



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: 09/01/2023 15:11 Received: 09/01/2023 15:11

Test Name Result Flag Ref-Ranges Units Site

Sensory Neuropathy Profile with Recombx® (3148)

Summary Interpretation See Note QCRL

POSITIVE
This panel of tests identified a positive result.

Interpretive Results Table See Note QCRL

Interpretive Result Table

TEST: anti-Sulfatide
METHODODOLOGY: ELISA
INTERPRETATION: Positive
TECHNICAL RESULT: anti-Sulfatide IgG <1:2,000; anti-Sulfatide IgM 1:16,000
REFERENCE RANGE: Negative <1:2000, Borderline, Positive >=1:2000

TEST: anti-GALOP
METHODODOLOGY: ELISA
INTERPRETATION: Negative
TECHNICAL RESULT: 2340
REFERENCE RANGE: Negative <10,000 Positive >=10,000

TEST: anti-Hu
METHODODOLOGY: Nanoliter scale immunoassay
INTERPRETATION: Negative
TECHNICAL RESULT: <1:100
REFERENCE RANGE: Serum <1:100

TEST: anti-SGPG
METHODODOLOGY: ELISA
INTERPRETATION: Inconclusive
TECHNICAL RESULT: anti-SGPG ELISA Inconclusive
REFERENCE RANGE: Negative <=1:3200, Positive >1:3200

TEST: anti-MAG
METHODODOLOGY: ELISA
INTERPRETATION: Negative
TECHNICAL RESULT: anti-MAG ELISA <1:1,600
REFERENCE RANGE: Negative <=1:1600, Positive >1:1600

TEST: anti-MAG
METHODODOLOGY: Western
INTERPRETATION: Negative

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



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Table with 6 columns: Test Name, Result, Flag, Ref-Ranges, Units, Site. Row 1: TECHNICAL RESULT: anti-MAG Western No abnormal levels of antibodies detected. REFERENCE RANGE: Negative. Row 2: Comments: See Note. QCRL

Comments: Positive test results are associated with a diagnosis of an autoimmune etiology for the neurological symptoms associated with peripheral neuropathy.

Recommendations:

Health care providers, please contact the Athena Diagnostics Client Services Department at 1-800-394-4493 if you wish to consult with a Laboratory Director regarding this test result.

Background information: GALOP, SGPG, MAG, Hu (ANNA-1), or sulfatide antibodies have been associated with autoimmune polyneuropathies including gait ataxia late-onset polyneuropathy (GALOP), distal acquired demyelinating symmetric neuropathy (DADS), sensory-predominant distal symmetric polyneuropathy and subacute paresthesias/pain in a multifocal/asymmetric distribution.

Background References:

- 1. Latov, N, et al. (1980) N Engl J Med 303: 618-21. (PMID: 6250029)
2. Niermeijer, JM, et al. (2010) Neurology 74: 406-12. (PMID: 20124206)
3. Pestronk, A, et al. (1994) Muscle Nerve 17: 1293-300. (PMID: 7523945)

Panel Methods and Method Limitations

Methods: Detection of antibodies was performed by ELISA, automated nanoliter scale immunoassay and western blot confirmation as indicated in the interpretative results table. Detection of GALOP autoantibodies was determined by the evaluation of IgM antibodies to GSC (a physiologic combination of GM1, sulfatide, and cholesterol), GGC (a physiologic combination GM1, galactocerebroside and cholesterol) and histone antigens individually. Elevated levels of IgM antibodies to GSC are considered specific for GALOP when the levels of GGC and histone antibodies fall within the normal reference range. An elevated level of GSC antibodies in the context of an elevated GGC, and/or histone is considered polyreactive and may not represent a true positive result for GALOP [denoted by an asterisk (*) in the interpretive results table]. Samples in the borderline range for ...

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Test Name Result Flag Ref-Ranges Units Site

sulfatide have an elevated level of anti-sulfatide antibodies on the screen assay, but the level of antibodies is below the positive cut off value.

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

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 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

Performing Site:

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

Reported Date: 2023.09.01 15:12 SENPR

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

F301000029 Ordered By: KAJAL SITWALA, MD, PhD
WX0000003826 WX00000000002353
Printed D&T: 09/01/23 15:12

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