CELL & GENE THERAPY INSIGHTS

INNOVATOR INSIGHT

Analytical strategies for sterility and mycoplasma testing in biotherapies: from early development to production scale-up

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Characterization of a biological product, including the determination of product safety and impurities, is necessary for regulatory compliance, along with patient safety. The cell therapy workflow is a complex process for which developing an analytical strategy to test for impurities such as mycoplasma can be challenging. There are several critical considerations when selecting analytical assays early in development: assays should meet or exceed the regulatory guidelines based on product, process, and region; an integrated sample-to-answer solution can make implementation faster, more efficient, and optimize routine; and scalability can enable larger-scale production following commercial product launch. This article will explore how leveraging rapid mycoplasma and sterility detection techniques can improve confidence in the final product by helping to detect potential contamination earlier in the production process.

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MYCOPLASMA AND STERILITY TESTING: A REGULATORY PERSPECTIVE

Recently updated US FDA guidance applicable to genetically engineered cell products such as CAR-T cell therapies recommends that mycoplasma and adventitious agent testing should be conducted at the manufacturing stage when contamination is most likely to be detected, such as after pooling of cultures for harvest prior to cell washing. However, traditional testing methods cannot be used with cellular products due to the lengthy timeframes involved and the limited product shelf-life available. Alternative methods that may be needed for such products include rapid sterility tests, rapid PCR-based mycoplasma tests, and rapid endotoxin tests. Any such rapid detection assays must offer adequate sensitivity and specificity.

Sterility testing guidance states that to ensure product safety, all cell therapies should be free of viable contaminating microorganisms. Importantly, the final drug product cannot be sterilized by filtration or permanently sterilized, as the cells must remain fully viable and functional. Therefore, product safety is further supported by the use of sterility testing per the *United States Pharmacopeia (USP)* <71>, or an appropriately validated alternative test method per *USP* <1223>.

Figure 1 illustrates how mycoplasma and sterility testing are typically applied within the CAR-T cell therapy manufacturing workflow.

RAPID MOLECULAR TESTING

The traditional method of testing for mycoplasma accepted by regulatory agencies leverages a 28-day culture-based test, which can lead to delays in lot disposition. This is a challenge for cell therapies, which often have a short shelf life and are used to treat critically sick patients. The 28-day test also requires specialized expertise, often leading to outsourcing at a high cost per sample and risk to project timelines.

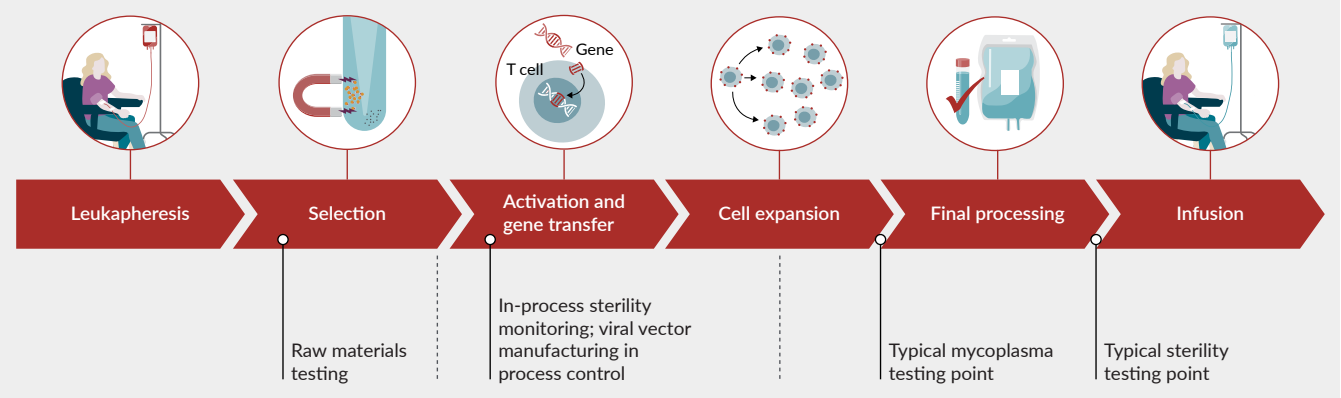
An alternative approach is to use a molecular or PCR-based test with a sensitivity that meets or exceeds the culture-based test, and that produces results in hours rather than days, allowing for same-day lot release. This is referred to as rapid PCR or nucleic acid-based testing (NAT). This approach leverages the high sensitivity and specificity of PCR to screen for the presence of mycoplasma nucleic acids in the test sample. PCR-based testing can offer a low cost per sample and if based on genomic DNA alone, it does not require live control organisms during test validation. Furthermore, a test solution that facilitates implementation into GMP lab operations is ideal—for example, through the availability of automation, 21 CFR Part 11 compliance software, and technical support. Specific guidance listed in the *European Pharmacopoeia* for NAT states that test performance should include a demonstration of specificity, both inclusivity and exclusivity, sensitivity with a limit of detection (LOD) of 10 colony forming units (CFU)/mL of sample or genomic copy (GC) equivalent, and assay robustness.

