

LABORATORY REPORT

Example Client, XYZ123 1234 Warde Road Ann Arbor MI 48108 **EXAMPLE, REPORT W**

WX0000003827 M 07/08/1978 45 Y

Referral Testing

Collected: 09/25/2023 08:25 Received: 09/25/2023 08:25

Test Name Result Flag Ref-Ranges Units Site

KIT D816 Mutation Analysis (Mastocytosis)

Specimen SourceBLOOD EDTAQCRLBlock / Specimen IdN/AQCRLClinical IndicationN/AQCRLKIT D816 MutationNot DetectedQCRL

Reference range: Not Detected

Interpretation See Note QCRL

Mutation in codon 816 of KIT is NOT observed.

DNA was analyzed for KIT codon 816 changes by a PCR-based pyrosequencing method with an approximate sensitivity of 2.0% mutation-bearing cells. KIT mutations outside of this codon will not be detected by this assay. Nearly all cases of systemic mastocytosis will show KIT D816V mutation, however occasional samples will show involvement below the sensitivity of this assay.

Nicole C. Christacos, Ph.D., FACMG Technical Director, Molecular Oncology

This test was developed and its analytical performance characteristics have been determined by Quest Diagnostics Nichols Institute Chantilly, VA. It has not been cleared or approved by the U.S. Food and Drug Administration. This assay has been validated pursuant to the CLIA regulations and is used for clinical purposes.

Test Performed at: Quest Diagnostics Chantilly Nichols Institute, 14225 Newbrook Dr. Chantilly, VA 20153-0841 P W Mason MD, PhD

Performing Site:

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

Reported Date: 2023.09.25 8:26 D816M

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

F325000008 WX0000003827 Printed D&T: 09/25/23 08:26 Ordered By: KAJAL SITWALA, MD, PhD WX00000000002365

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