

Final Report Date:	09-25-2018 15:21	Specimen Collected:	09-24-2018 15:21
Accession ID:	1809250279	Specimen Received:	09-25-2018 09:21

LAST NAME	FIRST NAME	MIDDLE NAME	GENDER	DATE OF BIRTH	ACCESSION ID
IBSSURE	DEMO		MALE	1996-04-13	1809250279

PATIENT

Name: DEMO IBSSURE
Date of Birth: 1996-04-13
Gender: Male
Age: 22
Height: 6'1" Weight: 169.0 lbs

Telephone #: 666-666-8888
Street Address: 1021 HOWARD AVENUE SUITE B
City: SAN CARLOS
State: CA Zip #: 94070
Email: demo@demo.com

Fasting: FASTING

PROVIDER

Practice Name: Demo Client, MD
Provider Name: Demo Client, MD (999994)
Street Address: 1021 HOWARD AVENUE
City: SAN CARLOS
State: CA
Zip #: 94070
Telephone #: 800-842-7268
Fax #: 222-222-2222

Vibrant Wellness is pleased to present to you, **IBSSure**, to help you make healthy lifestyle choices in consultation with your physicians and dietitians. It is intended to be used as a tool to encourage a general state of health and well-being.

Vibrant IBSSure is a tool to determine IgG antibodies to 2 antigens – Vinculin and Cytolethal Distending Toxin B (CdtB) tested using a chemiluminescent technology delivering high sensitivity and specificity of detection.

Interpretation of Report: The test results of IgG antibody levels to Vinculin and CdtB are calculated by comparing the average intensity of the respective antibody to that of a healthy reference population. Reference ranges have been established using a sample cohort comprising of 96 IBS-D, 96 IBD, 96 celiac and 192 healthy serum samples. The results are displayed in 3 columns surrounded by **GREEN (In Control)**, **YELLOW (Moderate)** or **RED (High Risk)** box. Related information and comments will populate if you have a **YELLOW** or **RED** result for any of the tests.

The Vibrant Wellness platform provides tools for you to track and analyze your general wellness profile. Testing for IBSSure offered by Vibrant Wellness is performed by Vibrant America LLC, a CLIA certified lab CLIA#:05D2078809. Vibrant Wellness provides and makes available this report and any related services pursuant to the Terms of Use Agreement (the "Terms") on its website at www.vibrant-wellness.com. By accessing, browsing or otherwise using the report or website or any services, you acknowledge that you have read, understood, and agree to be bound by these terms. If you do not agree to accept these terms, you shall not access, browse or use the report or website. The statements in this report have not been evaluated by the Food and Drug Administration and are only meant to be lifestyle choices for potential risk mitigation. Please consult your Physician/Dietitian for medication, treatment or life style management. This product is not intended to diagnose, treat, or cure any disease.

Please Note - It is important that you discuss any modifications to your diet, exercise and nutritional supplementation with your physician before making any changes.

To schedule an appointment with Vibrant Clinical Dietitians please call: Toll-Free 866-364-0963.

LAST NAME	FIRST NAME	MIDDLE NAME	GENDER	DATE OF BIRTH	ACCESSION ID
IBSSURE	DEMO		MALE	1996-04-13	1809250279

IBSSure	Test name	In Control	Moderate	High Risk	In Control Range	Moderate Range	High Risk Range	Previous
	Anti-Vinculin IgG			25.0	≤10.0	10.1~20.0	≥20.1	26.0 08/25/2018
	Anti-Cytolethal Distending Toxin B IgG			>30.0	≤10.0	10.1~20.0	≥20.1	>30.0 08/25/2018

Comments

Elevated antibodies to Vinculin suggest likely IBS-D or IBS-M. It can likely differentiate from IBD (inflammatory bowel disease).; Elevated antibodies to Cytolethal Distending Toxin B suggest likely IBS-D or IBS-M.



Test Risk and Limitations

This test is not intended to be used as a diagnostic tool for SIBO rather as an inclusive tool to help tell whether your cramps, gassiness, bloating, and diarrhea are being caused by a type of irritable bowel syndrome (IBS).

IBSSure testing is performed at Vibrant America laboratory, and utilizes ISO-13485 developed technology. However, laboratory error can occur, which might lead to incorrect results. Some of them may include sample mislabeling or contamination, operational error or failure to obtain data for certain proteins. Vibrant's laboratory may need a second sample to complete the testing.

Vibrant America has effective procedures in place to protect against technical and operational problems. However, such problems may still occur. Examples include failure to obtain the result for a specific protein due to circumstances beyond Vibrant's control. Vibrant may re-test a sample in order to obtain these results but upon re-testing the results may still not be obtained. As with all medical laboratory testing, there is a small chance that the laboratory could report incorrect results. A tested individual may wish to pursue further testing to verify any results.

The general wellness test intended uses relate to sustaining or offering general improvement to functions associated with a general state of health while making reference to diseases or conditions. This test has been laboratory developed and its performance characteristics determined by Vibrant America LLC, a CLIA and CAP certified laboratory performing the test. The test has not been cleared or approved by the U.S. Food and Drug Administration (FDA). Although FDA does not currently clear or approve laboratory-developed tests in the U.S., certification of the laboratory is required under CLIA to ensure the quality and validity of the tests.

A limitation of this testing is that most scientific studies have been performed in Caucasian populations only. The interpretations and recommendations are done in the context of Caucasian studies, but the results may or may not be relevant to tested individuals of different or mixed ethnicities. Please note that pediatric ranges have not been established for these tests. Interference studies have not been established for individuals on immunosuppressive drugs.

Based on test results and other medical knowledge of the tested individual, health care providers might consider additional independent testing, or consult another health care provider or genetic counselor.

References

1. Lin, Henry C. "Small Intestinal Bacterial Overgrowth: A Framework for Understanding Irritable Bowel Syndrome." *Jama* 292.7 (2004): 852. Web.
2. Pimentel Mark, Walter Morales, Ali Rezaie, Emily Marsh, Anthony Lembo, James Mirocha, Daniel A. Leffler, Zachary Marsh, Stacy Weitsman, Kathleen S. Chua, Gillian M. Barlow, Enoch Bortey, William Forbes, Allen Yu, and Christopher Chang. "Development and Validation of a Biomarker for Diarrhea-Predominant Irritable Bowel Syndrome in Human Subjects." *PLOS ONE* 10.5 (2015): n. pag. Web.
3. Pimentel Mark, Walter Morales, Venkata Pokkunuri, Constantinos Brikos, Sun Moon Kim, Seong Eun Kim, Konstantinos Triantafyllou, Stacy Weitsman, Zachary Marsh, Emily Marsh, Kathleen S. Chua, Shanthi Srinivasan, Gillian M. Barlow, and Christopher Chang. "Autoimmunity Links Vinculin to the Pathophysiology of Chronic Functional Bowel Changes Following *Campylobacter* Jejuni Infection in a Rat Model." *Dig Dis Sci Digestive Diseases and Sciences* 60.5 (2014): 1195-205. Web.
4. Pimentel Mark, Walter Morales, Ali Rezaie, Emily Marsh, Anthony Lembo, Daniel A. Leffler, Stacy Weitsman, Kathleen S. Chua, Gillian M. Barlow, Enoch Bortey. "Assessment of Anti-vinculin and Anti-cytotoxin B Antibodies in Subtypes of Irritable Bowel Syndrome." *Dig Dis Sci: Digestive Disease and Science*. 62.6 (2017)