

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: 10/20/2023 11:40 Received: 10/20/2023 11:40

<u>Test Name</u> <u>Result</u> <u>Flag Ref-Ranges</u> <u>Units</u> <u>Site</u>

Cytosolic 5'-Nucleotidase 1A (cN-1A) Ab (IgG) 14 Units

Reference Range:

<15: NEGATIVE
15-19: BORDERLINE
> OR = 20: POSITIVE

The cN-1A Ab assay is a useful aid for the diagnosis of inclusion body myositis (IBM). The analytical sensitivity of this assay is 35-70%, based on published reports. In our internal validation study with 120 healthy adult subjects, 1.7% had a positive cN-1A Ab result and 6.7% had an equivocal result. However, published reports and our own internal studies suggest that patients with Sjogren's syndrome, systemic lupus erythematosus, dermatomyositis (DM), or polymyositis (PM), are significantly more likely to have a positive cN-1A Ab result. In contrast, patients presenting clinically with IBM rarely produce autoantibodies associated with a diagnosis of DM or PM. Therefore, cN-1A Ab results must be interpreted in context with other details of the patient's clinical evaluation.

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

Reported Date: 2023.10.20 11:40

Performing Site:

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

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

F420000004 WX0000003826 Printed D&T: 10/20/23 11:40 Ordered By: KAJAL SITWALA, MD, PhD WX00000000002353

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