# Rapid Mycoplasma Testing Method for Lot-Release of Biotherapeutics

MycoSEQ™ Mycoplasma Detection System from Thermo Fisher Scientific

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# Rapid Mycoplasma Testing Method for Lot-Release of Biotherapeutics

**Regulators require that the cell culture-based bioprocesses used for manufacturing of protein therapeutics, vaccines, and cell and gene therapy products be tested to ensure they are mycoplasma-free. Traditionally, testing was done using a culture-based, 28-day mycoplasma test. More recently, PCR-based alternatives have evolved, driven by an industry move to shorten lot disposition cycles and the emergence of cell-based therapeutics that require a more rapid test. Recent regulatory guidance allows manufacturers to select rapid tests – as long as they are validated to demonstrate sensitivity and specificity that are comparable to or that improve upon traditional tests. The big question: how should manufacturers respond?**

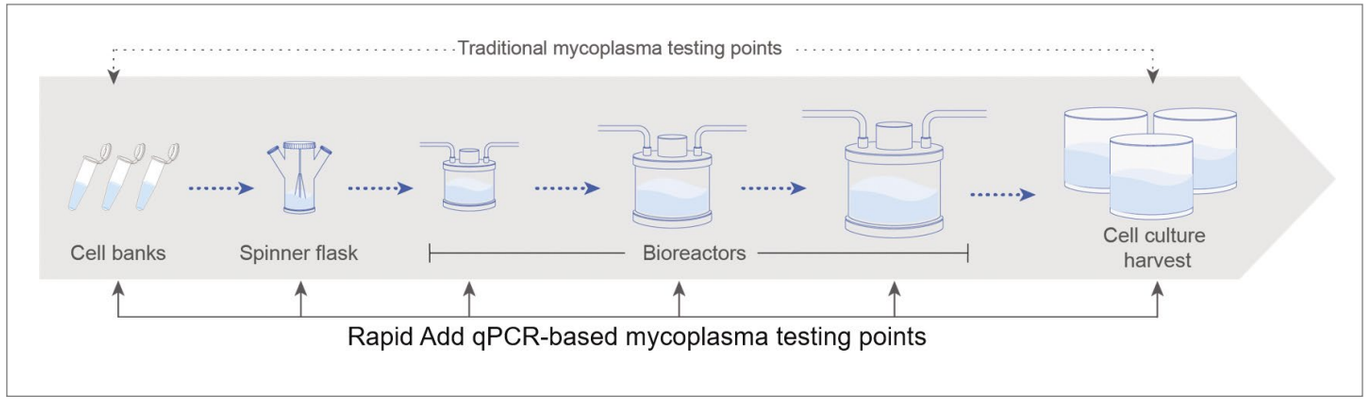


Figure 1. Rapid qPCR testing permits sampling, testing and decision-making throughout the bioprocess. Traditional testing methods are limited to analysis of samples from the beginning and end of the bioprocess, and therefore cannot provide actionable information regarding quality parameters at intermediate process stages. By contrast, rapid PCR-based tests allow repeated, real-time analysis throughout the process.

Mycoplasma contamination of manufacturing cell cultures is rare, but presents a threat for biologics manufacturers. Contamination sources can include raw materials used in the manufacturing of cell culture media, media supplements (especially if they are not animal origin-free), manufacturing personnel, and even the donors of cells used for cellular therapy products. Steps can be taken to reduce risk, but there have been reports of mycoplasma breaching sterile filtration processes, likely due to their deformability and unusually small size. And once in the cell culture environment, these bacteria can thrive without visible signs, enabling them to persist undetected for significant periods.

The impact of an undetected mycoplasma contamination can be extreme, starting with rejection of the contaminated lot and potentially other lots associated with shared equipment and raw materials. Other consequences include cell culture plant shutdown, time-consuming investigations into how the infection occurred, and costly corrective and preventive actions, such as decontamination operations and intensive testing to confirm mycoplasma eradication. Clearly, timely mycoplasma detection systems are essential to ensure safe and efficient biologics manufacture.