Thermo Fisher Scientific offers two options for rapid PCR-based testing of mycoplasma: the Applied Biosystems™ MycoSEQ™ and MycoSEQ™ Plus Mycoplasma Detection Kits. Both are designed to meet regulatory guidelines for lot release, including sensitivity, specificity, and robustness. Each kit may be used as part of a defined analytical solution that can be completed in 5 hours and includes relevant controls to help ensure reliable results. These tests allow for screening many mycoplasma species within a single PCR reaction and have been confirmed to meet or exceed sensitivity needs for species listed in the USA, European, and Japanese pharmacopeias.

The legacy MycoSEQ Rapid Mycoplasma Detection kit, launched 15 years ago, has an unparalleled track record for regulatory acceptance in the industry, having been used in over 40 approved biotherapies.

FIGURE 1

Mycoplasma and sterility testing in the CAR-T cell therapy manufacturing process.



Furthermore, the MycoSEQ Rapid Detection Kit was first accepted as an alternative to the traditional culture test by the FDA 10 years ago. Expert regulatory consultation and support for customers is offered alongside the kit, in addition to access to a drug master file (DMF) and a report on comparability to the *USP* <63> method. The MycoSEQ Plus Rapid Detection Kit, launched more recently, also has a DMF in place with the FDA.

The qPCR chemistry of the MycoSEQ Rapid Detection kit is based on the detection of SYBR™ Green intercalating dye. Forward and reverse primer targeted sequence designs provide amplification specificity, while the SYBR Green dye binds to double-stranded amplicons to provide a fluorescent signal. This signal is captured and reported via multi-component analysis. Parameters used for data analysis include the C_t, melting temperature (T_m), and derivative value (DV). The MycoSEQ Plus Detection Kit uses a TaqMan™ probe-based approach. Amplification specificity is provided by forward and reverse primers along with a target sequence-specific probe. As the reaction proceeds, the probe is degraded to release the fluorescent reporter dye away from the quencher, thus providing a signal. This signal is converted into a C_t value, forming the basis for analyzing and reporting final MycoSEQ Plus Mycoplasma Detection assay results. The MycoSEQ Plus Detection assay leverages a unique multiplex design strategy, as well as Taqman chemistry, to allow consistent sensitivity across a wide number of species, further enabling reliable detection.

Both MycoSEQ and MycoSEQ Plus Detection Kits have been confirmed to facilitate performance suitable to meet regulatory guidance for lot release within the established assay workflow. Options are available for either manual or automated sample preparation with the Applied Biosystems™ PrepSEQ™ nucleic acid extraction kits to provide a flexible and scalable testing platform. MycoSEQ and MycoSEQ Plus Detection Kits have been extensively tested using both the Applied Biosystems™ QuantStudio™ 5 and 7500 FAST Real-Time PCR platforms. The Applied Biosystems™ AccuSEQ™ software is also available to provide automated presence/absence calling, easily generated reports, and to enable CFR Part 11 compliance.

