



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: 08/28/2023 15:42 Received: 08/28/2023 15:42

Table with 6 columns: Test Name, Result, Flag, Ref-Ranges, Units, Site. Row 1: TMAO (Trimethylamine N-Oxide), 3.5, <6.2, uM, QCRL

Based on a population (N=4007) defined as ambulatory stable patients without acute coronary syndrome who underwent elective diagnostic coronary angiography (1) and a reference range study of apparently healthy donors (N=180), we have defined the following cut-offs for TMAO to assess relative risk of a cardiovascular event: A cut-off of <6.2 uM defines a population at optimal relative risk for a cardiovascular event relative to those above this level. 6.2-9.9 uM defines a population at moderate relative risk for a cardiovascular event (two-fold increased risk of MACE at 3 years) relative to those with TMAO <6.2 uM (1). Given the dose-dependent relationship between TMAO and cardiovascular event risk demonstrated across multiple clinical subgroups (2), those above the upper limit of the Cleveland HeartLab 95% population interval (>=10.0 uM) are defined as high relative risk for a cardiovascular event relative to those with TMAO <6.2 uM. (References: 1-Tang et al. N Engl J Med. 2013; 368:1575-1584. 2-Heianza Y, et al. J Am Heart Assoc. 2017;6(7)). This test was developed and its analytical performance characteristics have been determined by Quest Diagnostics Cardiometabolic Center of Excellence at Cleveland HeartLab. 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:
Cleveland HeartLab, Inc
6701 Carnegie Avenue Suite 500
Cleveland, OH 44103-4623 B G Richendollar MD

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

Reported Date: 2023.08.28 15:42

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

F228000061 Ordered By: KAJAL SITWALA, MD, PhD
WX0000003827 WX00000000002365
Printed D&T: 08/28/23 15:43

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