

ViralSEQ™ Vesivirus Detection Assay

Integrated sample preparation and real-time PCR assay for the detection of Vesivirus in cell culture samples

- Detection of known Vesivirus strains
- Rapid time-to-results in less than 5 hours
- TaqMan®-based real-time PCR assay
- Demonstrated sensitivity and specificity
- Proprietary optimized sample preparation for high RNA recovery

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 reemerged as a potential threat to mammalian cell culture production. To meet the challenge of rapid, specific, and sensitive detection of Vesivirus, Applied Biosystems has developed the first commercially available integrated kit for isolation and detection of Vesivirus from mammalian cell culture samples. The ViralSEQ™ Vesivirus Detection Assay is a PCR-based test that enables users to quickly isolate and detect Vesivirus 2117 and all other known strains with high sensitivity and specificity. The test utilizes PrepSEQ™ sample preparation magnetic beads to isolate viral RNA from a wide range of sample types, combined with TagMan®-based technology for sensitive and specific detection of the viral RNA. The kit also includes a proprietary positive control template that helps eliminate the possibility of false positive results arising from inadvertent contamination of test samples with the positive control.



Table 1. Exclusion Panel. The ViralSEQ[™] Vesivirus Detection Assay has been demonstrated to be specific for Vesivirus and does not detect RNA purified from related and unrelated species and organisms.

Bacillus	2.5 ng	Chicken	5 ng
Clostridium	2.5 ng	Dog	5 ng
E. coli	2.5 ng	Human	5 ng
Lactococcus	2.5 ng	MDCK	5 ng
Shigella	2.5 ng	Rat	5 ng
Yeast	5 ng	CH0	500 ng
		Human RNA	1 μg

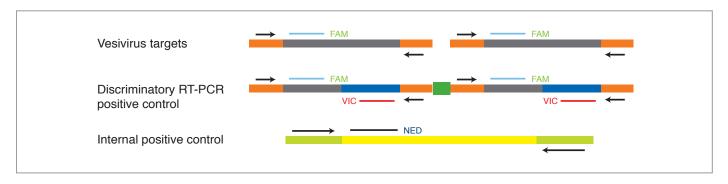


Figure 1. Multiplex Assay and Control Design. The ViralSEQ™ Vesivirus Assay's unique design includes two viral targets and discriminatory positive controls. This allows detection of known Vesivirus genomes. The discriminatory positive control helps monitor the real-time PCR reaction and cross-contamination of samples to reduce false positive results.

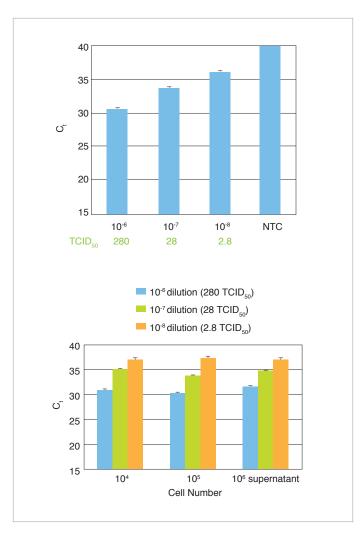


Figure 2. PrepSEQ $^{\text{TM}}$ 1-2-3 Sample Preparation Kit. Optimized for use with the ViralSEQ $^{\text{TM}}$ Vesivirus Assay, the sample preparation procedure allows detection of 2.8 TCID $_{50}$ in 100 μ L of cell culture and serum. In the above example, 10-6 to 10-8 dilutions of feline calicivirus (used as a surrogate for Vesivirus) were spiked into 100 μ L of fetal bovine serum (top panel) and cell culture (bottom panel). The serial dilutions of the virus correspond to TCID $_{50}$ of 280, 28, and 2.8.

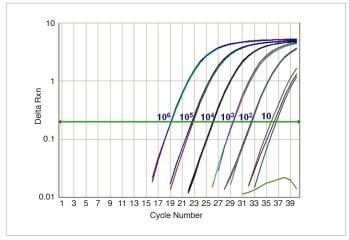


Figure 3. High Sensitivity and Broad Dynamic Range. The ViralSEQ $^{\text{TM}}$ Vesivirus Assay can detect from 10 4 down to 10 copies of *in vitro*-transcribed Vesivirus RNA per reaction.

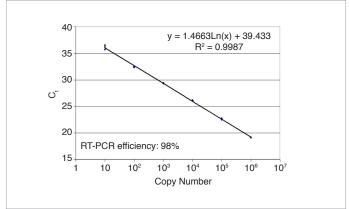


Figure 4. High PCR Efficiency. Using the viral RNA template, the ViralSEQ™ Vesivirus Assay demonstrated high real-time PCR efficiency and a broad linear detection range.

ORDERING INFORMATION

Description	Size	Part Number
ViralSEQ™ Vesivirus Detection Assay	100 rxns 4448398C	
Contains real-time PCR assay, buffer and enzyme mix, positive control & negative control PrepSEQTM 1-2-3 Nucleic Acid Extraction Kit		
Buffers, magnetic beads, and enzymes	100 rxns 4452222	

For Research Use Only. Not for use in diagnostic procedures.

Practice of the patented 5' Nuclease Process requires a license from Applied Biosystems. The purchase of TaqMan® Non-coding Assays includes an immunity from suit under patents specified in the product insert to use only the amount purchased for the purchaser's own internal research when used with the separate purchase of an Authorized 5' Nuclease Core Kit. No other patent rights are conveyed expressly, by implication, or by estoppel. For further information on purchasing licenses contact the Director of Licensing, Applied Biosystems, 850 Lincoln Centre Drive, Foster City, California 94404, USA.

Trademarks of Life Technologies Corporation and its affiliated companies: AB $Logo^{TM}$, Applied Biosystems®, FAMTM, Life TechnologiesTM (Stylized), NEDTM, PrepSEQTM, ViralSEQTM, VIC®. TaqMan is a registered trademark of Roche Molecular Systems, Inc. All other trademarks are the sole property of their respective owners.

© 2010 Life Technologies Corporation. All rights reserved. Printed in the USA. 06/2010 C013952

