



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 15:13 Received: 09/01/2023 15:13

Table with 6 columns: Test Name, Result, Flag, Ref-Ranges, Units, Site. Row 1: Sensory Neuropathy Profile with Recombx (3148), See Note, QCRL

NEGATIVE
This panel of tests did not identify any positive results.

Table with 3 columns: Interpretive Results Table, See Note, QCRL

Interpretive Result Table

TEST: anti-GALOP
METHODODOLOGY: ELISA
INTERPRETATION: Negative
TECHNICAL RESULT: 0
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-Sulfatide
METHODODOLOGY: ELISA
INTERPRETATION: Negative
TECHNICAL RESULT: anti-Sulfatide IgG <1:2,000; anti-Sulfatide IgM <1:2,000
REFERENCE RANGE: Negative <1:2000, Borderline, Positive >=1:2000
TEST: anti-SGPG
METHODODOLOGY: ELISA
INTERPRETATION: Negative
TECHNICAL RESULT: <1:3,200
REFERENCE RANGE: Negative <=1:3200, Positive >1:3200
TEST: anti-MAG
METHODODOLOGY: ELISA
INTERPRETATION: Negative
TECHNICAL RESULT: <1:1,600
REFERENCE RANGE: Negative <=1:1600, Positive >1:1600

Table with 3 columns: Comments, See Note, QCRL

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



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Test Name Result Flag Ref-Ranges Units Site

Comments: The likelihood that this individual's clinical symptoms are associated with these antibodies has been reduced. However, this test result does not rule out an autoimmune etiology for the neurological symptoms associated with a peripheral neuropathy. If the SGPG and/or MAG ELISA is positive or inconclusive in the context of a negative MAG Western blot the result is considered negative.

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.

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 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.

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)

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<u>Test Name</u>	<u>Result</u>	<u>Flag</u>	<u>Ref-Ranges</u>	<u>Units</u>	<u>Site</u>
3. Pestronk, A, et al. (1994) Muscle Nerve 17: 1293-300. (PMID: 7523945)					

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 15:13 SENPR

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

F301000030
WX0000003826

Ordered By: KAJAL SITWALA, MD, PhD
WX00000000002353

Printed D&T: 09/01/23 15:16

Kajal V. Sitwala, MD, PhD - Medical Director

Form: MM RL1

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