Sample preparation before qPCR can be addressed with several options depending on throughput and other processing needs. Both MycoSEQ and MycoSEQ Plus Detection Kits work well with the well-established the Applied Biosystems PrepSEQ chemistry, which is available for manual or automated workflows. The Applied Biosystems™ AutoMate Express™ Nucleic Acid Extraction System is the recommended instrument for the MycoSEQ workflow, allowing up

to 13 extractions in a single run. PrepSEQ chemistry has been pre-aliquoted into ready-to-load cartridges, reducing sample preparation time and providing low variability between extractions.

The AccuSEQ Real-Time PCR detection software is designed for GMP labs, enabling 21 CFR Part 11 compliance, and offering security, audit, and e-signature capabilities. Dedicated templates for use with both the MycoSEQ and MycoSEQ Plus Detection Kits provide simple automated presence/absence calling. The software also provides access to basic data for run review. The MycoSEQ Plus Detection kit includes a discriminatory positive control (DPC), which may either be used directly in the qPCR reaction as a positive control to confirm plate performance, or spiked into the sample before nucleic acid extraction as an extraction level control. The DPC contains a DNA-containing sequence for the FAM probe, helping to ensure all components are performing well for detection. It also includes a sequence for the VIC probe that is unique to the DPC, enabling a differentiated control signal from true mycoplasma contamination. The MycoSEQ Plus Rapid Detection assay also includes an internal positive control (IPC) to provide a readout of PCR reaction performance across all reactions and enable the detection of possible PCR inhibition. The DNA for the DPC is made with a mycoplasma amplicon modified to have a melting temperature outside the normal range, which allows discrimination between true mycoplasma and accidental contamination. This can be used as a surrogate for mycoplasma DNA during method qualification and enables simple extraction and control spiking of the test samples.

Confirmation of the detection sensitivity is a required performance attribute for a mycoplasma test used in lot release decisions. Mycoplasma testing is a threshold test, meaning that results are reported as either present or absent based on a specified level of detection. In this case, the threshold is 10 GC/mL of starting material with expected detection <95%. Mycoplasma genomic DNA from various species was spiked into a cell culture matrix background comprised of T cell spent media with T cells present, then processed as a sample. The final concentration of genomic DNA in the sample matrix is 10 GC/mL, and positive results were achieved for all species tested.

Another important test parameter is specificity. A mycoplasma test should not detect non-mycoplasma bacterial species per regulatory guidelines and should not detect possible bioproduction workflow contaminants to help ensure accurate results. When related bacteria have been tested using the MycoSEQ Plus Rapid Detection Kit, no false positives have been observed. The same is true for materials that may have residual amounts present from normal bioprocessing, such as human genomic DNA or lentivirus.

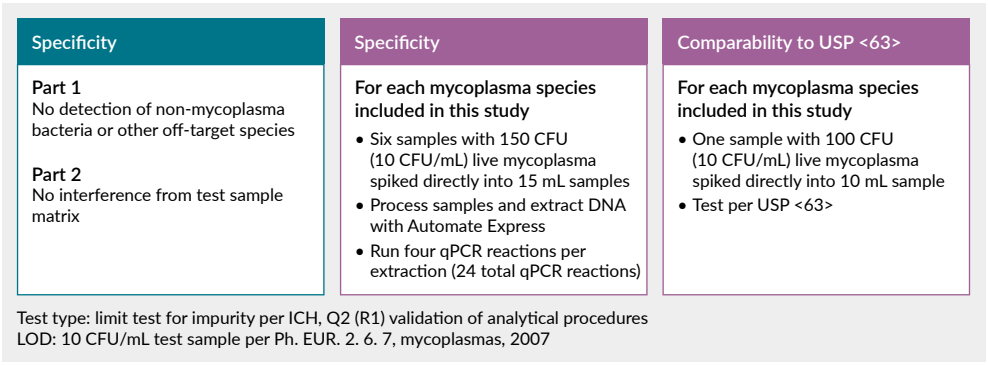
THE MYCOSEQ RAPID DETECTION KIT COMPARABILITY STUDY

A comparability study was designed to evaluate seven mycoplasma species. Seven samples were recovered from a test sample matrix—a CHO Bioreactor Bulk Rituximab Clarified Harvest sample—and prepared by spiking mycoplasma at 10 CFU/mL. This sample matrix was chosen as traditionally, modern CHO manufacturing processes are run at high cell densities and harvested at low cell viability, making for a challenging test sample matrix.