## Seeking assurance in a changing environment

Recognition of the issue resulted in regulations to guide detection of mycoplasma in bioprocesses. Early guidelines stipulated application of mycoplasma tests based on lengthy culture, particularly the broth culture followed by plating on agar method (1). This test – originally developed from a modification of a research tool developed by biologists studying mycoplasma – was hardly cutting-edge, but by default became the standard method. Today, it is recognized to have significant drawbacks:

- Time-consuming – a negative result requires a minimum of 28 days culture, which delays lot-release and prevents prompt response to contamination events
- Laborious – specific expertise in handling live mycoplasma is required
- Expensive – typically, companies must outsource the test to a specialist service provider
- Imperfect – false negatives may arise if a mycoplasma bacterium fails to give rise to a colony on the agar plate; false positives may occur if the positive controls contaminate the test sample

The shortcomings of culture-based tests have become more acutely exposed as the pharmaceutical industry has evolved; the introduction of advanced therapeutics, such as autologous cell therapies, has had a particular impact. For example, a CAR-T therapy production cycle – from harvesting of patient cells, genetic modification and ex vivo expansion to reinjection – requires only five to seven days. Clearly, this is incompatible with a 28-day test. Furthermore, cell therapies don't undergo the traditional viral inactivation and viral clearance steps that are required during purification of biologics manufactured in cell culture – steps that presumably would also inactivate any mycoplasma contamination that had been undetected in the cell culture. Evidently, sensitive and specific mycoplasma tests are essential to minimize or eliminate risk to patients from contamination that could occur during ex vivo manipulation and cell expansion. Thus, the emergence of cell and gene therapy products, and their need for rapid mycoplasma assays, has had a clear influence on regulatory acceptance of rapid methods (see "Evolving Regulatory Guidance: From 28-day Culture to 6-hour PCR").

A sign of increasing regulatory enthusiasm for rapid tests came in July of 2008, when the US Food and Drug Administration (FDA) convened a public workshop entitled "Rapid Methods for Detecting Mycoplasma

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Contamination in the Manufacture of Vaccines, Including Pandemic Influenza Vaccines, and Other Biological Products." Discussions with industry and regulatory experts at that workshop framed expectations on the desired attributes of rapid mycoplasma tests and provided some guidance as to how a rapid nucleic acid-based test could be validated (2).

Manufacturers have responded by developing increasingly sophisticated rapid nucleic acid-based tests. Such tests have advantages beyond lot-release testing to ensure product safety – they also enable effective risk mitigation (see Figure 1). Rapid testing permits in-process analysis at each step in the bioprocess, which means that manufacturing can be interrupted as early as possible if a contamination is detected, thereby preventing downstream propagation of the mycoplasma and consequent escalation of the problem. Additionally, negative results from in-process testing can enable conditional release of bioreactor harvests for downstream processing while the traditional culture-based tests are in progress – especially combined with in-process testing for mouse minute virus in CHO cell-based processes.

### Essence of a compliant test

Regulators are now clear that PCR-based tests can be acceptable alternatives to the 28-day culture-based test, provided appropriate sensitivity and specificity are demonstrated in validation. But what should manufacturers look for in a nucleic acid-based test?

In 2007, the European Pharmacopoeia released guidance on performance expectations and validation of nucleic acid-based mycoplasma detection methods (3). The guidance on sensitivity is 10 colony forming units (CFU) or genome copies (GC)/mL of test sample. Since then, that has been the limit of detection (LOD) target that is generally applied when the goal is to replace the use of the 28-day test. The expectation on specificity is that a test for mycoplasma should not detect non-mycoplasma species. That is critical in ensuring a positive result is definitely from mycoplasma and, given the ubiquity of non-mycoplasma bacterial DNA in the raw materials used for cell culture, this is an essential attribute. Another component of specificity that is sometimes overlooked is the ability of the method to detect mycoplasma after recovery from test sample matrices. A final expectation for an ideal rapid test is that it should be robust – that is, able to maintain performance despite test conditions that deviate from typical testing protocols and procedures.

