

ePlex RP Control M306

INTENDED USE:

The ePlex RP Control M306 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 the pathogens listed in Tables 1 & 2 on the ePlex® Respiratory Pathogen (RP) Panel performed on the ePlex System (GenMark Diagnostics, Inc.). The ePlex RP Control M306 is composed of synthetic DNA and RNA specifically designed for and intended to be used solely with the ePlex RP Panel on the ePlex System. This product is not intended to replace manufacturer internal ePlex RP Panel controls provided with the device. ePlex RP Control M306 is processed like a patient sample.

PRODUCT SUMMARY and PRINCIPLE:

ePlex RP Control M306 is composed of 5 controls, ePlex RP Positive A, ePlex RP Positive B, ePlex RP Positive C, ePlex RP Positive D and ePlex RP Negative. The ePlex RP Control M306 positive controls contain surrogate control material composed of synthetic DNA and RNA corresponding to genome segments of pathogens listed as detected in Tables 1 & 2. 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 Control M306 is comprised of 10 tubes, 2 tubes of each positive control, A, B, C, and D, and 2 tubes of negative control, 200 µL each. The controls are composed of synthetic DNA and RNA suspended in a non-infectious solution of buffers, preservatives and stabilizers. Tables 1 & 2 list the pathogens that are detected in the ePlex RP Control when tested by ePlex RP Panel on the ePlex System.

STORAGE and STABILITY:

ePlex RP Control M306 should be stored frozen (-25°C to -15°C). Unopened ePlex RP Control M306 material is stable through the expiration date printed on the kit label when consistently stored frozen. ePlex RP Control M306 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.
- This product is only for use with ePlex RP Panel on the ePlex System. It does not contain the entire genome of the pathogens listed in Tables 1 & 2.
- 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 Control M306 cannot be cloned, sold, or transferred without the explicit written consent of MMQCI

INSTRUCTIONS FOR USE:

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

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.

ORDERING INFORMATION:

ePlex RP Control M306

Part Number: M306

Kit Contains: 10 tubes x 200µL

2 each of Pos A, Pos B, Pos C, Pos D & Negative

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 Control M306

Control Name	ePlex RP Positive A	ePlex RP Positive B	ePlex RP Positive C	ePlex RP Positive D	ePlex RP Negative
Part Number	M30718	M30818	M30918	M31018	M31118
Viral Analytes					
Adenovirus	Detected	Detected	Not Detected	Not Detected	Not Detected
Coronavirus	Detected	Detected	Detected	Detected	Not Detected
Human Metapneumovirus	Not Detected	Detected	Not Detected	Not Detected	Not Detected
Human Rhinovirus/Enterovirus	Not Detected	Not Detected	Not Detected	Detected	Not Detected
Influenza A	Detected	Detected	Detected	Not Detected	Not Detected
Influenza A H1	Not Detected	Not Detected	Detected	Not Detected	Not Detected
Influenza A H1-2009	Not Detected	Detected	Not Detected	Not Detected	Not Detected
Influenza A H3	Detected	Not Detected	Not Detected	Not Detected	Not Detected
Influenza B	Not Detected	Not Detected	Not Detected	Detected	Not Detected
Parainfluenza Virus 1	Not Detected	Not Detected	Detected	Not Detected	Not Detected
Parainfluenza Virus 2	Not Detected	Detected	Not Detected	Not Detected	Not Detected
Parainfluenza Virus 3	Not Detected	Not Detected	Detected	Not Detected	Not Detected
Parainfluenza Virus 4	Detected	Not Detected	Not Detected	Not Detected	Not Detected
Respiratory Syncytial Virus A	Detected	Not Detected	Not Detected	Not Detected	Not Detected
Respiratory Syncytial Virus B	Not Detected	Detected	Not Detected	Not Detected	Not Detected
Bacterial Analytes					
<i>Chlamydia pneumoniae</i>	Detected	Not Detected	Not Detected	Not Detected	Not Detected
<i>Mycoplasma pneumoniae</i>	Not Detected	Not Detected	Not Detected	Detected	Not Detected

Table 2. NON-US customers Expected Results: ePlex RP Control M306

Control Name	ePlex RP Positive A	ePlex RP Positive B	ePlex RP Positive C	ePlex RP Positive D	ePlex RP Negative
Part Number	M30718	M30818	M30918	M31018	M31118
Viral Analytes					
Adenovirus	Detected	Detected	Not Detected	Not Detected	Not Detected
Coronavirus 229E	Not Detected	Not Detected	Detected	Not Detected	Not Detected
Coronavirus HKU1	Not Detected	Detected	Not Detected	Not Detected	Not Detected
Coronavirus NL63	Detected	Not Detected	Not Detected	Not Detected	Not Detected
Coronavirus OC43	Not Detected	Not Detected	Not Detected	Detected	Not Detected
Middle East Respiratory Syndrome Coronavirus	Not Detected	Not Detected	Not Detected	Detected	Not Detected
Human Bocavirus	Not Detected	Not Detected	Not Detected	Detected	Not Detected
Human Metapneumovirus	Not Detected	Detected	Not Detected	Not Detected	Not Detected
Human Rhinovirus/Enterovirus	Not Detected	Not Detected	Not Detected	Detected	Not Detected
Influenza A	Detected	Detected	Detected	Not Detected	Not Detected
Influenza A H1	Not Detected	Not Detected	Detected	Not Detected	Not Detected
Influenza A H1-2009	Not Detected	Detected	Not Detected	Not Detected	Not Detected
Influenza A H3	Detected	Not Detected	Not Detected	Not Detected	Not Detected
Influenza B	Not Detected	Not Detected	Not Detected	Detected	Not Detected
Parainfluenza Virus 1	Not Detected	Not Detected	Detected	Not Detected	Not Detected
Parainfluenza Virus 2	Not Detected	Detected	Not Detected	Not Detected	Not Detected
Parainfluenza Virus 3	Not Detected	Not Detected	Detected	Not Detected	Not Detected
Parainfluenza Virus 4	Detected	Not Detected	Not Detected	Not Detected	Not Detected
Respiratory Syncytial Virus A	Detected	Not Detected	Not Detected	Not Detected	Not Detected
Respiratory Syncytial Virus B	Not Detected	Detected	Not Detected	Not Detected	Not Detected
Bacterial Analytes					
<i>Bordetella pertussis</i>	Not Detected	Not Detected	Detected	Not Detected	Not Detected
<i>Chlamydia pneumoniae</i>	Detected	Not Detected	Not Detected	Not Detected	Not Detected
<i>Legionella pneumophila</i>	Not Detected	Detected	Not Detected	Not Detected	Not Detected
<i>Mycoplasma pneumoniae</i>	Not Detected	Not Detected	Not Detected	Detected	Not Detected

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