# iClean® Viral Tranport System (VTM-RT)

*Instructions for Use*

**Intended Use**

iClean® Viral Transport System (VTM-RT) is intended for the collection, storage, and transport of clinical specimens containing viruses, chlamydiae, mycoplasma, or ureaplasma from the collection site to the testing laboratory. It provides swabs for sample collection and labeled screw-cap tubes containing Viral Transport Medium (VTM) for culture, storage, and transport of these organisms. iClean® Viral Transport System (VTM-RT) has not been reviewed by the FDA, is intended to serve as a culture media, non-propagating transport, and is to be used by trained and qualified professionals only.

**Description and Summary**

The laboratory diagnosis of infectious diseases caused by viruses, chlamydiae, mycoplasma, and ureaplasma require proper specimen collection and transport, which can be accomplished with the iClean® Viral Transport System (VTM-RT). iClean® Viral Transport System (VTM-RT) is room temperature stable and consists of a balanced buffer to maintain a neutral pH, antibiotics to inhibit bacterial or fungal contamination, and a source of protein for stabilization.

Hank's balanced salts better preserve the integrity of virus and to improve the extraction from the media. Phenol red is a pH indicator which serves as a visual quality control mechanism. Gentamicin sulfate and amphotericin B inhibit growth of competing bacteria and yeast. The medium is isotonic and non-toxic to mammalian host cells.

**Media Formulation**

Hanks balanced salt solution(HBSS)
Bovine Serum Albumin (BSA)
Gentamicin sulfate
Amphotericin B
Colistin
L-glutamic acid
HEPES buffer
Phenol red

**Storage Conditions & Shelf-Life**

iClean® Viral Transport System (VTM-RT) should be stored in a clean, dry, ventilated environment at 2-25°C. The shelf-life of iClean® Viral Transport System (VTM-RT) is 12 months after the manufacture date.

**Usage**

Proper specimen collection plays a critical role for successful isolation and identification of infectious organisms. Once the sample is collected it should be placed immediately into the media inside the tube and transported to the laboratory. Although the media can maintain even fragile organisms for long periods of time at room temperature, it is recommended that specimens be refrigerated at 2-8°C while in transit. For long term storage, specimens should be frozen at °C-70 or colder. Refer to guidelines and standards for more information on specimen collection procedures.[2,4,7]

**Sterilization**

Swabs are sterile. All components are validated and sterilized following ANSI/AAMI/ISO 11137:2006, Sterilization of health care products — Radiation.

**Quality Control**

Each lot of media is tested for microbial contamination and toxicity to host cells. Refer to publications by ASM[1,2,4] and CLSI.[5,6]

**Instructions for Use**

1. Peel open the sealed pouch containing the swab(s).
2. Remove swab(s) from the pouch and collect a specimen using proper and recommended medical specimen collection procedures for nasopharyngeal and/or oropharyngeal swabs. Do not bend the swab.
3. After the specimen is collected, aseptically remove the cap from the tube and insert the swab into the media.
4. Break the swab shaft at its break-point by bending the swab again the tube wall. After breakage, discard the portion of the shaft outside the tube.
5. Replace the tube cap and secure tightly.
6. Record patient's information on the label.
7. Transport the sample to laboratory for immediate analysis.

**Limitations and Precautions**

- For In Vitro Diagnostics use only.
- To be used by trained and qualified professionals only.
- This system has not been reviewed by the FDA.
- Intended to serve as a culture media, non-propagating transport.
- If possible, freezing of specimens should be avoided.
- Freezing and thawing may decrease the recovery of viable organisms.
- Improper storage of Sample Collection Kit may lead to decreased antibacterial and antimicrobial activity.
- Do not use wooden shaft swabs with media because they may contain toxins and formaldehydes.
- Using product with tubes or swabs obtained from other sources may affect the performance of the product.
- Do not freeze or heat before use.
- Do not use after expiration date.
- Do not use if product appears damaged, broken, contaminated, is leaking, or the pouch is ripped or open.
- Do not use if the color of the medium has changed to light orange or yellow-pink.
- Do not contact reagent in the tube prior to collecting the sample.
- This is a single-use medical device.
- Do not reuse opened or previously used products.
- Do not ingest the medium.
- Do not attempt to repackage or re-sterilize the product.
- After collection, it is not recommended to remove the swab from the tube.
- Record information on the label prior to delivery and laboratory analysis.

