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Rapid Mycoplasma Testing Method Now Accepted by Regulators for QA/QC and Lot Release

MycoSEQ Mycoplasma Detection Method can accelerate production timelines for manufacturers of cell and gene therapies, biotherapeutics, vaccines and other cell-culture-based modalities

BEDFORD, Mass., April 3, 2018 /PRNewswire/ -- Manufacturers of cell-culture-based therapeutics can now rely on a faster method for detecting mycoplasma contamination. The **Applied Biosystems MycoSEQ Mycoplasma Detection Kit** is a fully integrated solution for real-time PCR-based mycoplasma detection. Used throughout the bioproduction workflow, the MycoSEQ method is an alternative to costly, time-consuming culture-based tests often done externally by contract labs, which can take up to 28 days.

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.

To date, nine global manufacturers of therapies subject to U.S. Food and Drug Administration, European Medicines Agency and/or local regulatory agency review have received regulatory acceptance for accelerated lot release protocols that specify the Thermo Fisher Scientific MycoSEQ method.

"Rapid microbiological detection methods for product testing and release are critical for cell culture-based therapies with short shelf lives," said John Duguid, senior director of research and development at Vericel Corporation. "It also makes sense to adopt new, proven methods during product development and licensure to avoid the time and expense of validation after a therapy is actively being marketed to patients."

In late 2017, Thermo Fisher received two patents from The U.S. Patent and Trademark Office for its MycoSEQ real-time PCR-based mycoplasma detection assay. These patents cover the assay's proprietary multiplexed PCR primer approach and the discriminatory positive/extraction control, which are new innovations to real-time PCR that enable this rapid test for mycoplasma to meet the rigorous requirements of regulatory authorities and manufacturers.

"Patient safety is the highest priority for manufacturers of cell-culture-based therapies, and they go to considerable lengths to ensure that," said Michael Brewer, head of pharma analytics at Thermo Fisher. "With the MycoSEQ method, manufacturers can continue that vigilance without the extra time and expense associated with conventional culture-based methods that were, until recently, the only approved method for lot release. Now they have a new solution that brings patented innovations to their processes."

With its combination of optimized sample preparation and multiplexed real-time PCR based detection, the MycoSEQ assay can detect more than 90 mycoplasma species in under five hours, with well-documented sensitivity and specificity. This enables manufacturers to use it at multiple points in their process, from raw material acceptance to lot release, helping to ensure product quality and patient safety.

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