



Influenza A (H1N1)

1. Product Overview

Product Name:

Influenza A (H1N1)

Intended Use:

Control material designed to monitor the performance of molecular diagnostic assays (e.g., RT-qPCR) for the detection of Influenza A (H1N1) virus. Used for assay validation, quality control, and process monitoring from nucleic acid extraction through amplification.

2. Product Description

This control material contains non-infectious Influenza A (H1N1) RNA or inactivated viral particles standardized to a known copy number and packaged for use as an external control in molecular assays such as real-time RT-PCR. It may be provided in lyophilized or liquid form depending on the supplier.

Key Features:

- Non-infectious & non-replicative (safe for laboratory use)
 - Complete viral genome or targeted RNA segments included
 - Compatible with a wide range of RT-qPCR assays
 - Stable under recommended storage conditions
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3. Specifications

Parameter	Data / Description
Organism	Influenza A virus, subtype H1N1
Material Type	Purified RNA or inactivated viral particles
Genome Type	Single-stranded RNA (ssRNA)
Format	Lyophilized pellet or liquid suspension



Quantification Method	Digital PCR / qPCR assignment
Typical Concentration Range	$1 \times 10^4 - 1 \times 10^5$ copies/vial (varies by product)
Volume per Vial	1 mL
Stability	>12 months at recommended temperature

4. Intended Use & Applications

This control material is intended for:

- Positive control in molecular assays
- External run control for routine quality assurance
- Monitoring nucleic acid extraction efficiency
- Verification of amplification efficacy and specificity
- Validation of new assay lots or instruments

Compatible with (but not limited to):

- Real-time RT-PCR platforms (CFX96, QuantStudio, Rotor-Gene, etc.)
- Diagnostic kits for Influenza A H1N1 detection
- Laboratory quality systems

5. Storage & Stability

Condition	Requirement
Storage (unopened)	-20°C recommended
After reconstitution	Follow manufacturer instructions (usually 2–8°C for short periods)
Freeze-thaw	Avoid repeated cycles
Shelf Life	24 months

6. Handling Instructions



1. Equilibrate control material to room temperature before use.
 2. Resuspend lyophilized controls as directed.
 3. Mix gently but thoroughly to homogenize.
 4. Use in parallel with clinical samples, beginning at extraction step.
 5. Include corresponding negative controls to monitor contamination risk.
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7. Safety & Precautions

- Handle as potentially biohazardous, even if inactivated.
 - Use appropriate PPE.
 - Do *not* ingest; avoid aerosol generation.
 - Follow institutional biosafety guidance.
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8. Quality Control Recommendations

- Include at least one positive and one negative control per assay run.
 - Monitor Ct values (or assigned copies) over time to detect drift.
 - Controls should produce expected Ct ranges consistent with their quantified levels.
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10. Regulatory & Usage Notes

- Control materials are typically labeled For In Vitro Diagnostic Use (IVD) or For Research Use Only (RUO) depending on supplier.
- Check regional regulatory requirements before use in clinical settings.