



ePlex RP Negative

INTENDED USE:

The ePlex RP Negative is intended for use as an external negative quality control to monitor the performance of *in vitro* laboratory nucleic acid testing procedures for the qualitative detection of the pathogens listed in Tables 1 & 2 on the ePlex[®] Respiratory Pathogen (RP) Panel performed on the ePlex System (GenMark Diagnostics, Inc.).

PRODUCT SUMMARY and PRINCIPLE:

ePlex RP Negative contains non-target DNA and RNA.

Quality controls can be used for routine monitoring of test systems, validation, verification, proficiency assessment, and training procedures. Routine use of quality controls assists the laboratory in identifying shifts, trends, and increased frequency of random errors caused by variations in the test system, such as failing reagents or malfunctioning equipment. Early investigation can prevent failed assay runs.

COMPOSITION:

ePlex RP Negative is comprised of 6 tubes of negative control, 200 µL each. Tables 1 & 2 list the pathogens that are detected in the ePlex RP Negative when tested by ePlex RP Panel on the ePlex System.

STORAGE and STABILITY:

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

PRECAUTIONS and WARNINGS:

- Use the control as provided. Do not dilute or transfer to another tube.
- This product is intended for *in vitro* analytical testing and is provided for Research Use Only, not for use in diagnostic procedures.
- ePlex RP Negative is only for use with ePlex RP Panel on the ePlex System.
- This product is not intended for use as a substitute for the internal controls provided in ePlex RP Panel.
- 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 RP Negative 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) before testing.
2. 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.
3. Gently tap the ePlex Sample Delivery Device on the counter or benchtop surface to collect liquid that may have adhered to the sides of the vial.
4. Unscrew the purple cap from the Sample Delivery Device.
5. Use a calibrated pipette to aspirate 200 µL of control and transfer into the Sample Delivery Device.
6. Replace purple cap on Sample Delivery Device. Ensure that cap is securely fastened on the Sample Delivery Device. Vortex for 10 seconds immediately before loading onto the cartridge.
7. Continue to process and analyze the control with the ePlex RP Panel test on the ePlex System as you would a patient sample.

Note: Sample can be pre-defined as External Control to generate an RP Panel External Control Report. Refer to ePlex Operator Manual for more information on defining external controls on ePlex System.

8. Discard after use according to your local and federal regulations.

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

EXPECTED VALUES:

The expected results when the controls are tested with ePlex RP Panel test are listed in Tables 1 & 2.

Table 1. US customers Expected Results: ePlex RP Negative

Control Name	ePlex RP Negative
Part Number	M31118
Viral Analytes	
Adenovirus	Not Detected
Coronavirus	Not Detected
Human Metapneumovirus	Not Detected
Human Rhinovirus/ Enterovirus	Not Detected
Influenza A	Not Detected
Influenza A H1	Not Detected
Influenza A H1-2009	Not Detected
Influenza A H3	Not Detected
Influenza B	Not Detected
Parainfluenza Virus 1	Not Detected
Parainfluenza Virus 2	Not Detected
Parainfluenza Virus 3	Not Detected
Parainfluenza Virus 4	Not Detected
Respiratory Syncytial Virus A	Not Detected
Respiratory Syncytial Virus B	Not Detected
Bacterial Analytes	
<i>Chlamydia pneumoniae</i>	Not Detected
<i>Mycoplasma pneumoniae</i>	Not Detected

Table 2: NON-US customers Expected Results: ePlex RP Negative

Control Name	ePlex RP Negative
Part Number	M31118
Viral Analytes	
Adenovirus	Not Detected
Coronavirus 229E	Not Detected
Coronavirus HKU1	Not Detected
Coronavirus NL63	Not Detected
Coronavirus OC43	Not Detected
Middle East Respiratory Syndrome	Not Detected
Human Bocavirus	Not Detected
Human Metapneumovirus	Not Detected
Human Rhinovirus/ Enterovirus	Not Detected
Influenza A	Not Detected
Influenza A H1	Not Detected
Influenza A H1-2009	Not Detected
Influenza A H3	Not Detected
Influenza B	Not Detected
Parainfluenza Virus 1	Not Detected
Parainfluenza Virus 2	Not Detected
Parainfluenza Virus 3	Not Detected
Parainfluenza Virus 4	Not Detected
Respiratory Syncytial Virus A	Not Detected
Respiratory Syncytial Virus B	Not Detected
Bacterial Analytes	
<i>Bordetella pertussis</i>	Not Detected
<i>Chlamydia pneumoniae</i>	Not Detected
<i>Legionella pneumophila</i>	Not Detected
<i>Mycoplasma pneumoniae</i>	Not Detected

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

ORDERING INFORMATION:

ePlex RP Negative

Part Number: M31118-6

Kit Contains: 6 tubes of Negative x 200µL