

# HOW TO INTERPRET ibs•smart™ TEST RESULTS

**Final Report**

**Patient Information**

Last, First Name: **Lark, F**  
DOB: 01/09/1999  
Sex: **Unknown**  
Lab Accession: 12346789  
Collected: 10/16/2018  
Received: 10/17/2018  
Reported: 10/20/2018

**Ordering Physician**

Account No. 1130  
Physician Name  
Practice Name  
Address  
City, State  
ZIP, Country

**RESULTS**

Antibody Detected	Patient Value (OD)	Antibody Levels
Anti-CdtB Ab	2.71	Elevated
Anti-Vinculin Ab	1.61	Elevated

**ABOUT THE ASSAY**

**Reference Interval**  
Anti-CdtB Ab: 0.00 - 1.50  
Anti-Vinculin Ab: 0.00 - 1.00

**Reportable Range**  
0.00 - 4.00  
0.00 - 4.00

## RESULTS

Antibody Detected	Patient Value (OD)	Antibody Levels
Anti-CdtB Ab	2.71	Elevated
Anti-Vinculin Ab	1.61	Elevated

**If either antibody is 'Elevated', the test results can be considered positive and the patient can be confidently diagnosed with IBS.**

**If both antibodies are 'Not Elevated', the test results can be considered non-indicative of post-infectious IBS. Further testing may be required in this case.**

**CAP ACCREDITED**  
COLLEGE OF AMERICAN PATHOLOGISTS

ibs-smart™ is a Lab Developed Test (LDT) conducted at a CLIA Certified (CAP Accredited) Lab

## SUGGESTED INTERPRETATION OF ibs-smart™ RESULTS

Anti-CdtB	Anti-Vinculin	Test Result	Result Interpretation
Elevated	Not Elevated	<b>POSITIVE</b>	<ul style="list-style-type: none"> <li>Suggests recent or past gastroenteritis.</li> <li>Immune system has responded to CdtB toxin with antibodies.</li> </ul> <p>Studies show that anti-CdtB predicts a disturbed microbiome has occurred after gastroenteritis.</p>
Not Elevated	Elevated	<b>POSITIVE</b>	<ul style="list-style-type: none"> <li>Initial gastroenteritis may have occurred a long time ago.</li> <li>Anti-vinculin, an autoimmune response, has developed and altered microbiome may be seen.</li> </ul> <p>Based on published data, it is believed that having elevated anti-vinculin levels indicate a more severe condition and a greater chronicity of disease. (Anti-vinculin autoimmunity usually develops 3-4 months after the infection.) Furthermore, there is data to suggest that the patient is at higher risk for subsequent infectious enteritis.</p>
Elevated	Elevated	<b>POSITIVE</b>	<ul style="list-style-type: none"> <li>Immune response is fighting toxin with antibodies and fueling increasing Anti-vinculin.</li> <li>Anti-vinculin autoimmune response has developed and an altered microbiome may be seen.</li> </ul> <p>This profile suggests a recent infection or an infection in the more distant past. Based on published data, it is believed that having elevated anti-vinculin levels indicate a more severe condition and a greater chronicity of disease. Furthermore, there is data to suggest that the patient is at higher risk for subsequent infectious enteritis.</p>
Not Elevated	Not Elevated	<b>NON-INDICATIVE</b>	<ul style="list-style-type: none"> <li>Patient could still have IBS, but it may not be post-infectious in nature.</li> <li>Additional testing may help determine another cause for symptoms.</li> </ul>

### Potential Errors:

- QNS – Quantity not sufficient  
< 1 mL whole blood provided
- QNS – Quality not sufficient  
Sample age is > 5 days old  
Incorrect blood collection tube  
Incorrect sample type submitted
- Exceeds Reportable Range  
Further testing may be needed

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