Warde Medical Laboratory

TEST DIRECTORY UPDATE

JULY 2020

Update Notes

Update Summary		
New Test Activation	7/28/2020	GANGL - "Ganglioside (Asialo-GM1, GM1, GM2, GD1a, GD1b, GQ1b) Ab"
New Test Activation	7/28/2020	VEDOZ - "Vedolizumab QN with Antibodies, Serum"
Update Existing Test	7/13/2020	ACYLP - "Acylcarnitine, Plasma"
Update Existing Test	6/9/2020	IL6 - "Interleukin 6"

Warde Medical Laboratory

TEST DIRECTORY UPDATE

JULY 2020

New Test Activation			
Effective Date	7/28/2020		
Name	Ganglioside (Asialo-GM1, GM1, GM2, GD1a, GD1b, GQ1b) Ab		
Code	GANGL		
CPT Code(s)	83516 x 6 (RUO)		
Notes			
Specimen Requirements			
Specimen Required	Draw blood in SST. Centrifuge, separate serum immediately and send 0.3 mL serum (0.1 mL minimum) refrigerated in a screw-capped plastic vial.		
Rejection Criteria	Specimens received at room temperature. Plasma, CSF or other body fluids. Contaminated, heat-activated, hemolyzed or severely icteric or lipemic specimens		
Stability	Room temperature: Unacceptable; Refrigerated: 2 weeks; Frozen: 1 year		
Performing Information			
Methodology	Semi-quantitative Enzyme-Linked Immunosorbent Assay		
Reference Range	See report		
Performed Days	Monday, Wednesday, Friday		
Turnaround Time	2 - 6 days		
Performing Laboratory	ARUP Reference Laboratory		
Interface Information			
Legacy Code[1]	GANGL		
Interface Order Code	3600161		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt[2]**
3600162	Asialo-GM1 Ab, IgG/IgM	88723-2	No
3600163	GM1 Ab, IgG/IgM	31500-2	No
3600164	GM2 Ab, IgG/IgM	88731-5	No
3600165	GD1a Ab, IgG/IgM	88724-0	No
3600166	GD1b Ab, IgG/IgM	88730-7	No
3600167	GQ1b Ab, IgG/IgM	88729-9	No

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT
WX0000003039 M 12/05/1988 31 Y

Referral Testing

Collected: 06/01/2020 10:00 Received: 06/05/2020 09:01

Test Name	Result	Flag	Ref-Ranges	Units	Site
Ganglioside (Asialo-GM1,GM1,GM2,GD1a,GD1b,GQ1b) Ab					
Asialo-GM1 Ab, IgG/IgM	8		0-50	IV	ARRL
GM1 Ab, IgG/IgM	7		0-50	IV	ARRL
GM2 Ab, IgG/IgM	**53**	**H**	0-50	IV	ARRL
GD1a Ab, IgG/IgM	**54**	**H**	0-50	IV	ARRL
GD1b Ab, IgG/IgM	6		0-50	IV	ARRL
GQ1b Ab, IgG/IgM	**56**	**H**	0-50	IV	ARRL

INTERPRETIVE INFORMATION: Ganglioside (Asialo-GM1, GM1, GM2, GD1a, GD1b, and GQ1b) Antibodies, IgG/IgM

29 IV or less: Negative
30-50 IV: Equivocal
51-100 IV: Positive
101 IV or greater: Strong Positive

Ganglioside antibodes are associated with diverse peripheral neuropathies. Elevated antibody levels to ganglioside-monosialic acid (GM1), and the neutral glycolipid, asialo GM1 are associated with motor or sensorimotor neuropathies, particularly multifocal motor neuropathy. Anti-GM1 may occur as IgM (polyclonal or monoclonal) or IgG antibodies. These antibodies may also be found in patients with diverse connective tissue diseases as well as normal individuals. GD1a antibodies are associated with different variants of Guillain-Barre syndrome (GBS) particularly acute motor axonal neuropathy while GD1b antibodies are predominantly found in sensory ataxic neuropathy syndrome. Anti-GQ1b antibodies are seen in more than 80 percent of patients with Miller-Fisher syndrome and may be elevated in GBS patients with ophthalmoplegia. The role of isolated anti-GM2 antibodies is unknown. These tests by themselves are not diagnostic and should be used in conjunction with other clinical parameters to confirm disease.

