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

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

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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Test Definition: VEDOZ
Vedolizumab QN with Antibodies, S

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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>
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<tr>
<th>Reason</th>
<th>Status</th>
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<tr>
<td>Gross hemolysis</td>
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<td>Gross lipemia</td>
<td>OK</td>
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<tr>
<td>Gross icterus</td>
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Specimen Stability Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
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<tbody>
<tr>
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<tr>
<td></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 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


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.
Test Definition: VEDOZ
Vedolizumab QN with Antibodies, S

- 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

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