Six of the samples were processed and tested with the MycoSEQ and MycoSEQ Plus Rapid Detection assay as follows: following a low-speed spin to remove any potential cellular debris, the supernatant was treated with DNase/RNase and Proteinase K (this step was eliminated for MycoSEQ Plus); the mycoplasma was then recovered by high-speed centrifugation; following this, the mycoplasma pellet was re-suspended and DNA extracted with the AutoMate Express; and finally, four replicate qPCR reactions were analyzed to

FIGURE 2

MycoSEQ™ comparability validation study plan.



yield 24 total results per species. Concurrently, one sample was tested with the *USP* <63> mycoplasma cell culture test.

The *USP* <63> mycoplasma compendial method is carried out using a sufficient number of both solid and liquid media to help ensure the growth of present mycoplasmas in the chosen incubation conditions. The test also has an indicator cell culture method arm in which mycoplasmas are detected by their characteristic particulate or filamentous pattern under a microscope. The test sample is positive for mycoplasma if either arm of the test is positive for mycoplasma.

The study contained three arms to enable comparability for all three methods - the compendial method, the MycoSEQ kit for LOD, and the MycoSEQ Plus kit for LOD—and used the same test sample and mycoplasma stocks. These stocks were prepared either by American Type Culture Collection (ATCC) or Bionique testing labs. The validation study plan is further detailed in **Figure 2**.

The results for the MycoSEQ arm of the study are shown in **Table 1**. For all of the seven mycoplasma species tested, 100% positivity was achieved in the 24 test replicates for each species.

Results from the comparability study that utilized the MycoSEQ Plus Rapid Detection assay are shown in **Table 2**. Again, for all seven mycoplasma species tested, 100% of the 24 replicates for each species were positive for mycoplasma. A spike verification test before the LOD testing for each diluted mycoplasma stock was performed. With the MycoSEQ Plus Kit protocol, both *Mycoplasma pneumonia* and *Mycoplasma fermentans* showed evidence of excess GC to CFU. To compensate for that and avoid bias, for *M. pneumonia*, the spike amount was adjusted to 1 CFU/mL and for *M. fermentans*, the spike amount was adjusted to 2–3 CFU/mL. This is a known issue with mycoplasma stocks.

The comparability testing results for *USP* <63> are shown in **Table 3**. Results were comparable, indicating that this comparability study can be performed to assess performance between *USP* <63>, MycoSEQ, and MycoSEQ Plus Rapid Detection System methods.

Mycoplasma salivarium and *Mycoplasma orale* were not detected in the Indicator Cell Arm of the *USP* <63> test, demonstrating a risk of a potential false negative result with the *USP* <63> tests, especially if the mycoplasmas do not either propagate in culture or produce colonies on the agar plate. The indicator cell test is added to the *USP* <63> test to enable the detection of mycoplasma species that are not culturable or do not produce colonies on agar. Furthermore, the *USP* <63> mycoplasma test can be affected by the test sample matrix. For previous compatibilities conducted as part of customer validation studies, data indicates that some mycoplasma species or strains are not detectable in the *USP* <63> test and that this is sample matrix dependent.

TABLE 1

Summary of LOD results: MycoSEQ.

Mycoplasma species (type strain)	Total number tests/ positive reactions	% Positive	Mean Ct (n=24)	SD	CV (%)
Mycoplasma arginini 23206-TTR	24/24	100	30.42	0.32	1.1
Mycoplasma pneumoniae 15531-TTR	24/24	100	30.99	0.18	0.6
Mycoplasma hyorhinis BTS7^{T}	24/24	100	33.28	0.23	0.7
Mycoplasma fermentans 19989-TTR	24/24	100	29.28	0.11	0.4
Acholeplasma laidlawii 23206-TTR	24/24	100	31.64	0.25	0.8
Mycoplasma orale 15531-TTR	24/24	100	34.24	0.14	0.4
Mycoplasma salivarium 23064	24/24	100	31.73	0.19	0.6

Live mycoplasma, 10 CFU/mL LOD using 15 mL test sample, AME extraction.
All strains were procured from ATCC except for *M. hyorhinis* BTS7^{T} that was supplied by Bionique.