One test that meets these criteria is the Applied Biosystems™ MycoSEQ™ Mycoplasma Detection Kit from Thermo Fisher Scientific (see "MycoSEQ™ assay:"). The assay has demonstrated sensitivity that meets or exceeds the sensitivity guidance of the European Pharmacopoeia. For specificity, the qPCR primers were designed to exclude detection of non-mycoplasma species and this capability has been demonstrated in multiple studies. Additionally, when combined with the PrepSEQ™-based sample preparation protocols – which incorporate background reduction and highly efficient nucleic acid extraction and purification – sensitivity and specificity are achieved from a variety of test sample matrices typically tested for mycoplasma. And finally, robustness: during the development of the MycoSEQ assay, robustness was confirmed by completion of a multi-variant design of experiments (DOE) to assess the impact of deliberate variations of experimental conditions. In fact, multiple customer studies have validated application of the MycoSEQ assay at a LOD of at least as sensitive as 10 GC or CFU/mL test sample (or both). Assay sensitivity of 1–3 GC per PCR reaction is well established and when combined with our protocol for lot-release testing, which tests the equivalent of 1 mL test sample per qPCR reaction, enables meeting or exceeding the European Pharmacopoeia guidance of 10 GC or CFU/mL.

### Evolving Regulatory Guidance: From 28-day Culture to 6-hour PCR

- **1978** (1) FDA's 21 CFR 610.30 specifies use of agar media/semisolid broth media, under both aerobic and anaerobic conditions, in conjunction with control cultures of at least two known strains of mycoplasma, to test for mycoplasma contamination.
- **1987/1993** (4) FDA "Points to consider" document: "Each biological product produced in cell substrates [...] must be tested to ensure the absence of mycoplasmal contamination [...] by [...] the agar and broth media procedure [...] or by a procedure demonstrated to be comparable."
- **2007** (3) European Pharmacopoeia guidance sets LOD of 10 colony forming units (CFU) or genome copies (GC)/mL of test sample.
- **2008** (5) FDA's CMC guidance: "Due to the limited dating period of many cellular products, it is frequently not feasible for a sponsor to perform the recommended culture-based assay for release testing. In those cases, we recommend the use of PCR-based mycoplasma assays or another rapid detection assay during product development. As part of your BLA, you should submit appropriate data to demonstrate that the PCR or alternative test has adequate sensitivity and specificity."
- **2012** (6) US Pharmacopeia (Chapter 63): "A validated nucleic acid amplification technique [...] or an enzymatic activity-based method may be used [...] provided such a method is shown to be comparable to [the agar/broth method]. Alternative methods must be suitably validated."
- **2018** (7) PCR-based rapid mycoplasma testing method is now accepted by regulators for QA/QC and lot-release
- **2020** (8) FDA final rule:"The FDA is issuing a final rule to remove the specified test for the presence of Mycoplasma for live virus vaccines and inactivated virus vaccines produced from in vitro living cell cultures. The rule is being finalized because the existing test for Mycoplasma is overly restrictive in that it identifies only one test method in detail to be used even though other methods also may be appropriate. More sensitive and specific methods exist and are currently being practiced, and removal of the specific method to test for Mycoplasma provides flexibility for accommodating new and evolving technology and capabilities without diminishing public health protections."
- **2020** (9) FDA CMC Guidance: "Analytical procedures different from those outlined in the US Pharmacopeia, FDA Guidance or CFR may be acceptable under an IND if you provide adequate information about your test method, including specificity, sensitivity and robustness. Examples of alternative methods, which may be needed for live cells, include [...] rapid mycoplasma tests (including PCR-based tests) [...] For these non-compendial tests we recommend that you qualify/validate them to ensure they are fit for their intended use."

| Product category | Number of approved products | Number of products in the process of validation and approval | Regulatory agency for approval |
|---|---|---|---|
| Cell/Gene therapy | 22 | 19 | EMA/FDA/PMDA/local agencies |
| Tissue therapy | 3 | | EMA/FDA/local agencies |
| Recombinant protein | 1 | 1 | EMA/FDA |
| Monoclonal antibodies | 5 | 6 | EMA/FDA |
| Vaccines | 3 | 4 | MFDS/local agencies |
| Contract Services / Others | 8 | 2 | Local agencies |
| **Total** | **42** | **32** | |

