

LABORATORY REPORT

Example Client, XYZ123 1234 Warde Road Ann Arbor MI 48108

p190 % Ratio

BCR-ABL1 Comment

EXAMPLE, REPORT W

see below

WX0000003827 M 07/08/1978 45 Y

Molecular Collected: 08/31/2023 10:40 Received: 08/31/2023 10:40 **Test Name** Result Flag Ref-Ranges Units <u>Site</u> BCR-ABL1 Rearrangement, Quantitative PCR with Reflex p210 Result **DETECTED** WMRL see below WMRL p210 %IS 0.002 % see below WMRL p210 MR 46 see below L WMRI p190 Result

The transcript for the p210 product was detected at the stated MR/\$IS. This test does not differentiate between e13a2 or e14a2 fusion transcripts and does not monitor other rare fusion transcripts resulting from t(9;22). This test is not intended for the diagnosis of CML.

See below

This test was performed using the QuantideX® qPCR BCR-ABL IS Kit (Assuragen) and, if negative, reflexed to the QuantideX® qPCR BCR-ABL minor Kit (Assuragen). Both kits are reverse transcription-quantitative PCR performed on the Applied Biosystems 7500 Fast Dx Real-Time OCR Instrument and is intended to measure BCR-ABL1 to ABL1. The QuantideX® qPCR BCR-ABL IS kit (major) is an in vitro nucleic acid amplification test for the quantitation of BCR-ABL1 and ABL1 transcripts in total RNA from whole blood of diagnosed t(9;22) positive Chronic Myeloid Leukemia (CML) patients expressing BCR-ABL1 fusion transcripts type e13a2 and/or e14a2. BCR-ABL1 to ABL1 is expressed as a log molecular reduction (MR value) from a baseline of 100% on the International Scale, in t(9;22) positive CML patients during monitoring of treatment with Tyrosine Kinase Inhibitors (TKIs).

The QuantideX® qPCR BCR-ABL minor Kit is an in vitro nucleic acid amplification test for the quantitation of BCRABL1 and ABL1 transcripts in total RNA from whole blood of diagnosed t(9;22) positive Chronic Myeloid Leukemia (CML) patients expressing BCR-ABL1 fusion transcript type e1a2. BCR-ABL1 to ABL1 is expressed as a percent ratio (BCR-ABL1 to ABL1) in t(9;22) positive CML patients during monitoring of treatment with Tyrosine Kinase Inhibitors (TKIs).

Performing Site:

WMRL

WMRL

WMRL: WARDE MEDICAL LABORATORY 300 West Textile Road Ann Arbor MI 48108

LAB: L - LOW, H - HIGH, AB - ABNORMAL, C - CRITICAL, . - NOT TESTED

F231000019 WX0000003827 Printed D&T: 11/20/23 15:38 Ordered By: KAJAL SITWALA, MD, PhD WX00000000002365

Kajal V. Sitwala, MD, PhD - Medical Director Form: MM RL1 PAGE 1 OF 1