Nordic Laboratories

PATIENT: XXXXXXXXXXXXX

TEST NUMBER: G-NL-XXXXX
GENDER: XXXXXX
AGE: XX

COLLECTED: 00-XXX-2024
RECEIVED: 00-XXX-2024
TESTED: 00-XXX-2024

TEST REF: GNL-NL-XXXXX

PRACTITIONER:
XXXXXXXXXXXXX

XXXXXXXXXXXXXXXXXXXXX

TEST: ibs-smart sample report

FINAL REPORT

Patient Information		Sample Information	
Lab Accession:		Sample Type:	**EDTA Blood**
First Name:		Collected:	
Last Name:		Received:	
DOB:		Reported:	
Sex:			

Ordering Physician			
Account No:		Address:	
Physician Name:		City, State:	
Practice Name:		Zip, Country:	

Antibody Detected	Patient Value (OD)	Antibody Levels
Anti-CdtB Ab	**1.97**	**Elevated**
Anti-Vinculin Ab	**2.56**	**Elevated**

About the Assay

ibs-smart® measures validated biomarkers, anti-CdtB and anti-vinculin, used to diagnose irritable bowel syndrome (IBS) with 96%-100% positive predicted value.[1] These biomarkers are elevated in >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.[2]

Elevated anti-CdtB levels indicate an immune response to an instance of gastroenteritis. Elevated anti-vinculin levels indicate an autoimmunity has developed.[2]

If either antibody is 'Elevated', the test results are **positive** and **indicative of IBS**. If both antibodies are 'Not Elevated', the test results are considered **non-indicative of post-infectious IBS**, and further testing may be required to diagnose the patient's GI symptoms.

	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

For more information, visit **ibssmart.com/results**

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: _____ **3/2/2022 10:13 PST**

This test was developed and its performance characteristics determined by PacificDx (CLIA: 05D2243972). 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 PacificDx or Gemelli Biotech and shall not be held liable for interpretation of the results or effects or adverse events associated with subsequent treatment.

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