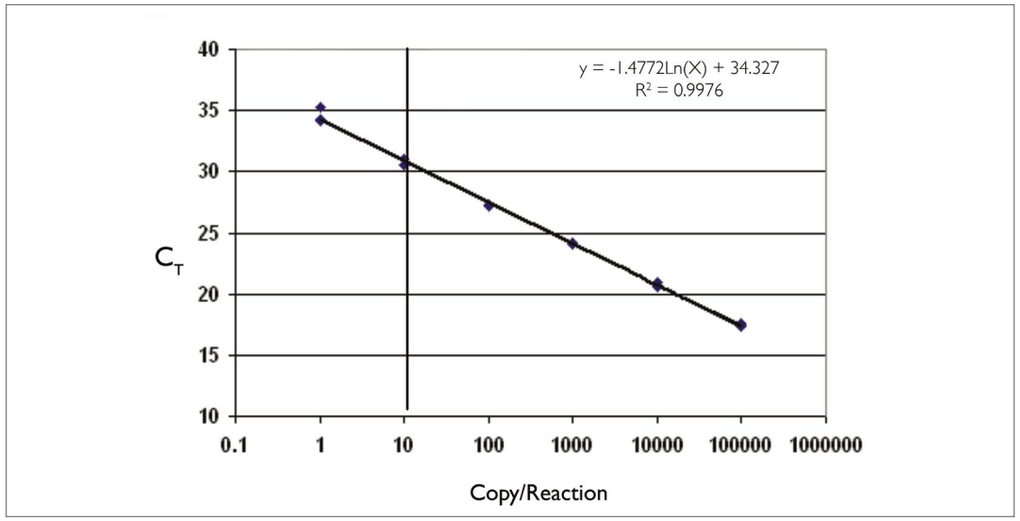


Figure 2. Lower limit of detection assessment using principles of qPCR. The MycoSEQ™ Ct values generated by assay of samples containing 10 GC or CFU / mL can be extrapolated to provide accurate values for the lower limit of detection. This is a consequence of highly accurate qPCR technology and the linear relationship between Ct value and GC number.

Regulatory guidelines (3) require validation of analytical methods used for testing the quality and safety of commercial products; thus, a rapid mycoplasma test must be validated, submitted for regulatory review and accepted prior to implementation into a commercial manufacturing process. Design and execution of a validation study can be challenging, so choosing a testing solution that is supported by a team with experience in design and execution of validation studies accepted by regulators can be a significant advantage.

For example, LOD validation using live mycoplasma stocks may require demonstration of a GC:CFU ratio that is low enough to provide assurance that the sensitivity of the PCR-based assay is not influenced by the presence of DNA from non-viable mycoplasma (that could not generate a CFU in viable titer testing).

Multiple variables may impact the GC:CFU ratio and therefore a well-characterized mycoplasma stock is recommended for LOD validation. For GC/CFU assessment, curves generated from MycoSEQ™ qPCR analysis of known amounts of purified, accurately quantitated mycoplasma DNA can be utilized for estimating the number of GC in mycoplasma stocks (see Figure 2).

### The future lies in rapid assays

Most biomanufacturers could benefit from rapid mycoplasma testing – either for in-process testing as a risk mitigation tool or for release testing to accelerate lot disposition cycles. For clinical-stage products, rapid test methods should be adopted early in development; it is easier to include a new method in the initial regulatory application than to change a method in an approved process.

Furthermore, manufacturers of approved biologics have often streamlined as many production processes as possible, leaving the 28-day test as the critical bottleneck. Switching to a rapid test removes this restriction

## Case Studies: MycoSEQ Assay in the Real World

**Case study #1: Octopharma AB (OAB) (10)**

The largest privately owned plasma fractionator in the world, Octapharma manufactures medicines in the form of human proteins sourced from human plasma and human cell lines; for example, Nuwiq human recombinant factor VIII.

The company tests two million samples of donor plasma annually by PCR. When implementing PCR-based testing, Octapharma scientists decided to assess the MycoSEQ Assay (Thermo Fisher Scientific) in preference to in-house assay development, partly because:

- many processes that used the MycoSEQ assay were being approved
- Thermo Fisher Scientific offered comprehensive support – training, instrument qualification services, assay optimization support, design of validation studies, support for regulatory submissions.

The MycoSEQ assay was validated for assessment of spent media in a continuous process (production of recombinant enzyme from HEK293 suspension culture), using:

- The Applied Biosystems™ PrepSEQ™ nucleic acid extraction kit;
- MagMax™ Express-96 magnetic particle processor now Pharma KingFisher™ Flex, (reduced hands-on time);
- Applied Biosystems™ 7500 Fast real-time PCR system;
- AccuSEQ™ 2 real-time PCR analytical software from Thermo Fisher Scientific (offers security, auditing and e-signature capabilities to meet 21 CFR Part 11 compliance; software permits automated mycoplasma detection.

