

## DIAGNOSTIC BLOOD TESTING FOR IBS



The **American College of Gastroenterology's Clinical Guidelines for the Management of IBS** suggest "a positive diagnostic strategy" (ruling in IBS) as compared to "a diagnostic strategy of exclusion" (ruling out other diseases) "...to improve time to initiate appropriate therapy...and to improve cost-effectiveness."



**ibsmart is the only licensed, mail-in blood test for IBS** and provides the positive diagnostic strategy recommended by the ACG Guidelines. ibs-smart measures anti-CdtB and anti-vinculin antibodies to diagnose IBS with **up to 100% positive predictive value**,<sup>1</sup> allowing your patients to **access treatment quickly**.

ibsmart is a Laboratory Developed Test (LDT) and is conducted in a CLIA-certified lab.

## IBS BIOMARKERS

Recent research clearly suggests that **food poisoning is the leading known cause of IBS**.<sup>2</sup>

- **1 in 9** people who experience food poisoning **develop IBS**; however, the patient may not recall the past infection.
- **Post-infectious IBS** could make up more than **60% of diarrheal IBS cases**.

Post-infectious IBS presents itself as **diarrhea-predominant or mixed-type IBS** (IBS-D or IBS-M).<sup>3</sup>

- **All common bacteria which induce food poisoning** release a toxin called Cytotoxin Distending Toxin B (CdtB). This triggers an immune response: **anti-CdtB**.
- Due to molecular mimicry, this can lead to the development of an autoimmune response, **anti-vinculin**, that can cause **gut nerve damage** and improper functioning of the Interstitial Cells of Cajal (ICC) and Migrating Motor Complex (MMC).

## IS ibs-smart RIGHT FOR YOUR PATIENT?

**ibsmart** has broad applicability to patients with **diarrheal symptoms**. Patients that experience the following for at least **one day a week for at least four weeks** could benefit from ibs-smart:

- **Diarrhea** or a **mix of diarrhea and constipation**
- **Stomach pain** and cramping
- Frequent **bloating**

If ibs-smart result is **POSITIVE** → Rule in IBS, confirm root cause, and proceed to treatment immediately.

If ibs-smart result is **NOT POSITIVE** → Patient is a good candidate for further testing.

Alarm symptoms like blood in stool or unintentional weight loss may require more urgent testing for other disorders.

## ORDER ibs-smart

Please complete the attached requisition form and email it to **support@ibssmart.com** or fax it to **(888) 675-9961**. You can also order online by visiting **orderibssmart.com**.

1. Lacy, Brian E., et al. **Clinical Guideline: Management of Irritable Bowel Syndrome**. The American Journal of Gastroenterology (2021).  
 2. Pimentel, M. et al. **Microbiome and Its Role in Irritable Bowel Syndrome**. Dig Dis Sci (2020).  
 3. Morales, W. et al. **Second-Generation Biomarker Testing for Irritable Bowel Syndrome Using Plasma Anti-CdtB and Anti-Vinculin Levels**. Dig Dis Sci (2019).  
 4. Klem F, et al. **Prevalence, Risk Factors, and Outcomes of Irritable Bowel Syndrome After Infectious Enteritis: A Systematic Review and Meta-analysis**. Gastroenterology (2017).  
 5. Rezaie, A. et al. **Autoimmunity as a Potential Cause of Post-Infectious Dysmotility: A longitudinal Observation**. American College of Gastroenterology (2017).  
 6. Pimentel M. et al. **Development and Validation of a Biomarker for Diarrhea-Predominant Irritable Bowel Syndrome in Human Subjects**. PLoS ONE (2015).

