Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT W
WX0000003826 F 12/05/1988 34 Y

Referral Testing

Collected: 08/31/2023 11:11 Received: 08/31/2023 11:11

Test Name	Result	Flag	Ref-Ranges	Units	Site
Calreticulin (CALR) Mutation Analysis					
Clinical Indication:	na				QCRL
Specimen Source:	na				QCRL
Block/Specimen ID:	na				QCRL
CALR Exon 9 Mutation	**DETECTED**	**AB**			QCRL
Reference Range: NOT DETECTED					
Gene	SEE NOTE				QCRL
CALR					
Amino Acid	SEE NOTE				QCRL
p.Leu367Thrfs*46					
Mutation Frequency	SEE NOTE				QCRL
59.3					
Mutation Type	SEE NOTE				QCRL
frameshift					
Exon	SEE NOTE				QCRL
Exon 9					
Nucleotide Change	SEE NOTE				QCRL
c.1099_1150del					
Reference	SEE NOTE				QCRL
COSM1738055					
Interpretation	SEE NOTE				QCRL

A type 1 frameshift mutation is detected in exon 9 of CALR. Mutations of this type are associated with essential thrombocythemia (ET) and primary myelofibrosis (PMF). Insertions up to 30bp and deletions up to 52bp have been successfully detected by the assay. CALR mutational analysis can be performed on sequential samples to assess for treatment response.

This data was reviewed and interpreted by Charles Ma, PhD. HCLD(ABB)

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

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Assay Details	SEE NOTE				QCRL

This PCR-based advanced sequencing assay interrogates DNA from leukocytes for the presence of mutations in exon 9 of calreticulin (CALR). The sensitivity of mutation detection is approximately 5% but may vary depending on the particular mutation type. Insertions up to 30bp and deletions up to 52bp have been successfully detected by the assay. Alterations outside of the tested areas of this gene will not be detected. Synonymous or known non-synonymous polymorphic changes (SNPs) are not reported. Frameshift mutations in this region of CALR are associated with myeloproliferative neoplasms (MPNs), particularly essential thrombocythemia (ET) and primary myelofibrosis (PMF). Results of this assay should be correlated with morphology and other laboratory testing for final diagnosis and classification. If this test is negative, additional testing that may be useful for workup of MPNs, depending on presenting hematologic features, includes BCR-ABL1 rearrangement (test code 91065 or 12070X) or mutational analysis of JAK2 V617F (polycythemia vera (PV)/ET/PMF, 92473), JAK2 exon 12 (PV, 92474), MPL (ET/PMF, 92476) or CSF3R (chronic neutrophilic leukemia, 92477). Residual material from this sample may be used except for BCR-ABL1 testing; call lab to add.

DNA was aligned to GRCh37(hg19) for analysis and transcript ID ENST00000316448 was used as reference for CALR sequence.

For additional information, please refer to
http://education.QuestDiagnostics.com/faq/FAQ211
(This link is being provided for informational/educational purposes only.)

This test was developed and its analytical performance characteristics have been determined by Quest Diagnostics Nichols Institute San Juan Capistrano. It has not been cleared or approved by FDA. This assay has been validated pursuant to the CLIA regulations and is used for clinical purposes.
Test Performed at:
Quest Diagnostics Nichols Institute
33608 Ortega Highway
San Juan Capistrano, CA 92675-2042 I Maramica MD, PhD, MBA

Performing Site:
QCRL: QUEST DIAGNOSTICS REFERENCE LAB CAPISTRANO 33608 Ortega Highway San Juan Capistrano CA 92675

Reported Date: 2023.08.31 11:13 CALRA

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