**Preliminary work:** Assay development and optimization to ensure sensitivity of 10 GC (CFU)/mL as required by regulators; also optimized cell removal conditions, enzymatic digestion, extraction wash, elution volume and PCR annealing temperatures (Octapharma material and process required annealing temperature two degrees higher than normal).

**Timelines:** Four years from initial investigation to first regulatory submission (validation process: 3 months); facilitated by a large number of MycoSEQ assay users with regulatory approval worldwide, and by complementary data provided by Thermo Fisher Scientific (which supported Octapharma throughout this period).

**Validation methods**: Used DNA from A. laidlawii and M. arginini; tested material from 11 harvests with 18 separate extractions and 21 independent qPCR analyses

**Results:** Excellent! Met 10 CFU or GC/mL test sample requirement; validation package compiled and submitted to FDA, EMA, and Health Canada.

## MycoSEQ Assay User Tips from Octapharma

- Use pipetting robot; easier than the manual method, saves reagents, and prevents errors
- Optimize the method for a given process
- Ensure you understand the method
- Be aware of material availability for assay development and validation work
- Test many different harvests so that you collect data at different cell densities and viabilities.

LINKS

**Webinar**

*Bringing Rapid Mycoplasma Testing In-House to Expedite Lot-Release of Recombinant Protein Product*

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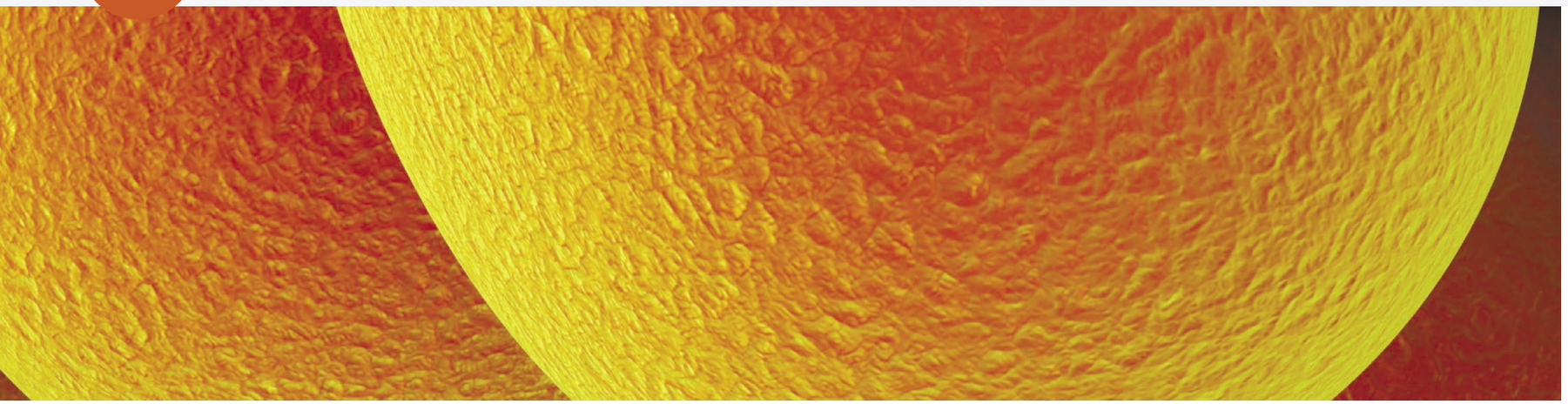

and improves production efficiency. There are also significant cost-savings: a qPCR test is ten-fold cheaper than the 28-day culture test on a cost per sample basis. In fact, the only barrier to rapid test adoption for most companies today is a lack of experience with the test.

### What are the key considerations for manufacturers who recognize the need to shift to a rapid assay?

Firstly, it may be better to buy a proven system than to attempt development de novo; the latter requires specialized expertise and significant time. Biopharmaceutical company Octapharma AB (OAB) (see "Case study #1: Octapharma") considered developing an in-house rapid test, but concluded it would be too onerous, requiring "definition of suitable instrumentation and development of several primer sets to cover the mycoplasma species stipulated by regulatory guidelines."

Secondly, not all rapid mycoplasma tests are acceptable to regulators at the NDA/BLA phase; the importance of selecting a testing solution that will be acceptable for use in commercial manufacturing processes cannot be overstated, and it is recommended to discuss this with both your supplier and regulators at an early stage.

