

**Influenza Virus Real-Time RT-PCR Assay**

**Catalog No. NR-15592**

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**For research use only. Not for human use.**

**Product Description:** The Influenza Virus Real-Time RT-PCR 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 seasonal (A/H1, A/H3 and B) and A/H5 (Asian-lineage) influenza viruses.

**Lot: 58893016**

**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 –Human Seasonal Virus Positive Control Containing BPL-Inactivated Virus and Human Cells (NR-15614, Mfg. Date: 27OCT2009)**

TEST	SPECIFICATIONS	RESULTS
<b>Innocuity</b> Hemagglutination Activity (HA) of Allantoic Fluid After Passage in Embryonated Chicken Eggs Human Seasonal Influenza Virus Positive Control (NR-15614) 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  HA activity HA activity HA activity	 No HA activity No HA activity No HA activity  HA activity HA activity HA activity
<b>Sterility (21-day incubation)</b> Harpo's HTYE broth <sup>1</sup> , 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 <sub>2</sub>	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
<b>Mycoplasma Contamination</b> DNA detection by PCR of extracted Test Article nucleic acid	None detected	None detected

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

**Table 4 –Influenza A/H5 (Asian-Lineage) Positive Control Containing Formalin-Inactivated and Detergent Disrupted Virus and Human Cells (NR-15615, Mfg. Date: 27OCT2009)**

TEST	SPECIFICATIONS	RESULTS
<b>Functional Activity</b>	Immunogenic Apathogenic in chickens	Immunogenic Apathogenic in chickens
<b>Sterility (21-day incubation)</b> Harpo's HTYE broth <sup>1</sup> , 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 <sub>2</sub>	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
<b>Mycoplasma Contamination</b> DNA detection by PCR of extracted Test Article nucleic acid	None detected	None detected

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

**Table 5 –Human Specimen Extraction Control (NR-15616, Mfg. Date: 27OCT2009)**

TEST	SPECIFICATIONS	RESULTS
<b>Sterility (21-day incubation)</b> Harpo's HTYE broth <sup>1</sup> , 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 <sub>2</sub>	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
<b>Mycoplasma Contamination</b> DNA detection by PCR of extracted Test Article nucleic acid	None detected	None detected

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

**Table 6 –Assay Detection**

TEST	SPECIFICATIONS	RESULTS
<b>PCR Amplification and Detection<sup>1</sup></b> Extracted nucleic acid from NR-15614, Human Seasonal Influenza Virus Positive Control Influenza A primer and probe set Influenza H1 primer and probe set Influenza H3 primer and probe set Influenza H5a primer and probe set Influenza H5b primer and probe set Influenza B primer and probe set Human RNase P Positive Control primer and probe set Extracted nucleic acid from NR-15615, Influenza A/H5 (Asian-Lineage) Positive Control Influenza A primer and probe set Influenza H1 primer and probe set Influenza H3 primer and probe set Influenza H5a primer and probe set Influenza H5b primer and probe set Influenza B primer and probe set Human RNase P Positive Control primer and probe set Extracted nucleic acid from NR-15616, Human Specimen Extraction Control Influenza A primer and probe set Influenza H1 primer and probe set Influenza H3 primer and probe set Influenza H5a primer and probe set Influenza H5b primer and probe set Influenza B primer and probe set Human RNase P Positive Control primer and probe set	Positive Positive Positive Negative Negative Positive Positive  Positive Report results Negative Positive Positive Negative Positive  Negative Negative Negative Negative Negative Negative Positive	Positive Positive Positive Negative Negative Positive Positive  Positive Positive <sup>2</sup> Negative Positive Positive Negative Positive  Negative Negative Negative Negative Negative Negative Positive

<sup>1</sup>For NR-15592, a cycle threshold value of  $\leq 37$  is considered positive.

<sup>2</sup>We have observed some limited cross reactivity (threshold cycles  $\leq 37$ ) between the H1 primer and probe set and the Influenza A/H5 (Asian-Lineage) Positive Control material (NR-15615).

**Date:** 15 JAN 2010

**Signature:** Signature on File

**Title:** Technical Manager, BEI Authentication or designee

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