



ePlex SARS-CoV-2 Control Panel M435

INTENDED USE:

The ePlex SARS-CoV-2 Control Panel M435 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 SARS-CoV-2 by the ePlex SARS-CoV-2 Test on the ePlex System (GenMark Diagnostics, Inc.).

PRODUCT SUMMARY and PRINCIPLE:

The ePlex SARS-CoV-2 Control Panel M435 is composed of 2 controls, ePlex SARS-CoV-2 Positive and ePlex SARS-CoV-2 Negative. ePlex SARS-CoV-2 Positive contains surrogate control material composed of synthetic RNA corresponding to genome segments of the SARS-CoV-2 pathogen detected by the ePlex SARS-CoV-2 Test. The ePlex SARS-CoV-2 Negative contains no 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:

The ePlex SARS-CoV-2 Control Panel M435 is comprised of 6 tubes, 3 tubes of ePlex SARS-CoV-2 Positive and 3 tubes of ePlex SARS-CoV-2 Negative, 200µL each. ePlex SARS-CoV-2 Positive control contains synthetic RNA suspended in a non-infectious solution of buffers, preservatives and stabilizers. ePlex SARS-CoV-2 Negative control contains buffers and preservatives. Table 1 lists the expected results when the ePlex SARS-CoV-2 Control Panel M435 is tested with the ePlex SARS-CoV-2 Test on the ePlex System.

INSTRUCTIONS FOR USE:

1. Allow control to be tested to come completely to room temperature (18°–25°C).
2. Use the control as provided. **DO NOT DILUTE.**
3. Immediately before use, mix the control thoroughly by flicking the tube several times, followed by vortexing for 5-10 seconds. Shake the tube down or tap it on bench to remove any droplets remaining in the cap.
4. 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.
5. Unscrew the purple cap from the Sample Delivery Device.
6. Use a calibrated pipette to aspirate 200 µL of control and transfer into the Sample Delivery Device.
7. Replace purple cap on Sample Delivery Device. Ensure that cap is securely fastened on the Sample Delivery Device.
8. Vortex for 10 seconds immediately before loading onto the cartridge.
9. Continue to process and analyze the control with the ePlex SARS-CoV-2 Test on the ePlex System as you would a patient sample. *Note: Sample can be pre-defined as External Control to generate a SARS-CoV-2 External Control Report. Refer to ePlex Operator Manual for more information on defining external controls on ePlex System.*

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

For complete ePlex SARS-CoV-2 Test instructions, refer to the ePlex SARS-CoV-2 Test package insert provided by GenMark Diagnostics, Inc.

PRECAUTIONS, WARNINGS and LIMITATIONS:

- Do not dilute. Use the control as provided.
- This product is intended for *in vitro* analytical testing.
- This product does not contain the entire SARS-CoV-2 genome.
- This product is not intended to replace manufacturer controls provided within the device.
- Appearance: Positive control is slightly 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 SARS-CoV-2 Control Panel M435 cannot be cloned, sold, or transferred without the explicit written consent of MMQCI.

STORAGE and STABILITY:

The ePlex SARS-CoV-2 Control Panel M435 should be stored frozen (-25°C to -15°C). Unopened ePlex SARS-CoV-2 Control Panel M435 material is stable through the expiration date printed on the kit label when continuously stored frozen. The ePlex SARS-CoV-2 Control Panel M435 components are for single use. Discard after use according to your local and federal regulations.

EXPECTED VALUES:

The laboratory should follow Good Laboratory Practice (GLP) and establish its own performance characteristics for ePlex SARS-CoV-2 Control Panel M435 in demonstrating adequate system performance.

Expected results when controls are analyzed on the ePlex System are listed in Table 1.

Table 1. Expected Results of ePlex SARS-CoV-2 Control Panel M435

Control:	ePlex SARS-CoV-2 Negative	ePlex SARS-CoV-2 Positive
Summary:	SARS-CoV-2 Not Detected	SARS-CoV-2 Detected

ORDERING INFORMATION:

ePlex SARS-CoV-2 Control Panel M435

Part Number: M435

Kit Contains: 6 tubes x 200µL

3 Positive controls & 3 Negative controls