

Swine Influenza A (H1N1) Real-Time RT-PCR Assay

Catalog No. NR-15577

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Product Description: The Swine Influenza A (H1N1) Real-Time RT-PCR Assay includes oligonucleotide primers and dual-labeled hydrolysis (TaqMan®) probes to be used in real-time RT-PCR assays for the *in vitro* qualitative detection and characterization of swine influenza viruses in respiratory specimens and viral cultures.

Lot: 58893015

Table 1 – Forward and Reverse Primers (Mfg. Date: OCT2009)

TEST	SPECIFICATIONS	RESULTS
Content	Report results	20 nmol

Table 2 – Probes (Mfg. Date: OCT2009)

TEST	SPECIFICATIONS	RESULTS
Content	Report results	5 nmol

**Table 3 –Positive Controls Containing BPL-Inactivated Virus and Human Cells
(NR-15590 Mfg. Date: 16SEP2009; NR-15627 Mfg. Date: 27OCT2009)**

TEST	SPECIFICATIONS	RESULTS
Innocuity Hemagglutination Activity (HA) of Allantoic Fluid After Passage in Embryonated Chicken Eggs NR-15590, Swine Influenza A (H1N1) Positive Control Passage 1 Passage 2 Passage 3 NR-15627, Novel H1N1 2009 (Swine) Influenza A Positive Control Passage 1 Passage 2 Passage 3 Influenza A Virus Positive Control for Innocuity Assay Passage 1 Passage 2 Passage 3	 No HA activity No HA activity No HA activity No HA activity No HA activity No HA activity HA activity HA activity HA activity	 No HA activity No HA activity No HA activity No HA activity No HA activity No HA activity HA activity HA activity HA activity
Sterility (NR-15590 and NR-15627; 21-day incubation) Harpo's HTYE broth ¹ , 37°C and 26°C, aerobic Trypticase soy broth, 37°C and 26°C, aerobic Sabouraud broth, 37°C and 26°C, aerobic Sheep blood agar, 37°C, aerobic Sheep blood agar, 37°C, anaerobic Thioglycollate broth, 37°C, anaerobic DMEM with 10% FBS, 37°C and 5% CO ₂	No growth No growth No growth No growth No growth No growth No growth No growth	No growth No growth No growth No growth No growth No growth No growth No growth
Mycoplasma Contamination (NR-15590 and NR-15627) DNA detection by PCR of extracted Test Article nucleic acid	None detected	None detected

¹Atlas, Ronald M. *Handbook of Microbiological Media*. 3rd ed. Ed. Lawrence C. Parks. Boca Raton: CRC Press, 2004, p. 798.

Table 4 –Human Specimen Extraction Control (NR-15591 Mfg. Date: 16SEP2009)

TEST	SPECIFICATIONS	RESULTS
Sterility (NR-15591; 21-day incubation) Harpo's HTYE broth ¹ , 37°C and 26°C, aerobic Trypticase soy broth, 37°C and 26°C, aerobic Sabouraud broth, 37°C and 26°C, aerobic Sheep blood agar, 37°C, aerobic Sheep blood agar, 37°C, anaerobic Thioglycollate broth, 37°C, anaerobic DMEM with 10% FBS, 37°C and 5% CO ₂	No growth No growth No growth No growth No growth No growth No growth	No growth No growth No growth No growth No growth No growth No growth
Mycoplasma Contamination (NR-15591) DNA detection by PCR of extracted Test Article nucleic acid	None detected	None detected

¹Atlas, Ronald M. *Handbook of Microbiological Media*. 3rd ed. Ed. Lawrence C. Parks. Boca Raton: CRC Press, 2004, p. 798.

Table 5 –Assay Detection

TEST	SPECIFICATIONS	RESULTS
PCR Amplification and Detection¹ Extracted nucleic acid from NR-15590, Swine Influenza A (H1N1) Positive Control Universal Influenza A primer and probe set Swine Influenza A primer and probe set Swine Influenza H1 primer and probe set Human RNase P Positive Control primer and probe set Extracted nucleic acid from NR-15627, Novel H1N1 2009 (Swine) Influenza A Universal Influenza A primer and probe set Swine Influenza A primer and probe set Swine Influenza H1 primer and probe set Human RNase P Positive Control primer and probe set Extracted nucleic acid from NR-15591, Human Specimen Extraction Control Universal Influenza A primer and probe set Swine Influenza A primer and probe set Swine Influenza H1 primer and probe set Human RNase P Positive Control primer and probe set	Positive Positive Positive Positive Positive Positive Positive Positive Positive Negative Negative Negative Positive	Positive Positive Positive Positive Positive Positive Positive Positive Positive Negative Negative Negative Positive

¹For NR-15577, a cycle threshold value of ≤ 37 is considered positive.

Date: 15 JAN 2010

Signature: Signature on File

Title: Technical Manager, BEI Authentication or designee

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