**Performance Characteristics**

The performance of iClean® Viral Transport System (VTM-RT) was determined by testing of viability of viruses, chlamydiae, mycoplasma, and ureaplasma. 100µL of diluted organism were directly inoculated in triplicate onto swabs. The swabs were then transferred into the transport medium system and held for 0, 24, 48h at both 4℃ and RT (20-25℃). At the appropriate time interval, each sample was vortexed and an aliquot of the suspension was inoculated into shell vials or suitable culture media. The cultures were processed by standard laboratory techniques and examined under a specified incubation time. Viability of viruses and chlamydia were determined by fluorescing foci counts and mycoplasma and ureaplasma by CFU counts.

Viruses tested were *Adenovirus, Cytomegalovirus, Echovirus Type 30, Herpes Simplex, Virus Type 1, Herpes Simplex, Virus Type 2, Influenza A, Parainfluenza 3, Respiratory Syncytial Virus, Varicella Zoster Virus, Chlamydia pneumoniae, Chlamydia trachomatis, Mycoplasma hominis, Mycoplasma pneumoniae, Ureaplasma urealyticum.*

Results obtained will largely depend on proper and adequate specimen collection, as well as timely transport and processing in the laboratory.

**Table 1**

| Organism | Organism Concentration [a] | Percent Infectivity of Host Cells | Storage Time (hours) | Incubation Time Prior to Reading (hours) | Viability Challenge at Foci of infected cells/200µL [b] | |
|---|---|---|---|---|---|---|
| | | | | | 4℃ | RT |
| Adenovirus | 1：100 | 2% | 0 | 24 | 415 | 415 |
| | | | 24 | | 627 | 500 |
| | | | 48 | | 795 | 497 |
| | 1：500 | 3% | 0 | 24 | 196 | 196 |
| | | | 24 | | 229 | 189 |
| | | | 48 | | 202 | 64 |
| Cytomegalovirus | 1：10 | 100% | 0 | 24 | 822 | 822 |
| | | | 24 | | 235 | 50 |
| | | | 48 | | 327 | 353 |
| | 1：100 | 100% | 0 | 24 | 249 | 249 |
| | | | 24 | | 147 | 52 |
| | | | 48 | | 121 | 317 |
| Echovirus Type 30 | 1：100 | 64% | 0 | 24 | 147 | 147 |
| | | | 24 | | 515 | 553 |
| | | | 48 | | 664 | 799 |
| | 1：500 | 2.91% | 0 | 24 | 111 | 111 |
| | | | 24 | | 328 | 322 |
| | | | 48 | | 283 | 192 |
| Herpes Simplex Virus Type 1 | 1：10 | 6% | 0 | 24 | 285 | 285 |
| | | | 24 | | 854 | 432 |
| | | | 48 | | 847 | 1015 |
| | 1：100 | 48% | 0 | 24 | 168 | 168 |
| | | | 24 | | 127 | 89 |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | 48 | | 110 | 142 |
| Herpes Simplex Virus Type 2 | 1：10 | 47% | 0 | 24 | 139 | 139 |
| | | | 24 | | 72 | 110 |
| | | | 48 | | 140 | 9 |
| | 1：100 | 97% | 0 | 24 | 32 | 32 |
| | | | 24 | | 40 | 40 |
| | | | 48 | | 23 | 14 |

[a]The test swab tip was inoculated in 100µL of suspension and then placed into test tubes with 3mL of iClean transport medium

[b]Average of triplicate tests performed on 200µL of VTM-RT at each time point

**Table 2**

| Organism | Organism Concentration[a] | Percent Infectivity of Host Cells | Storage Time (hours) | Incubation Time Prior to Reading (hours) | Viability Challenge at Foci of infected cells/200µL[b] | |
|---|---|---|---|---|---|---|
| | | | | | 4℃ | RT |
| Influenza A | 1：50 | 10% | 0 | 24 | 384 | 384 |
| | | | 24 | | 566 | 339 |
| | | | 48 | | 268 | 134 |
| | 1：100 | 12% | 0 | 24 | 316 | 316 |
| | | | 24 | | 165 | 298 |
| | | | 48 | | 118 | 43 |
| Parainfluenza 3 | 1：10 | 3% | 0 | 48 | 617 | 617 |
| | | | 24 | | 40 | 836 |
| | | | 48 | | 127 | 163 |
| | 1：100 | 25% | 0 | 48 | 445 | 445 |
| | | | 24 | | 34 | 352 |
| | | | 48 | | 60 | 77 |
| Respiratory Syncytial Virus | 1：10 | 76% | 0 | 24 | 159 | 159 |
| | | | 24 | | 196 | 184 |
| | | | 48 | | 102 | 157 |

| | | | | | | |
|---|---|---|---|---|---|---|
| | 1：100 | 100% | 0 | 24 | 31 | 31 |
| | | | 24 | | 89 | 67 |
| | | | 48 | | 78 | 78 |
| Varicella- Zoster Virus | 1：10 | 100% | 0 | 24 | 177 | 177 |
| | | | 24 | | 304 | 255 |
| | | | 48 | | 46 | 164 |
| | 1：100 | 100% | 0 | 24 | 177 | 177 |
| | | | 24 | | 109 | 100 |
| | | | 48 | | 156 | 143 |