TABLE 2

Summary of LOD results: MycoSEQ™ Plus.

Mycoplasma species (type strain)	Total number tests/ positive reactions	% Positive	Mean Ct (n=24)	SD	CV (%)
Mycoplasma arginini 23206-TTR	24/24	100	31.81	1.09	3.4
Mycoplasma pneumoniae 15531-TTR	24/24	100	31.81	1.06	3.3
Mycoplasma hyorhinis BTS7^{T}	24/24	100	34.10	1.08	3.2
Mycoplasma fermentans 19989-TTR	24/24	100	32.01	1.05	3.3
Acholeplasma laidlawii 23206-TTR	24/24	100	32.35	**0.94**	**2.9**
Mycoplasma orale 15531-TTR	24/24	100	34.00	1.00	3.0
Mycoplasma salivarium 23064	24/24	100	32.72	1.09	3.3

Live mycoplasma, 10 CFU/mL LOD* using 15 mL test sample, AME extraction.
All strains were procured from ATCC except for *M. hyorhinis* BTS7^{T} that was supplied by Bionique.

TABLE 3

Comparability study: *USP* <63>.

Mycoplasma species (type strain)	Source	Overall *USP* <63> results	Culture test arm	Indicator cell arm
Acholeplasma laidlawii PG8	ATCC 23206-TTR	+	+	+
Mycoplasma arginini G230	ATCC 23838–TTR	+	+	+
Mycoplasma fermentans PG18	ATCC 19989-TTR	+	+	+
Mycoplasma hyorhinis BTS7	Bionique	+	+	+
Mycoplasma orale CH19299	ATCC 23714-TTR™	+	+	-
Mycoplasma pneumoniae FH	ATCC 15531-TTR	+	+	+
Mycoplasma salivarium PG20	Bionique	+	+	-

RAPID STERILITY TESTING

The cornerstone of any cell therapy manufacturing process is the assurance of product safety. Sterility testing safeguards patient safety, helps maintain the quality and efficacy of the therapy, and supports regulatory compliance. Challenges facing cell therapy sterility testing include low production volumes, short product shelf-life, and the fact that terminal sterilization is not possible for living therapies.

Within regulatory guidelines for cell therapy products, *USP* <1071> can be referred to for specifics concerning the test sample size, LOD, specificity, etc. To overcome the challenges facing sterility testing, the Applied Biosystems™ SteriSEQ™ Rapid Sterility Testing Kit was designed as an Applied Biosystems TaqMan-based qPCR assay to

TABLE 4

Monitoring *Mycoplasma arginini* growth and viability using qPCR with the MycoSEQ Detection Kit.

Day	Hours	Positive/negative	Ct	GC/Rxn	T_m (°C)	Derivative
1	0	Low level positive	35.9	~1	79.6	0.06
	4	Low level positive	35.9	~1	79.9	0.05
	8	Low level positive	36.5	~1	79.6	0.06
2	24	Positive	32.0	~8	79.6	0.10
	28	Positive	31.2	~16	79.6	0.12
	32	Positive	28.4	~100	79.4	0.14
3	48	Positive	21.4	~10,000	79.6	0.14
	52	Positive	21.9	~10,000	79.6	0.13
	56	Positive	21.7	~10,000	79.6	0.14

determine the presence or absence of bacteria and fungi. This kit can provide a result within 5 hours. Specificity is achieved from probes and primers designed for the 16S region for bacteria or the 18S region for fungi. The microbial coverage is over 16,000 bacterial species and 2,600 fungi species. This kit can also work with up to one million cells and does not exhibit cross-reactivity to expected in-process cell byproducts.

Integrated controls can help to reduce false positives and confirm consistent performance. This kit also has an IPC, a DPC, and a reference dye. Leveraging the integrated controls helps to enable increased accuracy and consistent performance across the testing plate.