Test developed and characteristics determined by ARUP Laboratories. See Compliance Statement D: aruplab.com/CS
Performed By: ARUP Laboratories
500 Chipeta Way
Salt Lake City, UT 84108
Laboratory Director: Julio C. Delgado, MD, MS

Performing Site:
ARRL: ARUP REFERENCE LAB 500 Chipeta Way Salt Lake City UT 841081221

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

Warde Medical Laboratory

TEST DIRECTORY UPDATE

JULY 2020

New Test Activation			
Effective Date	7/28/2020		
Name	Vedolizumab QN with Antibodies, Serum		
Code	VEDOZ		
CPT Code(s)	80280 (Vedolizumab), 82397 (Antibodies)		
Notes	Patient Preparation: **12 hours prior to testing**: Do not take multivitamins or dietary supplements containing biotin (Vitamin B7). Nivolumab must be discontinued at least 4 weeks prior to testing.		
Specimen Requirements			
Specimen Required	Draw blood in red top. Centrifuge within 2 hours of collection and send 1.5 mL serum (0.75 mL minimum) refrigerated in a screw-capped plastic vial.		
Alternate Specimen	Serum: SST		
Rejection Criteria	Gross hemolysis, lipemia or icterus samples		
Stability	Room temperature: Unacceptable; Refrigerated: 28 days; Frozen: 28 days		
Performing Information			
Methodology	Vedolizumab Quant: Liquid Chromatography-Mass Spectrometry (LC-MS/MS) Vedolizumab Antibodies: Electrochemiluminescent Bridging Immunoassay		
Reference Range	VEDOLIZUMAB QUANTITATION: Vedolizumab lower limit of quantitation = 2.0 mcg/mL VEDOLIZUMAB ANTIBODIES: Antibodies to vedolizumab: <9.8 ng/mL		
Performed Days	Vedolizumab Quant: Monday, Thursday; Vedolizumab Antibodies: Tuesday, Friday		
Turnaround Time	8 - 16 days		
Performing Laboratory	Mayo Medical Laboratories		
Interface Information			
Legacy Code[1]	VEDOZ		
Interface Order Code	3800094		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt[2]**
3800095	Vedolizumab QN, S	90805-3	No
3800096	Vedolizumab Ab, S	86899-2	No
3800097	VEMAB Interpretation	59462-2	No

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT
WX0000003039 M 12/05/1988 31 Y

Referral Testing

Collected: 06/02/2020 13:00 Received: 06/05/2020 09:10

Test Name	Result	Flag	Ref-Ranges	Units	Site
Vedolizumab QN with Antibodies, Serum					
Vedolizumab QN, S	23.0			mcg/mL	MMRL

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-------------------REFERENCE VALUE--------------------------
Lower limit of quantitation = 2.0 mcg/mL

-------------------ADDITIONAL INFORMATION-------------------
This test was developed and its performance characteristics
determined by Mayo Clinic in a manner consistent with CLIA
requirements. This test has not been cleared or approved by
the U.S. Food and Drug Administration.
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Vedolizumab Ab, S	<9.8		<9.8	ng/mL	MMRL
VEMAB Interpretation	SEE BELOW				MMRL

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RESULT: Absence of detectable antibody-to-vedolizumab.

-------------------ADDITIONAL INFORMATION-------------------
This test was developed and its performance characteristics
determined by Mayo Clinic in a manner consistent with CLIA
requirements. This test has not been cleared or approved by
the U.S. Food and Drug Administration.

Test Performed by:
Mayo Clinic Laboratories - Rochester Superior Drive
3050 Superior Drive NW, Rochester, MN 55901
Lab Director: William G. Morice M.D. Ph.D.; CLIA# 24D1040592
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Performing Site:
MMRL: MAYO MEDICAL REFERENCE LAB 3050 Superior Drive NW Rochester MN 55901

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

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TEST DIRECTORY UPDATE

JULY 2020

Update Existing Test	
Effective Date	7/13/2020
Name	Acylcarnitine, Plasma
Code	ACYLP
Interface Order Code	3400204
Legacy Code	ACYLP
Notes	Additional alternate specimens accepted.
Required Testing Changes	
Alternate Specimen	**Serum: SST or red-top**

Update Existing Test	
Effective Date	6/9/2020
Name	Interleukin 6
Code	IL6
Interface Order Code	3000067
Legacy Code	IL6
Notes	Stability changes.
Required Testing Changes	
Stability	Room temperature: Unacceptable; Refrigerated: 48 hours; **Frozen: 14 days**