogens for accuracy of test results, transport the specimen to the laboratory as soon as possible.

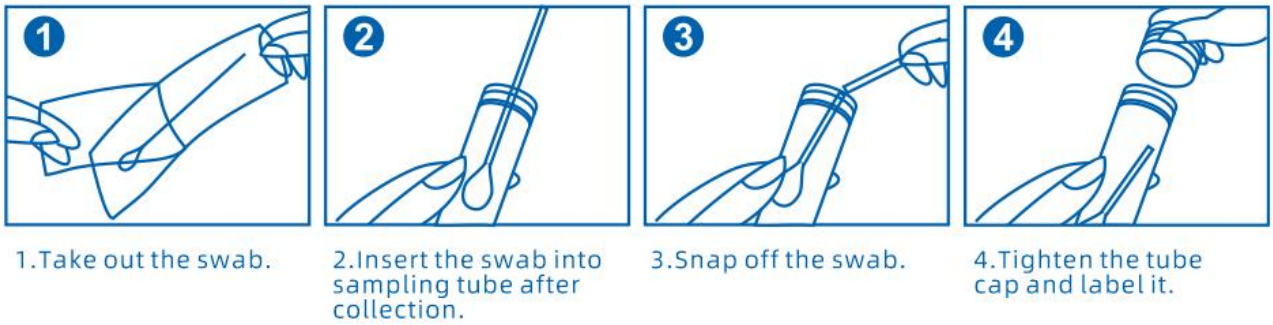
Better recovery is achieved when specimens are processed shortly after the time of collection and within 48 hours of collection when transported at 2–8°C compared to 20–25°C.

Proper specimen collection from the patient is extremely critical for successful isolation and identification of infectious organisms. For specific guidance regarding specimen collection procedures, consult published reference manuals [6].

[Procedures]

1. With the swab, collect specimens from body parts appropriate for the clinically suspected etiological agent.
2. Insert the swab into the tube with OmniTrans™ Transport Medium.
3. Snap off the swab shaft at the pre-scored line by bending it against the tube wall carefully to avoid outward splash.
4. Replace cap to tube and close tightly.
5. Label the tube with appropriate information as required.
6. Transport the samples to the laboratory as soon as possible.

7. Specimens collected using OmniTrans™ Transport System require nucleic acid extraction before nucleic acid detection.
8. The product usage diagram is as follow:



[Limitations]

- This product is only used for transport and storage of clinical specimens.
- Condition, timing, and volume of clinical specimen collected for culture are significant variables in obtaining reliable culture results. To obtain better results, it is necessary to follow the recommended guidelines to collect specimens.
- The OmniTrans™ Transport System is intended to be used with the medium tubes and swabs provided in the kit.
- The use of swab types that have not been validated (e.g., swabs from any other source) could affect the performance of the product.
- Calcium alginate swabs are toxic for many enveloped viruses and may interfere with fluorescent antibody tests, they should not be used for specimen collection. Wooden shaft swabs may contain toxins and formaldehyde and should not be used.
- Recovery performance is not known for other bacteria and viruses beyond the ones tested in the recovery study.

[Quality Control]

The product has been tested. Infectivity of the pathogens present in specimens stored in the Transport Medium remains stable for up to 48 hours.

For each batch of products, the following requirements should be met:

1. Appearance: the liquid of Transport Medium should be red, transparent, and free of precipitation, and the package should be intact.
2. Net content: the net content of constituents should not be less than the labeled amount.
3. pH value: the Transport Medium's pH value is 7.1–7.5.
4. The Transport Medium in the tube should be sterile.

Collection tubes should not be used if:

- there is evidence of damage or contamination to the product;
- there is evidence of leakage;
- there is any turbidity or precipitation;
- expiration date has passed;
- there are other signs of deterioration.

Swabs should not be used if the swab pouch is open or torn.

[Precautions]

1. For in vitro diagnostic use only.
2. For prescription use only.
3. Observe appropriate biohazard precautions and aseptic techniques. For professional use only.
4. Avoid direct physical contact of the Transport Medium with personnel.
5. Do not immerse the swab in the Transport Medium before collecting the clinical specimen.
6. The Transport Medium is not to be ingested or taken internally.
7. Single-use device, only for collection, transportation, and preservation of clinical specimen

collection, and not suitable for any other application than intended use.
8. Sterilize all biohazard waste including specimens, containers, and media after their use following approved guidelines and published reference manuals.
9. Dispose all containers in accordance with national regulations, including unused items and used items.
10. Do not use if the transport medium is beyond the date of expiry printed on the tube label or the medium is leaking from the tube.
11. Strictly follow the sampling procedures when using this product to collect specimens and operate in a laboratory that fits the appropriate security level when testing specimens.