Sterility testing guidelines recommend multiple test points as part of the risk mitigation approach. Testing the raw materials and at additional in-process points and lot release can detect a potential contamination event sooner and increase confidence in the final product.

Rapid testing enables immediate detection in response to a potential contamination event. Table 4 presents an example of how qPCR testing can be used to determine the viability of an active culture. While this example uses mycoplasma, the concept also applies to qPCR testing for sterility testing purposes. In this case, *Mycoplasma arginini* was inoculated into CHO culture and samples were tested at various timepoints using the MycoSEQ Rapid Detection Kit. DNA levels in the samples were estimated by comparing the Ct values determined with the MycoSEQ Rapid Detection kit, to a standard curve was generated from the qPCR analysis of purified *M. arginini* DNA. The decrease in Ct values at later time points indicate increases in DNA levels from replicating cells. This dataset highlights the ability of qPCR to assess viability of organisms utilizing its quantitative ability.

The SteriSEQ workflow begins with a sample preparation step to extract DNA from the sample. Then, qPCR reactions are set up and run using either the QuantStudio 5 or 7500 Fast Real-Time PCR System. Results are analyzed using the AccuSEQ software to generate a report with the presence/absence calling for samples.

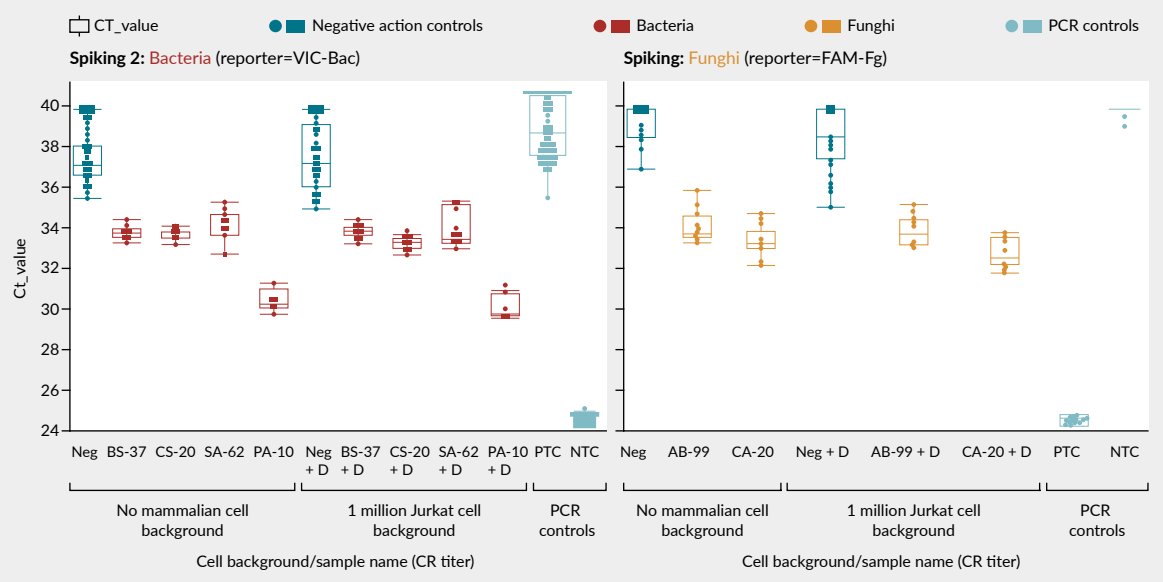
Figure 3 shows the results of an evaluation performed using several bacterial and fungal species, either without background or spiked into a 10^6 Jurkat cell background. Species were detected within the LOD range. The SteriSEQ Rapid Sterility Testing kit was compatible with cell culture matrices containing 10^6 mammalian cells.

SUMMARY

The MycoSEQ and MycoSEQ Plus Mycoplasma Detection Kits deliver same-day actionable results from a variety of starting sample types, including cell banks or bioreactors, raw materials, in-process samples, or lot release samples. These methods enable validation per the guidance from multiple pharmacopeias to help ensure regulatory compliance of the final product. They offer

FIGURE 3

LOD evaluation of the six microbial species in *USP* <71>.



a straightforward and validated qPCR workflow as part of a complete sample-to-answer solution.

