



ePlex RP2 Control M451

INTENDED USE:

The ePlex RP2 Control M451 is intended for use as an external positive and negative quality control to monitor the performance of *in vitro* laboratory nucleic acid testing procedures for the qualitative detection of pathogens: Adenovirus, Coronavirus (229E, HKU1, NL63, OC43), SARS-CoV-2, Middle East Respiratory Syndrome Coronavirus, Human Bocavirus, Human Metapneumovirus, Rhinovirus/Enterovirus, Influenza A, Influenza A H1, Influenza A H1 2009, Influenza A H3, Influenza B, Parainfluenza 1, Parainfluenza 2, Parainfluenza 3, Parainfluenza 4, Respiratory Syncytial Virus A, Respiratory Syncytial Virus B, *Chlamydomphila pneumoniae*, *Bordetella pertussis*, *Legionella pneumophila* and *Mycoplasma pneumoniae* on the ePlex® Respiratory Pathogen Panel 2 (RP2) performed on the ePlex System (GenMark Diagnostics, Inc.). The ePlex RP2 Control M451 is composed of synthetic DNA and RNA specifically designed for and intended to be used solely with the ePlex RP2 Panel on the ePlex System.

PRODUCT SUMMARY and PRINCIPLE:

ePlex RP2 Control M451 is composed of 3 controls, ePlex RP2 Positive A, ePlex RP2 Positive B and ePlex RP2 Negative. The ePlex RP2 Control M451 positive controls contain surrogate control material composed of synthetic DNA and RNA corresponding to genome segments of pathogens listed as detected in Table 1. ePlex RP2 Negative contains no DNA or RNA.

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:

ePlex RP2 Control M451 is comprised of 12 tubes, 4 tubes of each positive control, A and B, and 4 tubes of negative control, 200 µL each. The ePlex RP2 Positive controls are composed of synthetic DNA and RNA suspended in a non-infectious solution of buffers, preservatives and stabilizers. The ePlex RP2 Negative control contains buffer and preservatives. Table 1 lists the pathogens that are detected in the ePlex RP2 Control M451 when tested by ePlex RP2 Panel on the ePlex System.

STORAGE and STABILITY:

ePlex RP2 Control M451 should be stored frozen (-25°C to -15°C). Unopened ePlex RP2 Control M451 material is stable through the expiration date printed on the kit label when consistently stored frozen. ePlex RP2 Control M451 components are for single use. Discard after use according to your local and federal regulations.

PRECAUTIONS and WARNINGS:

- Do not dilute. Use the control as provided.
- This product is intended for *in vitro* analytical testing and is provided for Research Use Only, not for diagnostic procedures.
- ePlex RP2 Control M451 is for use with ePlex RP2 Panel on the ePlex System. It does not contain the entire genome of the pathogens listed in Table 1.
- ePlex RP2 Control M451 may also be used with ePlex RP Panel but only when run as a patient sample, not as a pre-defined External Control. Testing of M451 positive controls pre-defined as “External Controls” with ePlex RP Panel will cause Invalid results.
- This product is not intended for use as a substitute for the internal controls provided in the RP2 Panel.
- Appearance: Positive controls are cloudy and Negative control is clear.
- This product does not contain any biological material of human or animal origin. Universal Precautions are NOT required when handling this product.
- Quality control materials should be used in accordance with local, state, federal regulations and accreditation requirements.
- ePlex RP2 Control M451 cannot be cloned, sold, or transferred without the explicit written consent of MMQCI.

INSTRUCTIONS FOR USE:

1. Allow the control to come completely to room temperature (18° – 25°C).
2. Use the control as provided. Do Not Dilute.
3. Immediately before use, thoroughly mix the control by flicking the tube several times, followed by vortexing for 3-5 seconds. Shake the tube down or tap it on bench to remove any droplets remaining in the cap.
4. Use a calibrated pipette to aspirate 200 µL of control and transfer into the Sample Loading Port of the ePlex RP2 cartridges.
5. Continue to process and analyze the control with the ePlex RP2 Panel test on the ePlex System as you would a patient sample.
Note: Sample can be pre-defined as External Control to generate an RP2 Panel External Control Report. Refer to ePlex Operator Manual for more information. Do not pre-define M451 controls as External Control when using ePlex RP Panel.
6. Discard after use according to your local and federal regulations.

For complete ePlex RP2 Panel instructions, refer to the appropriate package insert provided by GenMark Diagnostics, Inc.

EXPECTED VALUES:

The expected results when the controls are tested with ePlex RP2 Panel test are listed in Table 1.

Table 1. Expected Results: ePlex RP2 Control M451

Control Name	ePlex RP2 Positive A	ePlex RP2 Positive B	ePlex RP2 Negative
Viral Analytes			
Adenovirus	Detected	Not Detected	Not Detected
Coronavirus (229E, HKU1, NL63, OC43)*	Detected	Detected	Not Detected
SARS-CoV-2	Not Detected	Detected	Not Detected
Middle East Respiratory Syndrome Coronavirus*	Not Detected	Detected	Not Detected
Human Bocavirus*	Not Detected	Detected	Not Detected
Human Metapneumovirus	Detected	Not Detected	Not Detected
Human Rhinovirus/Enterovirus	Not Detected	Detected	Not Detected
Influenza A	Detected	Detected	Not Detected
Influenza A H1	Not Detected	Detected	Not Detected
Influenza A 2009 H1N1	Detected	Not Detected	Not Detected
Influenza A H3	Detected	Not Detected	Not Detected
Influenza B	Not Detected	Detected	Not Detected
Parainfluenza Virus 1	Not Detected	Detected	Not Detected
Parainfluenza Virus 2	Detected	Not Detected	Not Detected
Parainfluenza Virus 3	Not Detected	Detected	Not Detected
Parainfluenza Virus 4	Detected	Not Detected	Not Detected
Respiratory Syncytial Virus A	Detected	Not Detected	Not Detected
Respiratory Syncytial Virus B	Detected	Not Detected	Not Detected
Bacterial Analytes			
<i>Chlamydomphila pneumoniae</i> [§]	Detected	Not Detected	Not Detected
<i>Bordetella pertussis</i> *	Not Detected	Detected	Not Detected
<i>Legionella pneumophila</i> *	Detected	Not Detected	Not Detected
<i>Mycoplasma pneumoniae</i>	Not Detected	Detected	Not Detected

*Coronavirus strains (HKU1 and NL63 are detected with ePlex RP2 Positive A, 229E and OC43 are detected with ePlex RP2 Positive B), Middle East Respiratory Syndrome Coronavirus, Human Bocavirus, *Bordetella pertussis*, and *Legionella pneumophila* are reported out for NON-US customers only
[§]*Chlamydomphila pneumoniae* is reported out for US customers only

Notice: ePlex is a registered trademark of GenMark Diagnostics, Inc.

ORDERING INFORMATION:

ePlex RP2 Control M451

Part Number: M451

Kit Contains: 12 tubes x 200µL

4 each of Positive A, Positive B & Negative