# IBS-Smart Blood Test Requisition Form

PREScriBER#: \_\_\_\_\_

For Lab Use Only

**ibsmart**<sup>®</sup>  
Fax requisition to: (888) 675-9961  
Questions? support@ibssmart.com

## PATIENT INFORMATION

Name: \_\_\_\_\_ Address 1: \_\_\_\_\_  
First MI Last  
Date of Birth: \_\_\_\_\_ Address 2: \_\_\_\_\_  
mm/dd/yyyy  
Sex (Male, Female): \_\_\_\_\_ City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_  
Email: \_\_\_\_\_ Phone: \_\_\_\_\_

## PATIENT'S INSURANCE INFORMATION

Check one box (1, 2, or 3): **\*PLEASE PROVIDE FRONT & BACK COPY OF INSURANCE CARD.\***

1 ☐ **HMO, PPO, Commercial Insurance\***

Insurance  
Provider: \_\_\_\_\_

Group #: \_\_\_\_\_

Policy ID: \_\_\_\_\_

Policyholder  
Name: \_\_\_\_\_

2 ☐ **Medicare / Medicaid\***

Medicare # or Plan  
Medicaid ID: \_\_\_\_\_ Name: \_\_\_\_\_

3 ☐ **Cash Pay (\$249)** - Patient will be billed directly via mail.

An insurance claim for **\$249** will be filed on the patient's behalf. Patients with private insurance will be billed the balance of the cost not covered by insurance. Patients with Medicare or Medicaid will be billed copays or coinsurance, if applicable.

I authorize any physician or lab who has treated me or my dependent(s) to furnish any medical information requested. In consideration of services rendered, I transfer and assign any benefits of insurance to Pacific Diagnostics. I understand I am responsible for any co-pay or deductible amounts. I understand I am fully responsible for payment of my account if Pacific Diagnostics is not a participant with my health plan, and my health plan does not fully reimburse my medical services for any reason.

**PATIENT SIGN HERE**

(REQUIRED)

DATE \_\_\_\_\_

## ORDERING PRESCRIBER INFORMATION

Practice Name: \_\_\_\_\_ Address 1: \_\_\_\_\_  
Prescriber Name: \_\_\_\_\_ Address 2: \_\_\_\_\_  
NPI: \_\_\_\_\_ City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_  
DELIVER TEST RESULTS TO: \_\_\_\_\_ Phone: \_\_\_\_\_  
Enter Email Address or Fax Number

As the ordering prescriber named above, I certify that the patient whose specimen is being submitted for analysis has been informed of the benefits and limitations of the laboratory test(s) requested, has had the opportunity to have all questions answered adequately, and, if required by my institution, has given informed consent.

**PRESCRIBER SIGN HERE**

(REQUIRED)

DATE \_\_\_\_\_

## ICD-10 DIAGNOSIS CODE (REQUIRED)

☐ **R10.9** ☐ **R11.0** ☐ **R14.0** ☐ **R14.1**  
(Abdominal Pain) (Nausea) (Abdominal Distension) (Gas Pain)  
☐ **R14.2** ☐ **R14.3** ☐ **R19.7** ☐ **K59.00**  
(Eructation) (Flatulence) (Diarrhea) (Constipation)  
Other: \_\_\_\_\_

## LABORATORY TEST ORDERED

☒ **IBS-Smart** - PLA Code: 0164U

**PacificDx**

5 Mason, Suite 100, Irvine, CA 92618  
Laboratory Director: Elizabeth S Gunn, MD, PhD

**gemelli  
biotech**

2450 W Broadway Rd, Ste 120, Mesa, AZ 85202  
Laboratory Director: Boaz Kurtis, MD

## SAMPLE COLLECTION INFORMATION

☐ **Tasso+/BD Microtainer** ☐ **Whole Blood, EDTA (Lavender Top), >2mL**

Fasting and/or changes to current medications are **NOT** required prior to blood draw.

Collection Date: \_\_\_\_\_ Time: \_\_\_\_\_  
mm/dd/yyyy 24-hr (HH:mm)

Requisition  
completed by: \_\_\_\_\_

## RECEIVING LAB USE ONLY

Received Date/Time/Tech: \_\_\_\_\_

[Accession Label]