Thirdly, think beyond the test itself. Who can you turn to when regulatory questions (see "Common Questions") are raised? Not all test providers offer the same level of support throughout the qualification, validation, regulatory submission and review processes. And that difference can be particularly important during validation study design and execution; here, as evident from case studies (see "Case Studies: the MycoSEQ assay in the Real World"), Thermo Fisher Scientific assists with training, sample preparation optimization, pre-validation and qualification studies, validation studies and general guidance on the regulatory path. Additionally, Thermo Fisher Scientific has a drug master file (DMF) in place with the FDA and Health Canada that contains the details on design, development and performance of the MycoSEQ assay. A letter of access to the DMF can be provided as part of regulatory submissions that include use of the MycoSEQ assay. This enables reviewers to access all details of the assay, including confidential information, during the review process. For jurisdictions that do not utilize the DMF process, regulatory support files can be provided directly to regulatory authorities to answer specific questions that may arise during review.

*References*


1. *FDA, "US Code of Federal Regulations, Title 21, Section 610.30: Test for Mycoplasma." Available at: http://bit.ly/36kGG9x.*
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3. *EU Pharmacopoiea 5.0 Chapter 2.6.7 Mycoplasmas (2007). Available at: https://bit.ly/3taUgGn.*
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11. *J Duguid, "Autologous cell therapy product release: US Approval of three rapid microbiological methods for MACI release," BioProcess International (2017). Available at: https://bit.ly/2MjLRQl.*


### Case study #2: Vericel Corporation (11)

Vericel manufactures autologous cell therapy products (Epicel skin grafts for burns; Carticel and MACI for cartilage repair). Autologous cell manufacture is prone to contamination; sources include: original biopsy, raw materials used in manufacture, and personnel executing a highly manual process involving many open manipulations. Furthermore, these products have very short shelf-lives, and therefore require mycoplasma testing within a day of manufacture – incompatible with the standard 28-day test

Accordingly, Vericel opted for the MycoSEQ™ rapid test, attributing their decision to a number of qualities of the assay:

- uses real-time PCR and Power SYBR Green detection technology
- straightforward work-flow: cell lysis; DNA extraction/purification; real-time PCR analysis
- automated sample preparation with Thermo Fisher Scientific's AutoMate *Express*™; reduces cost, and frees up operator time, maintains sensitivity equivalent to manual method
- straightforward data analysis: Ct≤36 and melt temperature of 75–81°C = positive; Ct>36 = negative
- fast: six hours!

**Results:** Validation studies demonstrated the MycoSEQ assay specificity and LOD equivalent to or better than standard method. The MycoSEQ assay detects mycoplasma at or below 1 CFU/mL, allowing it to register contamination spikes that the standard method does not).

**Commercial advantage:** MycoSEQ assay test time is 5-6 hours at a cost of hundreds of dollars per test. Outsourced culture testing requires 28 days at thousands of dollars per test. Vericel achieved regulatory approval to use the MycoSEQ assay in MACI production from both EMA (2013) and FDA (2016).

**Vericel's conclusions:** "Regulatory approval of the MycoSEQ assay for lot-release testing applications has permitted its use in cell culture, cell therapy, tissue therapy [...] Regulatory acceptance is becoming more straightforward as more companies implement [rapid] methods."

LINKS

**Video**
*Vericel case study*

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## The MycoSEQ Assay: Key Features

### Sensitive

- Lowest limit of detection: 1–3 GC/qPCR reaction.
- Protocols designed to reduce background and concentrate mycoplasma from range of samples: raw materials, media, serum, cells, tissues, and large volumes (bioreactor harvests).
- Applied BioSystems™ PrepSEQ™ magnetic bead system enables highly efficient nucleic acid recovery; use in either automated or manual mode.

### Specific

- Patented detection system based on multiple primers in a single PCR reaction.
- Detection of at least 140 *Mycoplasma* species, including the closely-related *Acholeplasma* and *Spiroplasma*, while excluding detection of off-target species, including bacterial, fungal and host cells.
- Patented discriminatory positive control: generates a signal unique to the control, which minimizes risk of false positive test results from accidental contamination of a test sample with positive control.

### Rapid

- Total test time is 5–6 h; standard method requires 28 days. Thus, the MycoSEQ assay accelerates production timelines for manufacturers of advanced biologics.

