

Xpert Bladder Cancer Panel C104

INTENDED USE:

Xpert Bladder Cancer Panel C104 is intended for use as a quality control to monitor the performance of *in vitro* laboratory nucleic acid procedures for the qualitative detection of five RNA transcripts, CRH, IGF2, UPK1B, ANXA10, ABL1, performed on Cepheid GeneXpert® Systems with assays Xpert® Bladder Cancer Monitor and Xpert® Bladder Cancer Detection.

The American Cancer Society estimates over 70,000 new cases of bladder cancer for 2016 and it is currently the fourth most common cancer among men in the United States¹. Bladder cancer also has the highest reoccurrence rate of any malignancy; therefore, diligent and accurate detection and monitoring is crucial for early diagnosis and treatment.

PRODUCT SUMMARY and PRINCIPLE:

The Xpert Bladder Cancer Panel C104 kit contains Xpert Bladder Cancer Low Positive Control and Xpert Bladder Cancer Negative Control. Xpert Bladder Cancer Low Positive Control contains synthetic RNA transcripts carrying target sequences of CRH, IGF2, UPK1B, ANXA10 and ABL1 designed to be detected by Xpert Bladder Cancer assays. Xpert Bladder Cancer Negative Control contains synthetic RNA transcripts carrying target sequence of the endogenous control ABL1 only.

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:

Xpert Bladder Cancer Panel C104 contains 6 bottles of Xpert Bladder Cancer Low Positive Control and 6 bottles of Xpert Bladder Cancer Negative Control, 4mL each, composed of synthetic RNA transcripts suspended in a solution of synthetic urine, buffers, preservatives, and stabilizers. Table 1 lists the expected results for the Xpert Bladder Cancer Panel C104 when tested by Xpert Bladder Cancer assays on the GeneXpert Systems.

STORAGE and STABILITY:

Xpert Bladder Cancer Panel C104 should be stored at -20°C. Unopened Xpert Bladder Cancer Panel C104 material is stable through the expiration date printed on the kit label when continuously stored frozen. Xpert Bladder Cancer Low Positive Control and Xpert Bladder Cancer Negative Control are for single use. Discard after use according to your local and federal regulations.

PRECAUTIONS and WARNINGS:

Note: This product does NOT contain any biological material of human or animal origin.

- Do not dilute.
- For Research Use Only. The performance characteristics of this product have not been established.
- Xpert Bladder Cancer Panel C104 contains guanidinium chloride which is toxic if swallowed (H302), irritating to eyes and skin (H315, H319), and is harmful to aquatic life (H402). See Regulation EC 1272/2008 (EU CLP).
- Xpert Bladder Cancer Panel C104 cannot be cloned, sold, or transferred without the explicit written consent of MMQCI.



INSTRUCTIONS FOR USE:

Note: Use one Xpert Bladder Cancer assay cartridge to perform the negative control test, and another Xpert Bladder Cancer assay cartridge to perform the positive control test.

1. Allow the control to be tested to come to room temperature (18° – 25°C), approximately 30 minutes. Control should feel warm, not cool, to the touch prior to use.
2. Use the control as provided. **DO NOT DILUTE.**
3. Immediately before use, mix the control by inverting at least 10 times. Tap the bottle 3 times on the bench to remove any control caught in the cap before opening the bottle.
4. Open the cartridge lid. Using a clean transfer pipette (supplied with the cartridge), transfer 4mL of the control to the chamber via the large opening in the top of the cartridge. (Refer to Assay Package Insert for diagram).
5. Close the cartridge lid and process as a patient sample.
6. Discard control bottle after use according to your local and federal regulations.

EXPECTED VALUES:

Table 1: Xpert Bladder Cancer Panel C104 Test Result

Kit Component:	Test Result:
Xpert Bladder Cancer Low Positive Control	Positive
Xpert Bladder Cancer Negative Control	Negative

Table 2: Example of Analyte Results for Xpert Bladder Cancer Panel C104. Data represents the average of 14 replicates of each control.

Analyte	Low Positive Lot 1		Low Positive Lot 2	
	Ct	EndPt	Ct	EndPt
CIC	31.7	231	31.9	254
ABL1	32.5	399	33.0	409
ANXA10	32.6	453	34.0	429
UPK1B	32.9	236	34.3	230
CRH	32.9	398	34.3	383
IGF2	32.1	353	33.8	321
Analyte	Negative Lot 2		Negative Lot 3	
	Ct	EndPt	Ct	EndPt
CIC	31.9	263	32.0	259
ABL1	31.8	466	32.3	459
ANXA10	0.0	2	0.0	2
UPK1B	0.0	1	0.0	1
CRH	0.0	1	0.0	1
IGF2	0.0	-3	0.0	-2

ORDERING INFORMATION

Xpert Bladder Cancer Panel C104

Part Number: C104

Kit Contains: 12 bottles x 4mL
6 each of Low Positive & Negative Controls

¹ American Cancer Society. Cancer Facts & Figures 2016. Atlanta, Ga: American Cancer Society; 2016.