

# Rapid Molecular Methods for Pharmaceutical Manufacturing

Featuring MicroSEQ® Identification and Detection Systems

#### What's New

#### Introducing the ViralSEQ™ Vesivirus Detection Assay

Viral contamination in mammalian product manufacturing presents a serious risk to the manufacturing process, the manufacturing facility, and the integrity of the product. Vesivirus 2117 is an RNA virus that has emerged as a potential threat to mammalian cell culture production.

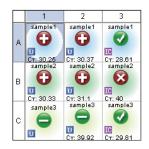


Applied Biosystems has developed the first commercially available integrated kit for isolation and detection of Vesivirus from mammalian cell culture samples.

- Sample prep solution with high recovery of RNA virus
- Detection of known Vesivirus strains
- Rapid time-to-results in less than 5 hours
- TaqMan® chemistry-based real-time PCR assay

## Introducing AccuSEQ $^{\mathbb{M}}$ Software: Mycoplasma and Custom Support for Residual DNA

The AccuSEQ™ Real-Time PCR Detection Software is part of a system that performs analytical testing for impurities and contaminants during the biopharmaceutical manufacturing process. Designed to work with the 7500 Fast Real-Time PCR instrument, the software supports the SEQ family of analytical detection and quantitation assays.



- Automated presence/absence calls for Mycoplasma detection
- Enables accurate quantitation of residual DNA in biological samples
- Single software platform for all current and future SEQ real-time PCR assays
- Helps enable 21 CFR Part 11 compliance

### 7500 FAST and AccuSEQ™ Software IQ/OQ Services

Quick and efficient instrument installation and operational qualification [IQ/OQ] of the real-time PCR instrument are critical to implement routine use of real-time PCR assays for contaminant and impurity analysis in pharmaceutical manufacturing. Now you can complete this critical step with confidence with the help of Applied Biosystems' 7500 FAST/ AccuSEQ™ Software Service and Training Programs.



- IQ/OQ Service—Helps laboratories overcome critical system qualification through a collaborative partnership with Applied Biosystems.
- Implementation & Training Programs—Covers laboratory design and workflow as well as additional training based on specific laboratory needs.
- User Workshops—Offered in various locations around the world, user workshops range from refresher courses to advanced user training.

For more information about these new products and services, contact us today at pharma@lifetech.com.

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#### SEQ Events

#### SEQ Rapid Molecular Methods Seminar

- February 23, Oxford, UK
- March 9, Seoul, Korea
- March 11, Kuala Lumpur, Malaysia
- March 16, Alsace, France

To find out more about our North American and International SEQ Events for 2010, email pharma@lifetech.com.

#### Upcoming Events Winter/Spring 2010

AP3 Journées de Microbiologie April 20–21, Tours, France

IBC Bioprocess International - Analytical Methods for Biologics May 19–20, Vienna, Austria

SFSTP - French Society of Pharmaceutical Science and Technology June 2–3, Montpelier, France

SFM - French Society for Microbiology June 2–4, Marseilles, France

