Overview

Useful For

Assessing the unexpected loss of response to therapy with vedolizumab over time

An aid to achieving desired serum levels of vedolizumab

Profile Information

Test ID	Reporting Name	Available Separately	Always Performed
VEDOL	Vedolizumab QN, S	Yes	Yes
VEMAB	Vedolizumab Ab, S	No	Yes

Testing Algorithm

When this test is ordered, vedolizumab quantitation and testing for antibodies to vedolizumab will always be performed.

This test includes both quantitation and antibody testing on all specimens. The therapeutic thresholds for vedolizumab and optimal concentrations associated with good outcomes are not well established. The American Gastroenterology Association (AGA) does not have a formal guideline on optimal thresholds for vedolizumab at this time.

If there is a known justification for performing both quantitation and antibody levels, this is the correct test to order. If there is not a known reason to perform the antibodies component, order VEDOL / Vedolizumab Quantitation with Reflex to Antibodies, Serum. VEDOL begins with quantitation and when quantitation results are 15.0 mcg/mL or less, testing for antibodies to vedolizumab will be performed.

Method Name

VEDOL: Liquid Chromatography-Mass Spectrometry (LC-MS/MS)

VEMAB: Electrochemiluminescent Bridging Immunoassay

NY State Available

Yes

Specimen

Specimen Type

Serum

Advisory Information

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Specimen Required

1. **Patient Preparation: For 12 hours before specimen collection do not** take multivitamins or dietary supplements containing biotin (vitamin B7), which is commonly found in hair, skin, and nail supplements and multivitamins.

2. Nivolumab (Opdivo) must be discontinued at least 4 weeks prior to testing for vedolizumab quantitation in serum.

Container/Tube:

Preferred: Red top

Acceptable: Serum gel

Specimen Volume: 1.5 mL

Collection Instructions:

1. Draw blood immediately before next scheduled dose (trough specimen).

2. Centrifuge within 2 hours of draw.

Forms

If not ordering electronically, complete, print, and send a Gastroenterology and Hepatology Client Test Request (T728) with the specimen.

Specimen Minimum Volume

0.75 mL

Reject Due To

Gross hemolysis	OK
Gross lipemia	OK
Gross icterus	OK

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Refrigerated (preferred)	28 days	
	Frozen	28 days	

Clinical and Interpretive

Clinical Information

Vedolizumab (Entyvio) is a humanized monoclonal antibody directed against integrin alpha-4 beta-7. Blocking the alpha-4 beta-7 integrin results in a gut-selective anti-inflammatory response. The drug is FDA-approved for the treatment of adult patients with moderately to severely active ulcerative colitis or Crohn disease. Although optimal therapeutic concentrations of vedolizumab are not well known, Mayo Clinic Gastroenterologists are working to correlate drug concentrations with patient outcomes. Vedolizumab testing will assess the patients loss of response to therapy, similar to therapy received using tumor necrosis factor (TNF) inhibitors, such as infliximab and adalimumab. Some patients on vedolizumab may develop antibodies to vedolizumab (ATV) over time. In clinical trials, approximately 4% of patients treated with vedolizumab were positive for ATV at any time and 1% or less were persistently positive. Therefore, simultaneous testing for measurement of ATV is recommended. ATV uses a bridging immunoassay on an electrochemiluminescence (Mesoscale Discovery) platform.

Reference Values

VEDOLIZUMAB QUANTITATION:

Vedolizumab lower limit of quantitation=2.0 mcg/mL

VEDOLIZUMAB ANTIBODIES:

Antibodies to vedolizumab: <9.8 ng/mL

Interpretation

Data in the literature with association of vedolizumab trough levels and improved outcomes is still scarce. The limit of quantitation of the test is 2.0 mcg/mL. In a retrospective Mayo Clinic study conducted from 2016-2017 with 171 patients (62% Crohn disease, 31% ulcerative colitis, and 7% indeterminate colitis), the median vedolizumab trough concentration was 15.3 mcg/mL. Minimum trough (immediately before next infusion) therapeutic concentrations of vedolizumab are expected to be above 15 mcg/mL.