The SteriSEQ Rapid Sterility Testing Kit can test for both bacterial and fungal contamination in a single well, delivering results within five hours. The kit optimizes the use of sample volume to facilitate preservation of the final product. It offers a simple, established qPCR workflow with optimized data analysis that aligns with additional analytical testing to minimize training requirements.

Q&A

Sharon Rouw and Mike Brewer

Q Can you test both the supernatant and cells for mycoplasma using your sample preparation protocol?

MB: Yes, you can test both. The regulatory guidance for CAR-Ts does specify both supernatant and cells should be evaluated. We have protocols that allow you to test both mycoplasma in the supernatant and any potential cell-associated mycoplasma. Our protocol is designed to preserve the maximum amount of modified CAR-T cells to be used in the final dosage form.

Q Is there DMF available for MycoSEQ Plus?

SR: There are DMF available for both MycoSEQ Rapid Detection kits. The MycoSEQ Plus Rapid Detection Kit has recently been placed on file with the FDA for review. Our field teams can help you request an authorization letter for your reviewer to gain access.

Q Do you use the same sample preparation method for both MycoSEQ and SteriSEQ Rapid Detection kits?

MB: We use different sample preparation methods for each assay. The primary reason is that mycoplasma are small and so can be easily lysed and the chemical component of the PrepSEQ kit is sufficient. However, bacterial and fungal testing of cell culture is difficult as the lysis requires a mechanical component to help ensure DNA extraction from difficult species such as fungi and other types of bacterial spores. Typically, you would process the whole sample including the mammalian cells for the SteriSEQ assay.

Q Do you need live mycoplasma for the MycoSEQ Rapid Mycoplasma Detection kit?

SR: You do not need to test with live mycoplasma. The kit uses DNA as the analyte, meaning you can use purified genomic DNA. You may also use live mycoplasma or inactivated mycoplasma as they all contain the requisite genomic DNA for testing.

Q What have regulatory agencies said about not using live mycoplasma as part of a matrix validation?

MB: We've had LOD validations accepted that use pure DNA only, a combination of two separate arms with live mycoplasma and purified DNA, and with live mycoplasma only. Critically, we have seen some pushback in regulatory reviews if validating with live mycoplasma stocks, so you must demonstrate that the C_t values are consistent within the range of

approximately 10 GC of mycoplasma DNA in the analysis. We have seen pushback from the regulators when C_t values have dropped significantly below the expected value, indicating an excess of GC to CFU in the mycoplasma stock. Many labs are not able to use live mycoplasma for their validation. As mycoplasma DNA is the analyte detected with the qPCR test, it is acceptable to use purified DNA for LOD validation.

Q Can we leverage this data for using the KingFisher™ for our extraction step?

SR: The team did some testing and development with the Applied Biosystems KingFisher Purification System We found that the workflow using KingFisher System was also able to meet the needed LOD for the mycoplasma species tested.

Q With the development of MycoSEQ Plus and its improvements on the current MycoSEQ kits, are there any plans to phase out the original MycoSEQ kit in the future?

SR: There are no current plans to phase out the original kit. The MycoSEQ Detection Kit is a great solution that many people are using. We intend to continue to support both products moving forward.

Q Am I correct in thinking that the rapid sterility test cannot replace the *USP* <71> sterility test?

MB: Currently, the rapid test cannot be used as an alternative to the traditional culture-based or growth-based sterility test. In the future, given the guidance in *USP* <1071> and following appropriate validation and demonstration of a high level of sensitivity, it may be possible to replace a culture or growth-based sterility test with the qPCR-based test.

Q Can you test mycoplasma directly from the frozen vial?

MB: This depends on the concentration of mycoplasma in the frozen vial. If it is at a high concentration, which is typical of the stocks obtained from culture collections such as ATCC, you can perform a simple dilution and direct qPCR analysis without any sample prep.