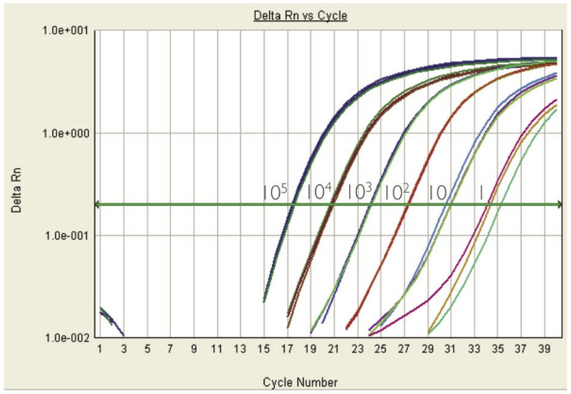
### Cost saving

- The MycoSEQ assay costs ~$300/test; outsourced testing by the standard method costs ~$4000/test. Thus the MycoSEQ assay costs less than methods of lower sensitivity, specificity and speed.

### Proven

- The MycoSEQ assay has more real-world regulatory acceptance for accelerated lot release protocols than any other PCR or qPCR-based mycoplasma detection test to date.
- Thermo Fisher Scientific has significant data to demonstrate that the MycoSEQ assay is highly robust. These data are detailed in a Drug Master File (DMF) in place with the FDA and Health Canada, and are available in a Regulatory Support File for jurisdictions that do not use the DMF process in support of regulatory submissions.

Analysis of a 10-fold dilution series of purified M. arginini DNA




Melt analysis at 1 GC/reaction

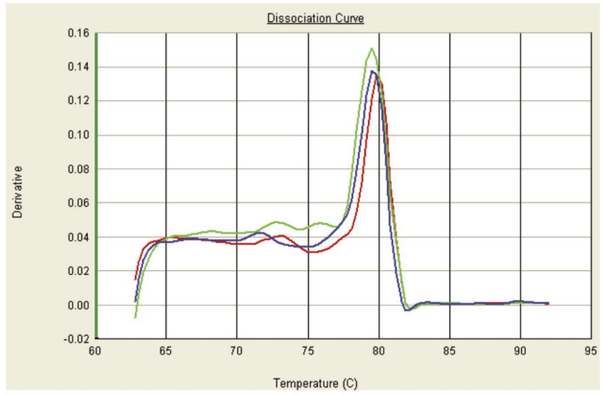



Figure 1. MycoSEQ assay sensitivity. Note that the MycoSEQ assay provides six orders of linear dynamic range, and an LOD of 1 GC per PCR reaction.