[Performance Characteristics]

Performance of the OmniTrans™ Transport System was evaluated by culture-based recovery studies for viruses, chlamydiae, mycoplasma and ureaplasma in appropriate negative clinical matrices. For viral recovery studies, fluorescent foci count method was utilized to evaluate the recovery of adenovirus (ATCC VR-1), cytomegalovirus (ATCC VR-977), echovirus type 30 (ATCC VR-1660), herpes simplex virus type 1 (ATCC VR-260), herpes simplex virus type 2 (ATCC VR-1779), vaccinia virus (ATCC VR-1354), influenza A (ATCC VR-1736), parainfluenza virus type 3 (ATCC VR-1782), and respiratory syncytial virus (ATCC VR-1400). This method was also utilized to evaluate the recovery of *Chlamydia pneumoniae* (ATCC VR-1360) and *Chlamydia trachomatis* (ATCC VR-880). The recovery of *Mycoplasma pneumoniae* (ATCC 15531) and *Ureaplasma urealyticum* (ATCC 27816) was determined using Roll-Plate Method and Swab Elution Method. Performance evaluation was carried out in several lots of media that included newly manufactured, middle-aged, and older media.

Negative clinical matrix appropriate for the anatomical localization of respective viral and bacterial infections were obtained. From donors testing negative for respective target pathogens, pooled sputum was used for respiratory pathogens adenovirus, influenza A, parainfluenza virus type 3, respiratory syncytial virus, chlamydiae, and *Mycoplasma pneumoniae*; pooled whole blood, for cytomegalovirus; pooled throat swabs, for the enterovirus echovirus 30; pooled skin-lesion exudates, for vaccinia and herpes simplex virus types 1 and 2; and pooled urine, for *Ureaplasma urealyticum*.

Virus or chlamydial stocks were diluted into two different dilutions in pooled negative clinical matrix and each dilution was transferred with a swab into OmniTrans™ Transport System in triplicate and stored at 2–8ºC or 20–25ºC. Testing was conducted at time zero, 24 hours, and 48 hours. At time points indicated in the Tables below following inoculation, each sample was vortexed, and an aliquot was taken for recovery study using suitable tissue culture medium and host cells. For tissue culture, host cells were seeded in a 96-well plate and allowed to adhere for 24–48 hours. MRC-5 cells (SCSP-5040) were used for the recovery test of adenovirus and cytomegalovirus, Vero cells (GNO10) for herpes simplex virus type 1, herpes simplex virus type 2, vaccinia virus and respiratory syncytial virus, LLC-MK2 (GNO6) for parainfluenza virus type 3 and echovirus type 30, and MDCK (GNO23) for influenza A recovery test. For chlamydiae recovery test, Hep-2 cells (ATCC CCL-23) were used for *Chlamydia pneumoniae* and McCoy cells (ATCC CRL-1696) for *Chlamydia trachomatis*.

The transport medium containing virus or chlamydiae was used to inoculate the cell monolayer plate. After incubation, specific immunofluorescent antibody staining was used for detection and enumeration of the viral or chlamydial foci.

The number of infectious particles of viruses and chlamydiae were counted as fluorescent foci and average recovery was calculated as mean of foci count per inoculum volume into 96-well plate (0.05 mL) for each storage temperature and time points. The changes (any increase or decrease) in the recovery between time points (0 to 48 hrs.) were presented in percent values (negative for decrease and positive for increase). Any change that was within one log difference (±90%) was considered acceptable. Results were combined for all the lots irrespective of age as all changes were acceptable. Representative results from the first microbial stock dilution in negative clinical matrix

are presented in the following tables:

Table: Recovery of viruses and chlamydiae at 2–8ºC storage.

