

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: 09/12/2023 13:59 Received: 09/12/2023 13:59

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

NAbFeron (IFNB-1) Neutralizing Antibody Test

Interpretation See Notes QCRL

This analysis did not detect an elevated level of neutralizing antibodies (NAbs) to human interferon (IFN) beta.

Methods See Notes QCRL

Detection of antibodies was performed using a viral cytopathic effect bioassay.

Limitations of analysis: Although rare, false positive or false negative results may occur. All results should be interpreted in the context of clinical findings, relevant history, and other laboratory data.

Comments See Notes QCRL

Recommendations: Health care providers, please contact the Athena Diagnostics Client Services Department at 1-800-394-4493 if you wish to speak with a clinical consultant regarding this test result.

Background information: The presence of neutralizing antibodies to interferon beta, especially in persistently high titers, may be associated with a reduction in the clinical effectiveness of interferon beta therapy (1). Although the measurement of NAbs can add to the clinical and imaging information used to assess the efficacy of interferon beta therapy, these results should be interpreted in the context of clinical presentation and medical history (2, 3).

References See Notes QCRL

- 1. Goodin, DS, et al. (2007) Neurology 68:977-984 (PMID:17389300)
- 2. Polman, CH, et al. (2010) Lancet Neurol 9:740-50 (PMID:20610349)
- 3. Creeke, PI, et al. (2013) Ther Adv Neurol Disord 6:3-17 (PMID:23277789)

This test was developed and its analytical performance characteristics have been determined by Athena Diagnostics. 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

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

F312000025 WX0000003827 Printed D&T: 09/12/23 14:01 Ordered By: KAJAL SITWALA, MD, PhD WX00000000002365



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purposes.

Laboratory oversight provided by Vivekananda Datta, M.D., Ph.D., CLIA license holder, Athena Diagnostics (CLIA# 22D0069726)

Testing performed at:
Athena Diagnostics 200 Forest Street Marlborough, MA 01752
Test Performed at:
Athena Diagnostics, Inc.
200 Forest Street, 2nd Floor
Marlborough, MA 01752 V Datta MD, PhD

Technical Results See Notes QCRL

Interpretive Result Table

INTERPRETIVE RESULT: Not Elevated

TEST: NAbs to IFN beta TECHNICAL RESULT: <1:20

REFERENCE RANGE: not elevated <1:20, mild/moderatly elevated

1:20-1:100, highly elevated >1:100

Performing Site:

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

Reported Date: 2023.09.12 13:59 IFNBA