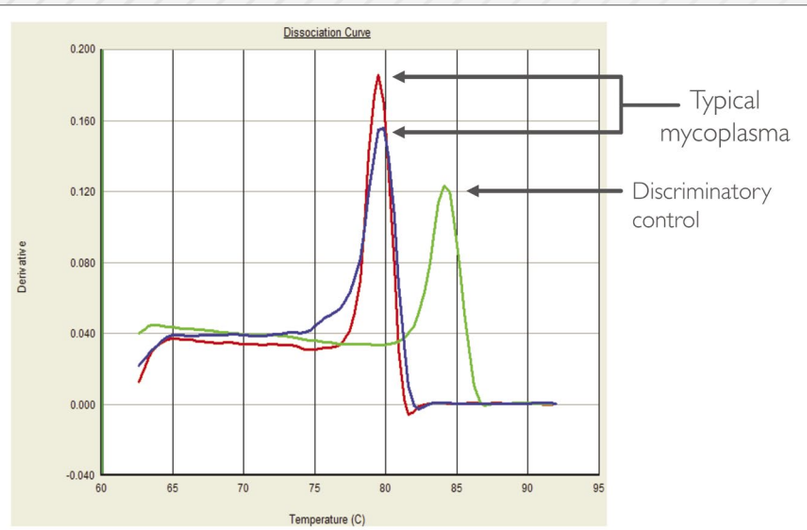
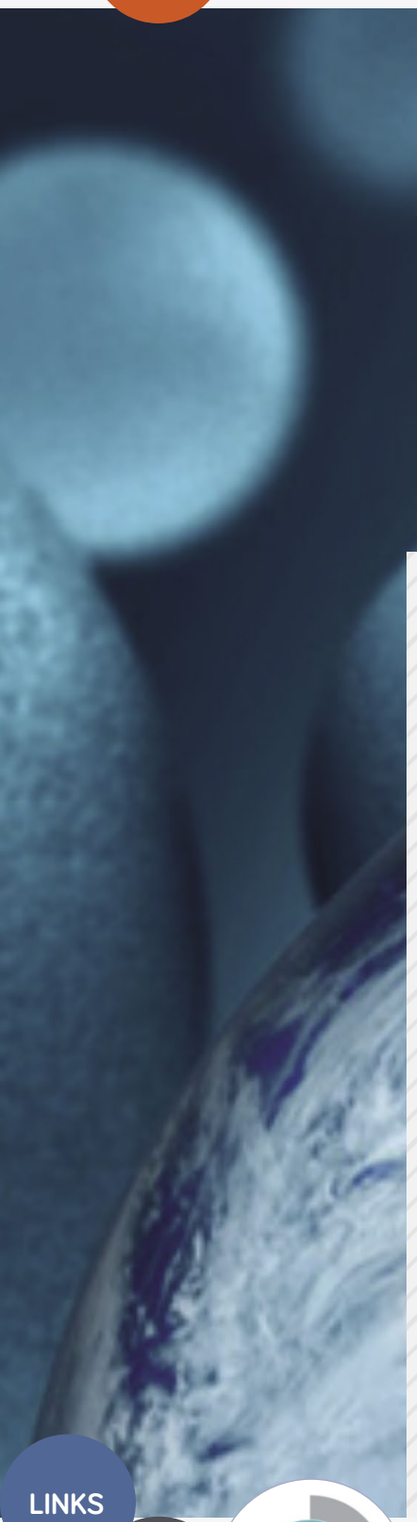



Figure 2. The MycoSEQ assay discriminatory positive control comprises a mycoplasma amplicon modified to have a melting temperature (Tm) outside the range of normal amplicons. This allows discrimination between natural mycoplasma DNA and accidental contamination with the positive control, thereby eliminating false positives.



## Common Questions

### Has the MycoSEQ assay been accepted by regulators for commercial lot-release testing?

Following validation, regulatory review, and acceptance, the MycoSEQ assay and method can be used for lot-release by manufacturers in different therapeutic modalities including biotherapeutics, cell and gene therapies, vaccines, and other cell-culture-based therapeutics.

### How should we validate the MycoSEQ assay sensitivity in a given bioprocess?

The team supporting the MycoSEQ assay has supported the design and execution of multiple validation studies and the subsequent regulatory reviews leading to acceptance of the MycoSEQ assay as the mycoplasma test for multiple therapeutic modalities. We encourage all customers to engage our team of experts to support the implementation and validation of the MycoSEQ assay for their specific processes.

### Regulatory guidance on robustness testing is not very detailed and testing in validation can be an open-ended process. What can you tell us about the robustness of the MycoSEQ assay?

We carried out extensive robustness testing during the development of the MycoSEQ assay. Robustness was confirmed by the completion of a multi-variant design of experiments (DOE) designed to assess the impact of deliberate variations of experimental conditions assessing multiple assay parameters. The details are included in the DMF on file with the FDA and Health Canada. For jurisdictions that do not use the DMF process, we can provide Regulatory Support Files to help answer questions on specific aspects of the robustness testing. Additionally, we can support design of experiments for customer validation studies in cases where it is appropriate to include robustness testing as part of qualification or validation.

### Can the MycoSEQ assay detect mycoplasma that may be associated with mammalian cells?

For some cell culture processes, there is an expectation that both free and potential mammalian cell-associated mycoplasma are tested for and detectable. We have helped customers with development, qualification, and validation of protocols that enable extraction and detection of mycoplasma from cell culture supernatant, concentrated mammalian cells, and a combination of both cells and supernatant. We work with customers to assess their specific cell culture process and design sample preparation and testing protocols that meet the regulatory expectations for the sample type and process.

### We test some samples immediately after receiving them in the lab, but we may store other samples prior to testing. What are your recommendations?

Samples can be stored at ambient temperature, refrigerated or frozen (followed by thawing) prior to testing. Our recommendation is that all sample storage options included in the customer's MycoSEQ™ method be evaluated either in qualification or validation to mitigate impacts on the performance of the method and that the expected LOD is achieved.

LINKS

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