

References:

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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* 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-cytolethal Distending Toxin B Antibodies in Subtypes of Irritable Bowel Syndrome." *Dig Dis Sci: Digestive Disease and Science*. 62.6 (2017)

Regulatory Statement

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).

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.

What does a positive IBSSure mean?



If your result is positive, it is highly likely that you have IBS. IBSSure may help avoid further costly testing or procedures. Work with your practitioner or dietitian to optimize diet and lifestyle practices to enhance motility and alleviate symptoms.



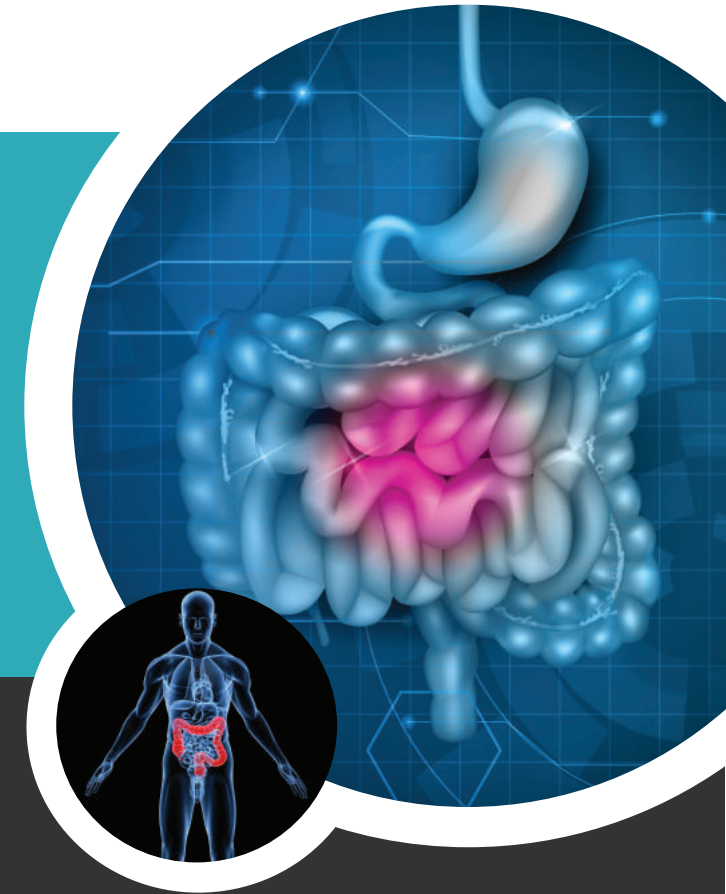
If IBSSure is inconclusive, you may benefit from taking a Hydrogen/Methane breath test.



If you are taking steroids, anti-inflammatory medications, biologic agents, or any other immunosuppressive medications, you may not get an accurate reading of your antibody levels.

What is the TAT for results?

7 days.



Contact Us



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IBSSure

A quick and reliable tool for determining IBS-D associated with Small Intestinal Bacterial Overgrowth (SIBO)

What is IBS?

Irritable bowel syndrome (IBS)

is a common disorder that affects the large intestine (colon). Irritable bowel syndrome commonly causes cramping, abdominal pain, bloating, gas, diarrhea and constipation. Even though signs and symptoms may be present, IBS, unlike ulcerative colitis and Crohn's

disease, (which are forms of inflammatory bowel disease) doesn't cause changes in bowel tissue or increase your risk of colorectal cancer.

IBS is a big issue in the world of gastroenterology. It is the most common GI disorder with worldwide prevalence rates ranging from 10-15%. There are between 2.4 and 3.5 million physician visits annually for IBS in the US. Recent research has shown that up to 84% of those with an IBS diagnosis test positive for a Small Intestinal Bacterial Overgrowth breath test.

CdtB toxins (cytolethal distending toxin B) are released by gastroenteritis causing bacteria against which antibodies are produced by the immune system. These antibodies interact with a protein, vinculin, present in the intestinal cell-lining matrix. This interaction compromises the intestinal barrier leading to impaired digestive motility. This pathogenic understanding is pinnacle in SIBO development and recurrence and has been well studied and documented.[1]

What is SIBO?

- Small intestinal bacterial overgrowth (SIBO) is defined as the presence of excessive bacteria in the small intestine.
- SIBO is frequently implicated as the cause of chronic diarrhea and malabsorption in addition to **Intestinal Permeability**.
- Patients with SIBO may also suffer from unintentional weight loss, nutritional deficiencies, and osteoporosis.
- A common misconception is that SIBO affects only a limited number of patients, such as those with an anatomic abnormality of the upper gastrointestinal (GI) tract or those with a motility disorder.
- SIBO may be more prevalent than previously thought. This apparent increase in prevalence may have occurred, in part, because readily available diagnostic tests have improved our ability to diagnose SIBO.

Symptoms associated with SIBO

- Abdominal pain/discomfort
- Bloating
- Abdominal distension
- Diarrhea
- Flatulence
- Weakness



Clinical Manifestations of SIBO (Small Intestinal Bacterial Overgrowth)

- Weight loss/Weight Gain
- Steatorrhea
- Vitamin/mineral deficiency
 - Fat-soluble vitamins (A, D, E, K)
 - Vitamin B12
 - Iron
- Vitamin excess
 - Folate
- Hypoproteinemia/hypoalbuminemia
- Mental acuity symptoms including brain fog, fatigue, anxiety, etc.
- Dietary intolerance to certain carbohydrates, fibers, and alternative sweeteners

Why Vibrant?

Vibrant IBSSure™ may help to

- Identify the patients with IBS-D associated with Small intestinal bacterial overgrowth (SIBO).
- Add a tool that can confirm IBS-D and IBS-M with 89% positive predictive rate.
- Reduce costs and prevent treatment delays.
- Help practitioners monitor risk for SIBO recurrence.
- Identify the pathophysiological reason behind IBS.

How IBSSure works?

Your physician orders the test from Vibrant and 1 SST tube (serum tube) is collected and shipped to a CLIA and CAP accredited laboratory.

Vibrant's proprietary array of protein chips capture antibodies to CdtB and Vinculin using a chemiluminescent technology delivering high sensitivity and specificity of detection compared to ELISA platforms.