Test Organism	Average Recovery in Foci Counts/mL (×10⁴ Foci Counts/mL)		% Change in 0–48h (negative value indicates reduction)
	0h	48h	
Adenovirus	2.50	2.48	-1%
Cytomegalovirus	0.95	0.76	-20%
Echovirus 30	1.77	1.04	-41%
Herpes Simplex Virus Type 1	1.02	0.89	-13%
Herpes Simplex Virus Type 2	11.04	6.42	-42%
Vaccinia Virus	11.55	8.30	-28%
Influenza A	13.89	12.21	-12%
Parainfluenza Virus Type 3	28.84	23.47	-19%
Respiratory Syncytial Virus	5.39	4.76	-12%
Chlamydia pneumoniae	1.33	1.49	12%
Chlamydia trachomatis	1.17	0.56	-52%

Table: Recovery of viruses and chlamydiae at 20–25ºC storage.

Test Organism	Average Recovery in Foci Counts/mL (×10⁴ Foci Counts/mL)		% Change in 0–48h (negative value indicates reduction)
	0h	48h	
Adenovirus	2.50	2.64	6%
Cytomegalovirus	0.95	0.51	-46%
Echovirus 30	1.77	0.97	-45%
Herpes Simplex Virus Type 1	1.02	1.09	7%
Herpes Simplex Virus Type 2	11.04	6.52	-41%
Vaccinia Virus	11.55	8.91	-23%
Influenza A	13.89	10.68	-23%
Parainfluenza Virus Type 3	28.84	8.39	-71%
Respiratory Syncytial Virus	5.39	3.17	-41%
Chlamydia pneumoniae	1.33	1.03	-23%
Chlamydia trachomatis	1.17	0.41	-65%

For mycoplasma and ureaplasma recovery studies, inocula were prepared in appropriate negative clinical matrix, and the microbial viability was determined using Roll-Plate Method and Swab Elution Method.

Table: Recovery of mycoplasma and ureaplasma at 2–8ºC storage.

Test Organism	Average Recovery in CFU counts using Roll Plate Method			Average Recovery using Swab Elution Method (×10^4 CFU/mL)		
	0h	48h	% Change in 0–48h (negative value indicates reduction)	0h	48h	Log_{10} Changes in 0–48 hrs. (positive indicates reduction)
Mycoplasma pneumoniae	243	227	-7%	5.96	5.47	0.04
Ureaplasma urealyticum	264	189	-28%	5.10	3.81	0.13

Table: Recovery of mycoplasma and ureaplasma at 20–25ºC storage.

Test Organism	Average Recovery in CFU counts using Roll Plate Method			Average Recovery using Swab Elution Method (×10^4 CFU/mL)		
	0h	48h	% Change in 0–48h (negative value indicates reduction)	0h	48h	Log_{10} Changes in 0–48 hrs. (positive indicates reduction)
Mycoplasma pneumoniae	243	187	-23%	5.96	4.14	0.16
Ureaplasma urealyticum	264	139	-47%	5.10	2.68	0.28

As observed in the recovery studies using OmniTrans™ Transport Medium lots of post-production ages up to 18 months, all the viral and bacterial recovery counts (Fluorescent Foci counts or CFUs, as applicable) at 48 hours satisfied the pre-set criterion of being within 1 Log_{10} (i.e., ±90%) of the counts at time 0. Therefore, the OmniTrans™ Transport System demonstrated the recovery of tested viruses, chlamydiae, mycoplasma, and ureaplasma at an acceptable rate when the specimen is stored at 2–25ºC for up to 48 hours.

[Supported Strains]
Adenovirus
Cytomegalovirus
Echovirus type 30
Herpes simplex virus type 1
Herpes simplex virus type 2
Influenza A
Parainfluenza virus type 3
Respiratory syncytial virus
Vaccinia virus
Chlamydia pneumoniae
Chlamydia trachomatis
Mycoplasma pneumoniae
Ureaplasma urealyticum

[References]
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5. Isenberg, H. D., 2004. Clinical Microbiology Procedures Handbook, 2nd ed. ASM, Washington, DC.
6. National Committee for Clinical Laboratory Standards (NCCLS). 1994. Procedures for Handling and Transport of Diagnostic Specimens and Etiologic Agents. Approved Standard H5-A3. p. 0021-0045.

[Basic Information]

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[User Instruction Approval and Revision Date]
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[Product Label Symbol Description]

Symbol	Description	Symbol	Description
REF	Catalogue number	LOT	Batch code
	Date of manufacture		Manufacturer
	Use-by date		Temperature limitation
	Do not use if package is damaged		Do not reuse
IVD	In vitro diagnostic medical device		Consult instructions for use
STERILE A	Sterilized using aseptic processing techniques	STERILE R	Sterilized using irradiation
#	Model number	Rx Only	For prescription use
Σ	Contains sufficient for <n> tests		