Research Use Only
Maine Molecular Quality Controls, Inc.
23 Mill Brook Road, Saco, ME 04072 USA
Phone: 207-885-1072, FAX: 207-885-1079
Web: www.mmqci.com, Email: info@mmqci.com

Xpert PML-RARA 0%

INTENDED USE:

The Xpert PML-RARA 0% is an assayed external quality control used to monitor the performance of *in vitro* laboratory nucleic acid testing procedures for the quantitative detection of PML-RARA transcript isoforms, bcr1, bcr2, bcr3, and ABL1 endogenous control mRNA transcript when analyzed using the Xpert® PML-RARA assay on Cepheid GeneXpert® Systems.

The translocation t (15;17) (q24;21) of the promyelocytic leukemia gene (PML) and retinoic acid receptor-α protein (RARA) gene results in PML-RARA, an oncogenic fusion gene. PML-RARA is a driver for acute promyelocytic leukemia (APL), a subtype of acute myeloid leukemia (AML), and is found in over 98% of APL patients. PML-RARA represses the transcription of multiple genes involved in myeloid differentiation and confers a survival and proliferative advantage to leukemic cells, resulting in accumulation of promyelocytes in bone marrow.[1] There are three typical PML-RARA isoforms: bcr1 (L or long), bcr2 (V or variant), and bcr3 (S or short). bcr1 and bcr3 isoforms are most common and found in 90-95% of APL patients[1]. Treatment involving all-trans-retinoic acid (ATRA), arsenic trioxide (ATO), and/or chemotherapy has been largely successful for pediatric and adult patients. Measurable residual disease monitoring (MRD) with qPCR-based detection of PML-RARA transcript is an important tool for use as a prognostic/predictive biomarker to inform treatment decision-making, a monitoring tool to identify impending relapse, and a potential surrogate end point for overall survival in clinical trials to accelerate the development of novel treatment strategies[2].

PRODUCT SUMMARY and PRINCIPLE:

The Xpert PML-RARA 0% is composed of one level, Xpert PML-RARA 0%, which contains wildtype ABL1 transcript only. This control is designed to represent a sample with no PML-RARA transcript isoforms present when analyzed on the GeneXpert system with the Xpert PML-RARA assay. Xpert PML-RARA 0% is also a component of Xpert PML-RARA Control Panel C215, part number C215.

Quality controls can be used for routine monitoring of test systems, validation, verification, proficiency assessment, and training procedures. Quality controls that are consistent from lot to lot assist 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:

Xpert PML-RARA 0% contains 5 single-use bottles of Xpert PML-RARA 0% consisting of synthetic ABL1 control gene transcript suspended in a stabilizing matrix with a non-infectious solution of buffers and preservatives.

STORAGE and STABILITY:

Xpert PML-RARA 0% should be stored at -25°C to -15°C. Unopened material is stable through the expiration date printed on the kit label when consistently stored frozen. Xpert PML-RARA 0% is for single use only. Discard after use according to your local and federal regulations.

PRECAUTIONS, WARNINGS, and LIMITATIONS:

- This product is intended for *in vitro* analytical testing and is provided for Research Use Only. It is not for use in diagnostic procedures.
- This product is slightly cloudy in appearance.
- This product does not contain any biological material of human or animal origin. Universal Precautions are NOT required when handling this product.
- Xpert PML-RARA 0% cannot be cloned, sold, or transferred without the explicit written consent of MMQCI.
- Quality control materials should be used in accordance with local, state, and federal regulations and accreditation requirements.

INSTRUCTION FOR USE:

1. Allow the Xpert PML-RARA 0% component to be tested to come completely to room temperature (18°C to 25°C), approximately 30 minutes, until bottles are warm to the touch. Immediately before pipetting, thoroughly mix the control bottle by inverting 8 times followed by 2 pulse vortexes, 2-3 seconds each, at maximum speed.
2. Add 4mL of the control sample to 100µL of Proteinase K in a conical tube, as you would a blood specimen.
3. Continue with the assay procedure according to manufacturer's instructions.
4. Discard after use according to local and federal regulations.

EXPECTED VALUES:

The expected result of Xpert PML-RARA 0% when tested with the Xpert PML-RARA assay on the Cepheid GeneXpert system is: Negative (sufficient ABL transcript).

Control	Test Result
Xpert PML-RARA 0%	Negative (sufficient ABL transcript)

ORDERING INFORMATION:

Xpert PML-RARA 0%
Part Number: C21612-5
Kit contains: 5 bottles x 4mL

References
[1] Liquori A, Ibañez M, Sargas C, Sanz MÁ, Barragán E, Cervera J. Acute Promyelocytic Leukemia: A Constellation of Molecular Events around a Single *PML-RARA* Fusion Gene [published correction appears in Cancers (Basel). 2021 Jul 09;13(14):]. *Cancers (Basel)*. 2020;12(3):624.
[2] Heuser M, Freeman SD, Ossenkoppele GJ, et al. 2021 Update on MRD in acute myeloid leukemia: a consensus document from the European LeukemiaNet MRD Working Party. Blood. 2021;138(26):2753-2767.