



Xpert SARS-CoV-2 Control Panel M430

INTENDED USE:

The Xpert SARS-CoV-2 Control Panel M430 is intended for use as reference material to monitor the performance of *in vitro* laboratory nucleic acid testing procedures for the qualitative detection of SARS-CoV-2 by the Xpert® Xpress SARS-CoV-2 and Xpert Xpress CoV-2 *plus* assays on the GeneXpert® DX, GeneXpert Infinity and GeneXpert Xpress systems (Cepheid®).

PRODUCT SUMMARY and PRINCIPLE:

The Xpert SARS-CoV-2 Control Panel M430 is composed of 2 controls, Xpert SARS-CoV-2 Positive and Xpert SARS-CoV-2 Negative. Xpert SARS-CoV-2 Positive contains surrogate control material composed of synthetic RNA corresponding to genome segments of the SARS-CoV-2 pathogen detected by Xpert Xpress SARS-CoV-2 and Xpert Xpress CoV-2 *plus* assays. The Xpert SARS-CoV-2 Negative contains no 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:

The Xpert SARS-CoV-2 Control Panel M430 is comprised of 6 tubes, 3 tubes of Xpert SARS-CoV-2 Positive and 3 tubes of Xpert SARS-CoV-2 Negative, 300µL each. Xpert SARS-CoV-2 Positive control contains synthetic RNA suspended in a non-infectious solution of buffers, preservatives and stabilizers. Xpert SARS-CoV-2 Negative control contains buffers and preservatives. Table 1 lists the expected results when the Xpert SARS-CoV-2 Control Panel M430 is tested with the Xpert Xpress SARS-CoV-2 and Xpert Xpress CoV-2 *plus* tests on GeneXpert systems.

PRECAUTIONS, WARNINGS and LIMITATIONS:

- 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 use in diagnostic procedures.
- 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.
- Xpert SARS-CoV-2 Control Panel M430 cannot be cloned, sold, or transferred without the explicit written consent of MMQCI.

STORAGE and STABILITY:

The Xpert SARS-CoV-2 Control Panel M430 should be stored frozen (-25°C to -15°C). Unopened Xpert SARS-CoV-2 Control Panel M430 material is stable through the expiration date printed on the kit label when consistently stored frozen. The Xpert SARS-CoV-2 Control Panel M430 components are for single use. Discard after use according to your local and federal regulations.

INSTRUCTIONS FOR USE:

1. Allow control to be tested to come completely to room temperature (18°C – 25°C), approximately 30 minutes.
2. Use the control as provided. DO NOT DILUTE.
3. Immediately before use, mix the control thoroughly by rapidly inverting the tube 5 times. Tap the tube several times on the bench to remove any liquid caught in the cap before opening the tube.
4. Open the GeneXpert cartridge lid.
5. Using a clean transfer pipette, transfer one draw of the control sample into the large opening (Sample Chamber) in the cartridge.
6. Close the GeneXpert cartridge lid.
7. Continue with the test procedure according to manufacturer's instruction.
8. Discard after use according to your local and federal regulations.

For complete Xpert Xpress SARS-CoV-2 and Xpert Xpress CoV-2 *plus* test instructions, refer to the Xpert Xpress SARS-CoV-2 and Xpert Xpress CoV-2 *plus* package inserts provided by Cepheid.

EXPECTED VALUES:

The laboratory should follow Good Laboratory Practice (GLP) and establish its own performance characteristics for Xpert SARS-CoV-2 Control Panel M430 in demonstrating adequate system performance.

Expected results when controls are analyzed on GeneXpert systems are listed in Table 1.

Table 1. Expected Results of Xpert SARS-CoV-2 Control Panel M430

Control:	Xpert SARS-CoV-2 Negative	Xpert SARS-CoV-2 Positive
Test Result:	SARS-CoV-2 NEGATIVE	SARS-CoV-2 POSITIVE
Analyte Result E:	NEG	POS
Analyte Result N2:	NEG	POS
Analyte Result RdRP ¹ :	NEG	POS

¹RdRP is reported on the Xpert Xpress CoV-2 *plus* assay only.

ORDERING INFORMATION:

Xpert SARS-CoV-2 Control Panel M430
Part Number: M430-OUS
Kit Contains: 6 tubes x 300µL
3 Positive controls & 3 Negative controls