

## Final Report

Patient Information
Last, First Name:
DOB:
Sex: <b>Female</b>
Lab Accession:
Collected:
Received:
Reported:
Sample Type: <b>EDTA Blood</b>

Ordering Physician
Account No.

Antibody Detected	Patient Value (OD)	Antibody Levels
Anti-CdtB Ab	2.29	<b>Elevated</b>
Anti-Vinculin Ab	1.09	<b>Not Elevated</b>

ABOUT THE ASSAY									
<p>ibs-smart™ measures validated biomarkers, anti-CdtB and anti-vinculin, used to diagnose irritable bowel syndrome (IBS) with 96%-100% positive predictive value.<sup>1</sup> These biomarkers are elevated in &gt;60% of patients with diarrheal IBS (IBS-D) and mixed diarrheal/constipation IBS (IBS-M) indicating the root cause of IBS is likely a lasting microbiome disruption from an instance of gastroenteritis.<sup>2</sup></p> <p>Elevated anti-CdtB levels indicate an immune response to an instance of gastroenteritis. Elevated anti-vinculin levels indicate an autoimmunity has developed.<sup>2</sup></p> <p>If either antibody is 'Elevated', the test results are <b>positive</b> and <b>indicative of IBS</b>. If both antibodies are 'Not Elevated', the test results are considered <b>non-indicative of post-infectious IBS</b>, and further testing may be required to diagnose the patient's GI symptoms.</p> <p>For more information, visit <a href="http://www.ibssmart.com/results">www.ibssmart.com/results</a></p> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 30%;"></th> <th style="text-align: center; border-bottom: 1px solid black;">Reference Interval</th> <th style="text-align: center; border-bottom: 1px solid black;">Reportable Range</th> </tr> </thead> <tbody> <tr> <td>Anti-CdtB Ab</td> <td style="text-align: center;">0.00 – 1.56</td> <td style="text-align: center;">0.00 – 4.00</td> </tr> <tr> <td>Anti-Vinculin Ab</td> <td style="text-align: center;">0.00 – 1.60</td> <td style="text-align: center;">0.00 – 4.00</td> </tr> </tbody> </table>		Reference Interval	Reportable Range	Anti-CdtB Ab	0.00 – 1.56	0.00 – 4.00	Anti-Vinculin Ab	0.00 – 1.60	0.00 – 4.00
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1. Morales, W., Rezaie, A., Barlow, G. et al. Second-Generation Biomarker Testing for Irritable Bowel Syndrome Using Plasma Anti-CdtB and Anti-Vinculin Levels. *Dig Dis Sci* 64, 2019.
2. Pimentel M, Morales W, et al. Development & validation of a biomarker for diarrhea predominant irritable bowel syndrome in human subjects. *PLoS One*, 2015.

eSignature: Shelly Gunn, M.D., Ph.D.  
Laboratory Director

This test was developed and its performance characteristics determined by Pacific Diagnostics (CLIA: 05D1103594). It has not been cleared or approved by the US Foods and Drug administration (FDA). The FDA has determined that such clearance or approval is not necessary. This laboratory is certified under the clinical laboratory improvement amendments act of 1988 (CLIA-88) as qualified to perform high complexity clinical testing. Final diagnosis will be made by a healthcare professional after reviewing and interpreting the results in correlation with other relevant clinical information. Diagnosis should not be made solely from the results of this test. No final diagnosis is being made by Gemelli or Pacific Diagnostics and shall not be held liable for interpretation of the results or effects or adverse events associated with subsequent treatment. v1.3