

Product Performance of Inactivated Virus Transport Medium (ITM)

Product description

An inactivated virus transport medium (ITM) contains guanidine salts and ionic detergents, which can lyse viruses and cells to release proteins and nucleic acids. The released proteins, such as DNases and RNases, will be quickly cleaved and denatured, whereas the reducing agent and protective agent in the preservation solution can protect the released nucleic acids from being degraded at normal temperatures. ITM can be used for the preservation and inactivation of clinical specimens, such as nasal and pharyngeal swabs. It can effectively prevent changes of microorganisms in such specimens in their types and relative abundance. After being preserved in the virus sampling tube, the nucleic acids in the microorganisms can maintain high integrity and can be used for various biological experiments such as enzymatic hydrolysis, PCR and next-generation sequencing. ITM is widely used in the collection and preservation of specimens in hospitals, scientific research institutions and households.

Intended use

For the collection, transport and preservation of specimens.

Performance

1. Preservation Stability

The preservation stability experiment was used to determine the capacity of ITM to preserve DNA and RNA. *Ureaplasma urealyticum* and parainfluenza virus type 2 were used as research materials and the preservation capacity of ITM was determined by different preservation conditions and duration.

Respectively add 1.0E+3 CCU/mL *ureaplasma urealyticum*, 1.0E + 3 copies/mL parainfluenza virus type 2 into an ITM preservation solution and store at 4 °C & 37°C , respectively. Then, test them using a PCR method at Day 0, 3, 9, 15, 21 and 27. Perform the test 20 times repeatedly for each detection point under each storage condition and the degree of difference in Ct values represents the preservation stability.

Table 1. Preservation Stability Experiment for *Ureaplasma Urealyticum*

Day		0	3	9	15	21	27
4°C	Mean (Ct)	21.32	22.53	21.74	22.45	22.54	21.87
	SD	5.26%	6.03%	4.73%	6.94%	5.75%	5.19%
37°C	Mean (Ct)	22.65	21.64	22.46	22.96	23.46	22.57
	SD	6.45%	5.83%	4.27%	6.03%	6.03%	5.39%

Table 2. Preservation Stability Experiment for Parainfluenza Virus Type 2

Day		0	3	9	15	21	27
4°C	Mean (Ct)	19.04	20.43	19.2	18.83	19.43	20.34
	SD	6.94%	7.54%	6.93%	7.16%	5.39%	7.94%
37°C	Mean (Ct)	22.54	21.56	19.54	20.57	22.63	23.79
	SD	7.93%	6.03%	6.5%	6.15%	5.93%	5.83

The results showed that ITM has good protective effects for ureaplasma urealyticum and parainfluenza virus type 2 at both 4°C and 37°C, and the preservation capability will not decrease over time.

2. Comparison between Different Preservation Solution in Preservation Performance

Respectively add 1.0E+3 CCU/mL ureaplasma urealyticum, 1.0E + 3 copies/mL parainfluenza virus type 2 into the ITM preservation solution, the competitive preservation solution and normal saline, and store them at 37°C. Test them using a PCR method at Day 20 and 27. Perform each test 20 times repeatedly, and the positive detection rate (number of positives/total number of tests) represents the performance of the preservation solution.

Table 3. Comparison Between Different Preservation Solution in Preservation Performance (for Ureaplasma Urealyticum)

Duration of preservation	Preservation solution	1.0E+4 CCU/mL Number of positives/total number of tests	1.0E+3 CCU/mL Number of positives/total number of tests
20 day	ITM	20/20	20/20
	Competitive preservation solution	20/20	20/20
	Normal saline ^{**}	18/20	15/20
27 day	ITM	20/20	19/20
	Competitive preservation solution	20/20	19/20
	Normal saline ^{**}	14/20	16/20

Table 4. Comparison between Different Preservation Solution in Preservation Performance (Parainfluenza Virus Type 2)

Duration of preservation	Preservation solution	1.0E + 4 copies/mL	1.0E + 3 copies/mL

		Number of positives/total number of tests	Number of positives/total number of tests
20 day	ITM	20/20	19/20
	Competitive preservation solution	20/20	17/20
	Normal saline [※]	15/20	15/20
27 day	ITM	20/20	20/20
	Competitive preservation solution	20/20	15/20
	Normal saline [※]	15/20	13/20

※: Bacteria grew in some of the tubes of normal saline for prolonged storage.

The results demonstrated that the ITM preservation solution has good preservation capability and is superior than the competitive preservation solution and the normal saline solution.

3. Comparison between different preservation solutions

Type of preservation solution	ITM	VTM	UTM
Product composition	guanidine salts, nucleic acid protectants, etc.	HBSS, FBS, gentamycin sulfate, antibiotics, etc.	HBSS, BSA, gelatin, sucrose, HEPES, L-glutamic acid, L-cysteine, gentamycin sulfate, antibiotics, etc.
Applicable microbial range	Virus, bacterium, mycoplasma, chlamydia, ureaplasma, parasites, etc.	Virus	Virus, mycoplasma, chlamydia, ureaplasma
Preservation capability	Long (Storage at 37 °C for 30 days after sampling, both DNAs and RNAs can be well preserved)	Short (Storage and transportation at a low temperature of 2-8 °C within 48h after sampling)	Short (Storage and transportation at a low temperature of 2-8 °C within 48h after sampling)
Product transportation conditions	Transported at ambient temperature	Transported at ambient temperature	Transported at ambient temperature

Post-sampling transportation conditions	30 days at ambient temperature	2-8°C 48h	2-8°C 48h
Usage after sampling	Nucleic acid detection	Nucleic acid detection, isolated culture	Nucleic acid detection, isolated culture
Functional characteristics	<p>1) Instantly inactivate viruses, bacteria, mycoplasmas, chlamydias ureaplasmas, etc., to reduce the risk of pathogen spreading;</p> <p>2) suitable for collection of potentially harmful pathogens and known pathogens of severe infectious diseases (such as 2019-nCoV, Ebola virus, etc.), and provides good protection for medical personnel;</p> <p>3) low requirements for transportation environments;</p> <p>4) good preservation capability, and more accurate test results for low-concentration samples.</p>	<p>1) Collection, nucleic acid detection and isolated culture of virus samples;</p> <p>2) contains pH indicator for real-time monitoring of pH stability of the preservation solution.</p>	<p>1) Collection, nucleic acid detection and isolated culture of virus and other related samples (mycoplasma, chlamydia, ureaplasma, etc.);</p> <p>2) contains pH indicator for real-time monitoring of pH stability of the preservation solution;</p> <p>3) greater buffering capability.</p>
Color	Colorless, clear	Red, clear (with phenol sulfonphthalein), or Colorless, clear (without phenol sulfonphthalein)	Red, clear (with phenol sulfonphthalein)