PrimeStore® MTM

An explanation of the differences between Molecular Transport Media and Viral Transport Media

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Summary

The main difference between MTM and VTM is that molecular transport media, such as PrimeStore® MTM, will fully deactivate viruses, bacteria, fungi and mycobacterium tuberculosis, allowing safe sample handling and transport to greatly reduce infection risk.

PrimeStore MTM is a FDA cleared and CE IVD marked infectious disease sample collection, storage and transport system which was specifically developed to overcome the short comings of standard viral transport media (VTM) and universal transport media (UTM) that do not inactivate microbes and can also inhibit molecular testing.

What is Molecular Transport Media?

PrimeStore MTM (molecular transport media) is specifically designed to safely inactivate pathogenic samples whilst preserving and stabilizing the released DNA and RNA. The guanidine thiocyanate contained in PrimeStore MTM destroys a virus's protective viral coat (the capsid) rendering it incapable of reinfection, whilst maintaining the viral nucleic acids for molecular diagnostics, sequencing and biobanking.

Molecular testing is now widespread due to its improved performance and turnaround times compared to traditional microbiology testing. Most currently approved tests for COVID-19 (SARS-CoV-2 virus) and other infectious diseases are nucleic acid based molecular assays, so removing the need for and risk of live pathogen transportation for routine testing.

Designed and optimized for molecular applications, including qPCR and next generation sequencing, PrimeStore MTM uses a unique patented technology for safely collecting samples from patients with highly infectious diseases. It was first introduced in 2006 in preparation for a worldwide pandemic and it has already been used in testing for many infectious diseases and high consequence pathogens, including influenza, RSV, TB, HIV and coronavirus.

COVID-19 has led to a significant increase in global demand for PrimeStore MTM, which is the only FDA Class II cleared device for microbial nucleic acid storage and stabilization (RNA and DNA) available for the safe transportation of samples which may contain viruses. There are already a number of published examples of its use in the workflow for SARS-CoV-2 RNA detection where it is used for initial virus inactivation[1].

Simple and safe sample collection

Advantages of MTM over VTM and UTM

PrimeStore MTM is seen as a real game changer for the sampling and transport of pathogenic samples from a safety, reliability and cost perspective. The key differences between MTM and generic UTM/VTM media are summarized in Table 1 (see page 9).

Standard UTM and VTM were designed for transporting intact viable microbial samples for culture; this means that there is still a biohazard which requires a controlled environment for subsequent laboratory work. Furthermore, as samples are live, cold chain storage and transportation are required.

These standard transport media may also contain enzymes and nucleases damaging to RNA and DNA, therefore inhibiting optimal molecular testing, such as PCR. However, modern molecular tests do not require viable virus, but just intact microbial nucleic acids.

Once a swab or biofluid is added to PrimeStore MTM the user has a 'snapshot' in time for that inactivated microbial sample. The microbe's DNA, and more importantly the labile RNA, is immediately stabilized and preserved at the point of sampling. So, samples in MTM do not have to be pre-processed in BLS-III or even BLS-II safety levels, just safe normal laboratory practices for testing are required.

Another key benefit of MTM is that a sample can be safely stored at ambient temperature for up to seven days (Figure 1. See page 8) or 28 days at 2 to 8°C and re-used several times. As well as reducing the risks of handling live pathogenic samples, this also cuts costs by eliminating cold chain requirement and, as previously mentioned, the need for Category 3 facilities, as testing can take place outside of containment.

Combined COVID-19 and flu testing

It's clear that a strong testing programme is needed the annual flu season and a potential further waves of COVID-19 – as thousands of people are going to start presenting with symptoms that could be either virus.

As multiple infectious disease tests can be processed from one sample swab, PrimeStore MTM is an ideal transport media. This is because samples collected and stored in MTM can be tested for both COVID-19 and influenza from a single swab sample that has been inactivated and stabilised. This, in addition to the fact that refrigerated transport and storage is not required, can assist with disease differentiation at reduced costs when compared to standard collection kits.

