



Test Description

Serum concentrations of vedolizumab (VDZ) may vary among equally dosed patients which can ultimately affect patient outcomes. Some patients may develop immunogenicity to VDZ by producing antibodies to vedolizumab (ATV) and the presence of persistent anti-vedolizumab antibody has been observed to substantially reduce serum concentrations of vedolizumab. The quantitative measurement of VDZ and ATV levels in serum provides healthcare providers with valuable information to help them gain a better understanding of the factors that may be affecting a patient’s loss of response.

The PROMETHEUS Anser VDZ test is a next generation and more sensitive quantitative monitoring assay that allows healthcare providers to measure and monitor serum VDZ and ATV levels at any time during therapy. Incorporating therapeutic drug monitoring may clarify what factors are contributing to a patient’s loss of response and help guide treatment decisions by providing information to help determine an appropriate course of action.

- A quantitative monitoring analysis of VDZ and ATV levels
- PROMETHEUS Anser VDZ is only offered at Prometheus
- **Specimen Requirements** - 2.0 ml Serum, SST or Red Top Tube
- **Shipping Requirements** - Ambient or cold pack
- **Storage /Stability** – 7 days ambient, 9 days refrigerated
- **Turn Around Time** - 3 business days from date of receipt

Test Information

Catalog Number	Test Name	Assay	Lower Limit of Quantification	Result Identifier*
3180	Anser VDZ	Serum vedolizumab concentration (VDZ)	<1.6 ug/ml	A00071
		Antibodies to vedolizumab (ATV) concentration	<1.6 U/ml	A00072

*Result identifier provided for use in HL7 applications.

Laboratory Description

- Prometheus is located in San Diego, CA. **Tax ID#** 33-0685754 **NPI#** 1073642641.
- Licensed in all states including New York and California.
- This test was developed and its performance characteristics determined by Prometheus Laboratories Inc. It has not been cleared or approved by the U.S. Food and Drug Administration. Prometheus Laboratories Inc. is a CAP-accredited CLIA laboratory.

CPT Codes (as applied by Prometheus)

84999 (x1), Unlisted Chemistry Procedure (Quantitative assay that simultaneously measures serum vedolizumab (VDZ) and antibodies to vedolizumab (ATV) concentrations).

Literature References

1. Data on File. Prometheus Laboratories Inc. DOF16-004, 06/2016.
2. Entyvio® (vedolizumab) Prescribing Information.
3. Raine T. Vedolizumab for inflammatory bowel disease: Changing the game, or more of the same? United European Gastroenterology Journal 2014, Vol. 2(5) 333-344.
4. Ben-Horin S., et al. Optimizing Biologic Treatment in IBD: Objective Measures, but When, How, and How Often? BMC Gastroenterology 2015;15(178)1-7.

Assays and methods within this test may be covered by one or more US pending patents. For details, please visit www.prometheuslabs.com

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