eSensor® XT-8 RVP Control Panel

INTENDED USE:

The eSensor® XT-8 RVP Control Panel is intended for *in vitro* use as a quality control to monitor the detection and identification of multiple respiratory viral nucleic acids in nasopharyngeal swabs (NPS) obtained from individuals exhibiting symptoms of respiratory infections when tested by the GenMark Dx eSensor® Respiratory Viral Panel (RVP) Assay on the eSensor® XT-8 instrument.

eSensor® XT-8 RVP Control Panel cannot be cloned, sold, or transferred without the explicit written consent of MMQCI.

PRODUCT SUMMARY and PRINCIPLE:

eSensor® XT-8 RVP Control Panel is synthetic RNA suspended in a non-infectious solution of buffers, preservatives and stabilizers.

Best practice is to establish a quality control program for every assay performed by the laboratory.[1, 2] Routine use of quality controls that are consistent lot to lot assists the laboratory in identifying shifts, trends, and increased frequency of random errors caused by variations in the test system, such as failing reagents. Early investigation can prevent failed assay runs.

COMPOSITION:

The eSensor® XT-8 RVP Control Panel is comprised of 12 tubes of synthetic RNA suspended in a non-infectious solution of buffers, preservatives and stabilizers. Table 1 lists the pathogens that are monitored by the eSensor® XT-8 RVP Control Panel when tested by the GenMark eSensor® Respiratory Viral Panel (RVP) Assay on the eSensor® XT-8 instrument.

STORAGE and STABILITY:

eSensor® XT-8 RVP Control Panel should be stored frozen (-25°C to -15°C). Unopened eSensor® XT-8 RVP Control Panel material is stable through the expiration date printed on the kit label when continuously stored frozen. eSensor® XT-8 RVP Control M244 and eSensor® XT-8 RVP Control M245 are for single use. Discard after use according to your local and federal regulations.

INSTRUCTIONS FOR USE:

1. Allow the control to be tested to come to room temperature (18° – 25°C).
2. Immediately before use, thoroughly mix the control by flicking the tube several times, followed by a quick vortex for 3-5 seconds and then shake down or tap on bench to remove any droplets remaining on cap.
3. Extract the control in the same manner as a patient sample. Use the recommended sample volume of 200µL and elution volume of 60µL.
   Note: Prepare the GenMark Dx® supplied tube of Bacteriophage MS2 (IC) according to manufacturer's instructions and add 10µL of IC to the bottom of easyMAG® disposable well (or bottom of disposable tube used in 'Generic' Extractions). Add 200µL of well-mixed control to the disposable well/tube containing the 10µL of IC. Mix and extract according to manufacturer's recommendations and elute in 60µL.
4. Analyze the extracted control with GenMark eSensor® Respiratory Viral Panel (RVP) Assay as you would a patient sample, being sure to thoroughly mix the extract with a quick 3-5 second vortex immediately before pipetting.
5. Discard after use according to your local and federal regulations.

PRECAUTIONS and WARNINGS:

- Use eSensor® XT-8 RVP Control Panel with GenMark Dx eSensor® Respiratory Viral Panel (RVP) Assay only.
- This product does not contain any biological material and is not biohazardous.
- Use the eSensor® XT-8 RVP Control Panel (single use) as provided. ***Do not dilute, re-freeze or transfer to another storage tube***.
- The eSensor® XT-8 RVP Control Panel has been tested with the following extraction protocols: bioMérieux NucliSENS® easyMAG® extraction system, Qiagen QIAamp Viral RNA Mini Kit, and Roche MagNA Pure LC Total Nucleic Acid Isolation kit.
- Due to the sensitivity of the eSensor® RVP assay, it is important when handling the eSensor® XT-8 RVP Control Panel to adhere to all precautions to prevent contamination.

EXPECTED VALUES:

The laboratory should follow Good Laboratory Practice (GLP) and establish its own performance characteristics for eSensor® XT-8 RVP Control Panel in demonstrating adequate system performance. Recoveries may vary depending on instrumentation, reagents and systematic or random errors. The expected results when the controls are analyzed are listed in Table 1.

GenMark eSensor® Respiratory Viral Panel (RVP) Result Details
Table 1

Targets	M244 Result	M245 Result
Influenza A	**Positive**	Target not detected
Influenza A H1	**Positive**	---
Influenza A H3	**Positive**	---
Influenza A 2009 H1N1	**Positive**	Target not detected
Influenza B	Target not detected	**Positive**
RSV A	**Positive**	Target not detected
RSV B	Target not detected	**Positive**
PIV 1	**Positive**	Target not detected
PIV 2	Target not detected	**Positive**
PIV 3	Target not detected	**Positive**
PIV4*	**Positive**	Target not detected
hMPV	Target not detected	**Positive**
HRV	Target not detected	**Positive**
Adenovirus B/E	Target not detected	**Positive**
Adenovirus C	**Positive**	Target not detected
Cov 229E*	**Positive**	Target not detected
Cov NL63*	**Positive**	Target not detected
Cov HKU1*	Target not detected	**Positive**
Cov OC43*	Target not detected	**Positive**

* Targets reported only with RUO Assay.

ORDERING INFORMATION:

eSensor® XT-8 RVP Control Panel
Part Number: M243
Kit Contains: 12 tubes x 200µL
6 each of M244 & M245

1. ISO 15189: Medical laboratories – Particular requirements for quality and competence.
2. CAP Molecular Pathology Checklist; Commission on Laboratory Accreditation, Laboratory Accreditation Program, Mol.20000