Overview

**Useful For**
Assessing the response to therapy with vedolizumab

An aid to achieving desired trough serum levels of vedolizumab

Monitoring patient compliance

**Reflex Tests**

<table>
<thead>
<tr>
<th>Test ID</th>
<th>Reporting Name</th>
<th>Available Separately</th>
<th>Always Performed</th>
</tr>
</thead>
<tbody>
<tr>
<td>VEMAB</td>
<td>Vedolizumab Ab, S</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

**Testing Algorithm**

Vedolizumab quantitation will be performed by liquid chromatography-mass spectrometry on all samples. When this test is ordered and vedolizumab results are 15.0 mcg/mL or less, then testing for antibodies to vedolizumab will be performed at an additional charge.

This test includes quantitation and, if appropriate, antibody testing will be performed. 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 both quantitation and antibody testing are needed, regardless of the quantitation results, order VEDOZ /
Vedolizumab Quantitation with Antibodies, Serum.

**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 this test 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**

<table>
<thead>
<tr>
<th>Gross hemolysis</th>
<th>OK</th>
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</thead>
<tbody>
<tr>
<td>Gross lipemia</td>
<td>Reject</td>
</tr>
<tr>
<td>Gross icterus</td>
<td>OK</td>
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**Specimen Stability Information**

<table>
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<tr>
<th>Specimen Type</th>
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<th>Time</th>
<th>Special Container</th>
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<td>Serum</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Frozen</td>
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**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 patient's 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 (in the form of depressed signal) with 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 if appropriate. Test results must be interpreted within the clinical context of the patient.

Clinical Reference
4. Ladwig PM, Barnidge DR, Willrich MA: Quantification of the IgG2/4 kappa Monoclonal Therapeutic Eculizumab


**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**

VEDOL: Monday, Thursday

VEMAB: 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.
Test Definition: VEDOL
Vedolizumab QN, S

- 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 (if appropriate)

LOINC® Information

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<td>Vedolizumab QN, S</td>
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