Cautions

Patients actively undergoing therapy with both vedolizumab and nivolumab (extremely rare scenario) should not have their therapeutic vedolizumab concentration assessed using this test. If the patient has taken nivolumab in the past, they should wait for 4 weeks after therapy with nivolumab has ended before being tested for vedolizumab quantitation using this method.

The presence of high concentrations of vedolizumab might inhibit the antibodies to vedolizumab (ATV) assay yielding false-negative results. In patients with concentrations of vedolizumab greater than 15.0 mcg/mL, the presence of an ATV is of little clinical significance.

Samples containing more than 100 ng/mL biotin (vitamin B7) may interfere with ATV (in the form of depressed signal) for VEMAB / Vedolizumab Antibodies, Serum. .

Clinical management decisions for patients receiving vedolizumab treatment should not be based solely on quantitation of vedolizumab and assessment of ATV. Test results must be interpreted within the clinical context of the patient.

Clinical Reference

1. Willrich MA, Murray DL, Barnidge DR, et al: Quantitation of infliximab using clonotypic peptides and selective reaction monitoring by LC-MS/MS. Int Immunopharmacol 2015 Sep;28(1):513-520

2. Katrangi W, Ladwig PM, Barnidge DR, et al: A-260 Vedolizumab Quantitation in Serum using SRM and micro LC-ESI-Q-TOF Mass Spectrometry. Clin Chem 2015;61

3. Ladwig PM, Barnidge DR, Willrich MA: Mass Spectrometry Approaches for Identification and Quantitation of

Therapeutic Monoclonal Antibodies in the Clinical Laboratory. Clin Vaccine Immunol 2017 May 5;24(5)

4. Ladwig PM, Barnidge DR, Willrich MA: Quantification of the IgG2/4 kappa Monoclonal Therapeutic Eculizumab from Serum Using Isotype Specific Affinity Purification and Microflow LC-ESI-Q-TOF Mass Spectrometry. J Am Soc Mass Spectrom 2017 May;28(5):811-817

5. Feagan BG, Rutgeerts P, Sands BE, et al: Vedolizumab as Induction and Maintenance Therapy for Ulcerative Colitis. N Engl J Med 2013;Aug 22;369(8):699-710

6. Schulze H, Esters P, Hartmann F, et al: A prospective cohort study to assess the relevance of vedolizumab drug level monitoring in IBD patients. Scand J Gastroenterol. 2018:1-7

7. Al-Bawardy B, Piovezani Ramos G, Willrich MAV, et al: P167 Vedolizumab Trough Levels and Antibodies in Inflammatory Bowel Disease: Updated Initial Experience. Gastroenterology154:S89

Performance

Method Description

Vedolizumab Quantitation:

Vedolizumab is extracted from serum and measured by liquid chromatography (high-resolution accurate-mass, HRAM) mass spectrometry.(Unpublished Mayo method)

Vedolizumab Antibodies:

Testing for antibodies to-vedolizumab is accomplished using a laboratory-developed immunoassay.(Unpublished Mayo method)

PDF Report

No

Day(s) and Time(s) Test Performed

Vedolizumab Quantitation: Monday, Thursday

Vedolizumab Antibodies: Tuesday, Friday

Analytic Time

7 days

Maximum Laboratory Time

14 days

Specimen Retention Time

14 days

Performing Laboratory Location

Rochester

Fees and Codes

Fees

- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their Regional Manager. For assistance, contact Customer Service.

Test Classification

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.

CPT Code Information

80280

82397

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
VEDOZ	Vedolizumab QN with Antibodies, S	90794-9

Result ID	Test Result Name	Result LOINC Value
602807	Vedolizumab QN, S	90805-3
603298	Vedolizumab Ab, S	86899-2
603299	VEMAB Interpretation	59462-2