Proven safe viral transport

PrimeStore MTM is proven technology. With millions of tubes already sold globally prior to and during the COVID-19 pandemic to hospitals and laboratories, it is evident that they trust that it provides safer and more reliable testing than generic VTM or UTM, saline, or RUO devices.

Multiple peer-reviewed scientific papers have been published from 2011 onwards, validating the use of PrimeStore MTM for reliable pathogen deactivation (Table 2. Page 9) and detection from a wide variety of clinical matrices and biofluid types, and with a range of analytical platforms.

In 2020 a consortium of researchers put forward the case for biosafety in pathogen transportation and testing through the adoption of virus-inactivating VTM which kill biological pathogens whilst ensuring DNA and RNA stabilisation and preservation for molecular applications.

They noted that PrimeStore MTM has been extensively analysed to effectively inactivate/kill viral, bacterial and fungal pathogens while preserving stability of the released DNA and RNA for diagnosis, and is FDA cleared. They also observed that,

"Moving to virus-inactivating VTM at collection allows risk mitigation from transportation and handling of bio-specimens for diagnosis and can potentially reduce the need for special packaging and transportation measures for SARS-CoV-2/COVID-19 test samples." [2]

Not all inactivation media are equal

To work safely with live human coronavirus SARS-CoV-2 requires the use of high-containment laboratories. However, after inactivation SARS-CoV-2 material can be handled at a lower containment level, thereby opening up testing capacity in more laboratories.

A study by Public Health England[3] investigated a wide array of apparent inactivation reagents in current use in UK laboratories during the COVID-19 pandemic for sample transportation and subsequent molecular processing. A total of 23 commercial reagents designed for virus inactivation, clinical sample transportation and nucleic acid extraction were assessed for their ability to inactivate SARS-CoV-2.

TCID50 and blind passage techniques were used to test for any infectious virus still recoverable from all samples treated with the inactivation reagents. Results showed that of the specimen transport reagents tested, PrimeStore MTM was one of just two such reagents from which no residual virus was detectable by either TCID50 or by the passaging of treated purified sample.

In conclusion

The novel, patented sample collection device, PrimeStore® MTM allows COVID-19 samples to be rapidly inactivated in the collection tube. This immediately eliminates infection risk and also preserves nucleic acids for downstream molecular processing without need for refrigeration.

In addition to removing the need for expensive cold chain transport and storage of samples, RNA and DNA are perfectly preserved by PrimeStore MTM for up to four weeks. This means that it is ready for safe testing immediately on arrival at a laboratory and without need for containment. In the case of COVID-19, this opens up options for more testing laboratories, making this device a key part of the testing supply chain which can underpin the safe and rapid increase of testing capacity.

PrimeStore MTM is also being used during the coronavirus pandemic by a number of businesses to provide COVID-19 testing services for their staff. This is enabling them to bring back those who may be self-isolating due to concerns over infection, or that of a family member. The fact that it also enables laboratories to test for both COVID-19 and influenza from a single sample will also be greatly beneficial as the flu season approaches.

It all starts with the sample

References

- Alessio Lorusso et al. (2020). A “One-Health” approach for diagnosis and molecular characterization of SARS-CoV-2 in Italy. One Health, Volume 10, 2020, Article 100135.
- Rajan Dewar et al. (2020). Viral transportation in COVID-19 pandemic: Inactivated virus transportation should be implemented for safe transportation and handling at diagnostics laboratories. Archives of Pathology & Laboratory Medicine. In-Press. Early Online Release.
- Stephen R. Welch et al. (2020). Inactivation analysis of SARS-CoV-2 by specimen transport media, nucleic acid extraction reagents, detergents and fixatives. bioRxiv – preprint paper.

Figures

Figure 1: Stability of Influenza A RNA in PrimeStore MTM. Unlike most standard sample collection systems MTM removes cold chain requirements for sample collection and transportation, ensuring RNA stability at ambient temperatures.

