In the presence of serum anti-vedolizumab antibodies, the vedolizumab drug level reflects the antibody-unbound (free) fraction of vedolizumab in serum.

Quantitation Limit: <1.5 ug/mL

Results of 1.5 or higher indicate detection of Vedolizumab.

COMMENTS:
- The optimal drug concentration depends upon patient-specific factors including the disease and desired therapeutic endpoint.
- Mucosal healing in Ulcerative Colitis was more common in patients with higher vedolizumab trough concentrations (>30 ug/mL) (1).
- Higher trough concentrations in UC at week 6 are associated with higher remission rates at week 14. Patients with highest levels (38-79 ug/mL) exhibited a 74% remission rate (2).
- At week 6, mean trough concentrations in Crohn's Disease were 27 ug/mL. At steady state, mean levels were 13 ug/mL and 35 ug/mL in patients receiving vedolizumab every 8 weeks and every 4 weeks, respectively (3).
- Patients with Crohn's Disease and Ulcerative Colitis had similar vedolizumab pharmacokinetic data (4).

Anti-Vedolizumab Antibody

Quantitation Limit: <25 ng/mL.

Results of 25 or higher indicate detection of anti-vedolizumab antibodies.

COMMENTS:
- Anti-vedolizumab antibodies developed in about 13% of IBD patients (5).
- Patients with persistently positive anti-vedolizumab
antibodies had undetectable or reduced vedolizumab levels (5).
- Anti-drug antibody positivity should be interpreted in the context of the concomitant free drug level.
- Serial measurements over time may be helpful.
- This anti-vedolizumab antibody assay is not impeded by the presence of vedolizumab in serum, and all positive anti-vedolizumab antibody results are verified by a confirmatory test.

References:

These tests were developed and their performance characteristics determined by LabCorp. They have not been cleared or approved by the Food and Drug Administration.

However, both drug and anti-drug antibody assays have been developed and validated in accordance with FDA Guidance for Industry documents: Bioanalytical Method Validation (2013) and Assay Development and Validation for Immunogenicity Testing of Therapeutic Protein Products (2016).
**Patient Details**

DOB: 01/01/1985  
Age(y/m/d): 03/04/00  
Gender: F  
SSN:  
Patient ID:  

**Specimen Details**

Date collected: 05/01/2017 0000 Local  
Date received: 05/01/2017  
Date entered: 05/01/2017  
Date reported: 05/03/2017 0000 ET

**Physician Details**

Ordering:  
Referring:  
ID:  
NPI:  

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**General Comments & Additional Information**

**Clinical Info:** NEGATIVE RESULT

**Ordered Items**

Vedolizumab and Anti-Vedo Ab

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Anti-Vedolizumab Antibody  

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