[a]The test swab tip is inoculated into 100µL of suspension and then placed into test tubes with 3mL of iClean transport medium

[b]Average of triplicate tests performed on 200µL of VTM-RT at each time point

**Table 3**

| Organism | Organism Concentration [a] | Percent Infectivity of Host Cells | Storage Time (hours) | Incubation Time Prior to Reading (hours) | Viability Challenge at Foci of infected cells/200µL[b] | |
|---|---|---|---|---|---|---|
| | | | | | 4℃ | RT |
| Chlamydia Pneumoniae | 1：10 | 100% | 0 | 48 | 202 | 202 |
| | | | 24 | | 426 | 524 |
| | | | 48 | | 422 | 401 |
| | 1：100 | 100% | 0 | 48 | 71 | 71 |
| | | | 24 | | 187 | 169 |
| | | | 48 | | 134 | 164 |
| Chlamydia Trachomatis | 1：10 | 100% | 0 | 48 | 290 | 290 |
| | | | 24 | | 283 | 824 |
| | | | 48 | | 246 | 336 |
| | 1：100 | 100% | 0 | 48 | 83 | 83 |
| | | | 24 | | 72 | 188 |
| | | | 48 | | 76 | 124 |

[a]The test swab tip is inoculated into 100µL of suspension and then placed into test tubes with 3mL of iClean transport medium

[b]Average of triplicate tests performed on 200µL of VTM-RT at each time point

**Table 4**

| Organism | Organism Concentration [a] | Incubation Time Prior to Reading (Days) | Storage Time (hours) | Viability Challenge at CFU/100µL [c] | |
|---|---|---|---|---|---|
| | | | | 4℃ | RT |
| Mycoplasma hominis | 1：500 | 3 | 0 | TNTC[b] | TNTC[b] |
| | | | 24 | TNTC[b] | 39 |
| | | | 48 | TNTC[b] | 86 |
| | 1：1000 | 5 | 0 | 213 | 213 |
| | | | 24 | 145 | 35 |
| | | | 48 | 179 | 14 |
| Mycoplasma pneumoniae | Neat | 6 | 0 | TNTC[b] | TNTC[b] |
| | | | 24 | TNTC[b] | TNTC[b] |
| | | | 48 | TNTC[b] | 1235 |
| | 1：10 | 6 | 0 | 1221 | 1221 |
| | | | 24 | 869 | 337 |
| | | | 48 | 903 | 197 |
| **Organism** | **Organism Concentration [a]** | **Incubation Time Prior to Reading (Days)** | **Storage Time (hours)** | **Viability Challenge at CFU/100µL [c]** | |
| | | | | **4℃** | **RT** |
| Ureaplasma urealyticum | 1：500 | 5 | 0 | TNTC[b] | TNTC[b] |
| | | | 24 | TNTC[b] | TNTC[b] |
| | | | 48 | TNTC[b] | TNTC[b] |
| | 1：1000 | 5 | 0 | 1122 | 1122 |
| | | | 24 | 1379 | 1081 |
| | | | 48 | 700 | 620 |

[a] The test swab tip is inoculated into 100µL of suspension and then placed into test tubes with 3mL of iClean transport medium

[b]TNTC, Too numerous to count
[c] Average of triplicate tests performed on 100µL of VTM-RT at each time point

**Bibliography**

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**Manufacturer**

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**Product Descriptions and Catalog Number**

| Catalog No. | Description | Pack |
|---|---|---|
| CY-F005-20 | 3ml transport medium vial with iClean® nasal flocked Swab | Single pack, 100 units/box |
| CY-F005-20 | 3ml transport medium vial with iClean® buccal flocked Swab | Single pack, 100 units/box |
| CY-F005-20 | 3ml transport medium vial with iClean® throat flocked Swab | Single pack, 100 units/box |
| CY-F005-20 | 3ml transport medium vial with iClean® nasal flocked Swab and throat flocked Swab | Single pack, 100 units/box |
| CY-F005-20 | 3ml transport medium vial with polyester tip swab | Single pack, 100 units/box |
| CY-F005-20 | 3ml transport medium vial with 2 polyester tip swabs | Single pack, 100 units/box |