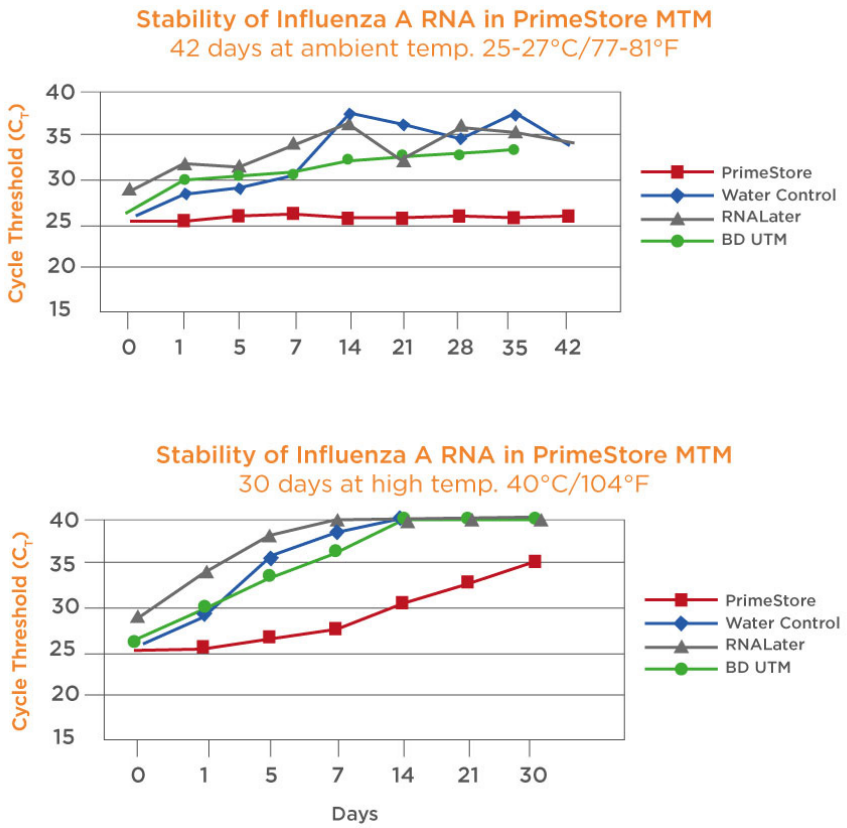

Table 1

Key differences between PrimeStore MTM and generic UTM/VTM.

VTM and UTM's are designed for transporting samples intact for lab culture and contain components that inhibit optimal molecular testing, in comparison PrimeStore MTM was invented and optimised for molecular testing.

	PrimeStore MTM	Generic VTM / UTM
Cold chain storage and transportation required?	No	Yes
Sample incativated?	Yes*. Testing can take place outside of containment	No. Virus is still abiohazard and testing should be under controlled containment
Sample integrity	Destroys enzymes and nlucleases, preserving RNA and DNA	May contain enzymes and nucleases that damage RNA and DNA
Inhibit PCR?	No	Yes
Shelf life	24 months	Less than 6 months

Table 2

Antimicrobial effectiveness testing of PrimeStore MTM (BioReliance Corp, Rockville, Maryland, USA (2010))

Bacteria and fungi

Organism	Positive control (cfu/mL)	PrimeStore MTM + Organism (% killed)
E. coli	6.4×10^7	100
S. aureus	6.0×10^7	100
MRSA	4.7×10^6	100

*Antibacterial effectiveness testing, cert. USP 32-NF 27<51>

Viruses

Organism	Positive control ($TCID_{50}$/mL)	PrimeStore MTM + Organism (% killed)
Influenza A (H3N2)	7.5×10^8	>99.99
Adenovirus type 5	7.5×10^8	>99.99
Influenza A (H5N1)	7.5×10^7	>99.99

*Initial 4-log dilutions of PrimeStore MTM + viruses were required due to PrimeStore lysis of tissue culture.

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