BIOGRAPHIES

MICHAEL BREWER is the Director, Global Principal Consultant, Regulatory for the BioProduction Group (BPG) at Thermo Fisher Scientific, Bedford, MA, USA. In this role, Michael is responsible for providing global support to BioProduction customers and serving as the regulatory thought leader and expert across all technology areas within BPD. Prior to moving to this role, he led the Pharma Analytics business, a team responsible for development and commercialization of testing applications for microbiology, analytical sciences and quality control. The products are fully integrated solutions for glycan profiling, bacterial and fungal identification, mycoplasma and viral detection, and host cell DNA and protein quantitation. Michael has over 30 years of experience in the biopharma industry, including, Scios, Synergen and Amgen in a variety of roles including discovery research, analytical sciences and quality control. Prior to joining Thermo Fisher Scientific, he led a group at Amgen that developed qualified, validated and implemented molecular methods for host cell DNA quantitation, contaminant (mycoplasma, virus, and bacteria) detection, contaminant identification, strain typing, and genotypic verification of production cell lines. Additionally, his group supported regulatory submissions including IND, NDA, and CMC updates, regulatory inspections, NC/CAPA investigations, contamination investigations and remediation, and developed regulatory strategy for implementation of new methods.

SHARON ROUW is a Senior Product Manager with the BioProduction Group (BPG) at Thermo Fisher Scientific. She is part of the Pharma Analytics business, a team responsible for development and commercialization of testing applications for microbiology, analytical sciences, and quality control. The products are fully integrated solutions for bacterial and fungal identification, mycoplasma and viral detection, and host cell DNA and protein quantitation. In this role, Sharon is responsible for managing the MycoSEQ Mycoplasma Detection products used by BioProduction customers worldwide. Sharon has over 20 years of experience across the biopharma, pharma, and life science industries. Prior to joining Thermo Fisher Scientific, she served in a variety of roles including product management, marketing management, and R&D for companies such as MilliporeSigma, Integrated DNA Technologies and Pfizer. Sharon holds a master's degree in cell and molecular biology and an MBA from the Washington University, St Louis, MO, USA.

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AUTHORSHIP & CONFLICT OF INTEREST

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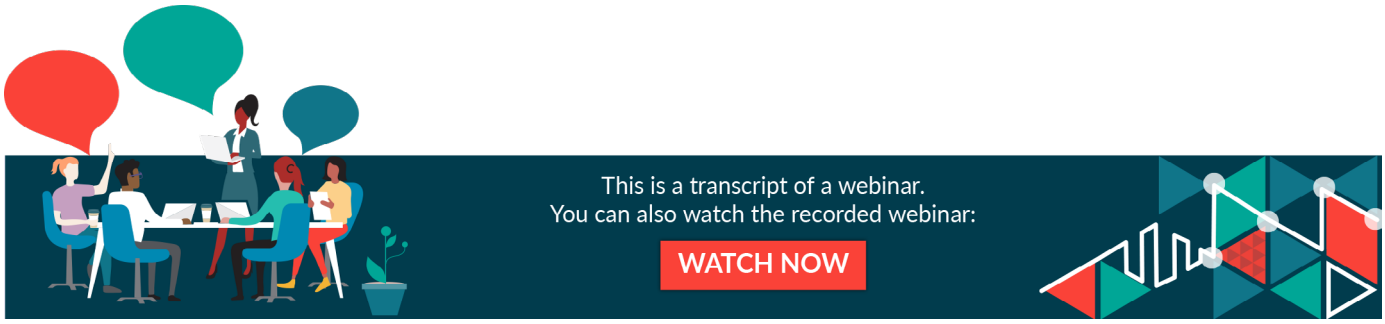

The way forward in mycoplasma detection.

A proven, regulatory-accepted method for QA/QC and lot-release testing

The Applied Biosystems™ MycoSEQ™ Mycoplasma Detection Kit is designed to meet or exceed regulatory guidance for mycoplasma detection. The kit integrates real-time PCR assays, instruments, and software, and is optimized with Applied Biosystems™ PrepSEQ™ sample preparation reagents to deliver same-day, actionable results that can detect mycoplasma early.

Find out more at **thermofisher.com/mycoseq**

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