Now you can finally get your patients a confident*

Introducing IBSchek™, the only quick and reliable blood test for a diagnosis of Irritable Bowel Syndrome (IBS)

*Based on a >90% specificity level for IBS associated with diarrhea in a large, randomized, controlled trial of >2,500 patients.
Now...A Diagnosis of IBS Is No Longer a Diagnosis of Exclusion

One of the most common functional gastrointestinal (GI) disorders—but one of the hardest to diagnose

- The diagnostic process is clouded by symptoms that mimic those of other GI disorders
- IBS symptoms are one of the top 10 reasons patients visit Primary Care Physicians

Many IBS patients often have comorbid GI and non-GI conditions

~50% of patients present with headache, back pain, poor sleep, and fatigue

Abdominal pain and discomfort are the 2 most common reasons patients seek medical care

As a result:
Physicians may have difficulty correlating these symptoms to IBS, resulting in a long lag time—often more than 5 years—before a formal diagnosis is made.
Newly established biomarkers result in a faster diagnosis of IBS

The presence of anti-CdtB* and anti-vinculin antibodies in patients with IBS associated with diarrhea:

• Suggests a pathophysiology of IBS based on postinfection molecular changes
• Can help identify IBS without excessive investigation
• Helps to overcome the difficulty in making a differential diagnosis of IBS from Inflammatory Bowel Disease (IBD) based on ROME III criteria

*CdtB=cytolethal distending toxin B.

“As a biomarker, measurements of anti-vinculin and anti-CdtB antibodies could help to identify IBS without excessive investigation and may help to target investigations in those where the test is negative.”

Mark Pimentel, MD
Director of the Gastrointestinal Motility Program and Laboratory
Cedars-Sinai
One Test

• A simple blood test means that patients may no longer be required to undergo invasive body imaging, including colonoscopy and endoscopy, to rule out alternative organic explanations for their symptoms

• IBSchek™ tests for the presence of antibodies to a toxin from gastroenteritis called CdtB, as well as vinculin, a protein commonly found in the lining of the gut
  – Levels of the 2 antibodies are complementary and together enable clinicians to make a diagnosis of IBS

• IBSchek requires just 3 cc of blood, which can be drawn in the healthcare provider’s office—or at one of our 180 Collection Sites

One Answer

• Proprietary ELISA* test based on 2 validated serum biomarkers with a high specificity provides a confident diagnosis

• Results of a study with more than 2,500 people confirmed that IBSchek can differentiate between IBS associated with diarrhea and IBD

• By year-end, results from studies validating the efficacy of the test in identifying IBS associated with constipation are expected

*ELISA=enzyme-linked immunosorbent assay.
In One Day

• All IBShck tests are analyzed at Commonwealth Laboratories’ state-of-the-art facilities, located in Salem, MA
• Results are reported back to the ordering healthcare provider within 24 hours after receipt of the sample via your choice of fax or our HIPAA-compliant, secure, web-based reporting system

90% SPECIFICITY for CdtB

(+ ) POSITIVE for IBS, initiate appropriate therapy

(?) INCONCLUSIVE for IBS, continue with further investigation
New Insights Into the Pathogenesis of IBS

A cascade that leads from immune response to autoimmune disorder

• Studies have demonstrated a direct causal relationship between an episode of acute gastroenteritis, or food poisoning, and the development of IBS
• Animal studies confirm the link between food poisoning and bacterial overgrowth
• Specific bacteria—such as *Campylobacter jejuni*, *Escherichia coli*, *Salmonella*, and *Shigella*—play an integral role in the pathogenesis
• These bacteria often generate a toxin called CdtB
• The body reacts to CdtB with an immune response—generating antibodies in the bloodstream
• Because of structural similarities, these antibodies cross-react to a protein in the nerves of the gut known as vinculin
  – This process is called molecular mimicry and results in an autoimmune response
• This autoimmunity affects the function of the gut
• The loss of function leads to neuronal degradation and reduced motility

Gut nerve damage

• With gut motility reduced, stasis occurs as the natural flow pattern is disrupted
• This stasis leads to bacterial overgrowth, also known as SIBO, or small intestine bacterial overgrowth

Bacterial overgrowth

• The entire process leads to the bloating and abdominal pain that are the initial signs and symptoms of IBS

**IBSchek™ is designed to detect the antibody response**

• A standard serum-based ELISA panel tests for the presence and levels of both anti-CdtB and anti-vinculin
• A positive result provides a confident diagnosis based on this mechanism of action

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Ordering IBSchek™ Is Quick and Easy

Draw the specimen in YOUR office or facility...

**OPTION 1: Use OUR kits**

Order IBSchek Kits for everything you need to draw and ship the specimen

Visit our website IBSchek.com

Call our toll-free number 1-877-IBS-CHEK (427-2435)

**OPTION 2: Use YOUR supplies**

Order ReqDek™ a pad of 50 IBSchek Laboratory Requisition Forms

Draw the blood

Ship the specimen

Results back within 24 hours of receipt

*Optical density values are corrected for nonspecific binding and cross-reactivity within the human serum sample.

† A positive IBSchek™ result suggests that there is a >90% specificity for IBS and that the IBS may be due to previous gastroenteritis. An inconclusive IBSchek result does not exclude IBS. It might mean that further studies are needed to rule out other causes for the patient’s gastrointestinal complaints.

The IBSchek™ test was developed and its performance characteristics determined by Commonwealth Laboratories, Inc. It has not been cleared or approved by the U.S. Food and Drug Administration. Performance characteristics refer to the analytical performance of the test. These standards are guidelines only. The provider should use this data in conjunction with additional clinical information that is unavailable to Commonwealth to make a clinical diagnosis. Commonwealth is a Clinical Laboratory Improvement Amendment (CLIA)–certified, independent clinical laboratory and is required under CLIA to ensure the quality and validity of the IBSchek™ test.

Notes:

Summary of Results:

<table>
<thead>
<tr>
<th>Antibody Reference Range</th>
<th>Patient Value</th>
<th>Clinical Significance of Patient Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Optical density</td>
<td></td>
<td>* Inconclusive IBS positive†</td>
</tr>
<tr>
<td>Cytolethal distending toxin B (CdtB) ≥ 2.8</td>
<td>2.85</td>
<td>✓</td>
</tr>
<tr>
<td>Vinculin</td>
<td>≥ 1.68</td>
<td>0.60</td>
</tr>
</tbody>
</table>

All logos and trademarks are the intellectual property of Commonwealth Laboratories, Inc., Salem, MA.
...Or use one of OUR 180 Collection Sites

Finding an IBSchek Collection Site Is Easy...

Visit our website IBSchek.com

Call our toll-free number
1-877-IBS-CHEK (427-2435)

Complete the IBSchek Laboratory Requisition Form

1. Send patient—with completed form—to one of 180 Collection Sites

2. Lab will draw blood and send the specimen to Commonwealth Laboratories
   – Patient will be responsible for a $25 processing fee

3. You will have results within 24 hours of Commonwealth Laboratories’ receipt of the specimen

If there are no Collection Sites in your area, call Commonwealth Laboratories toll-free at 1-877-IBS-CHEK (427-2435). We will work out a way for you and your patients to take advantage of this exciting new diagnostic test.
Comprehensive Kits Ensures Turnkey Testing

What’s in the kit?

Everything you need to draw—and ship—the specimen

• Blood Collection Tube
• Blood Collection Needle
• Tourniquet
• Alcohol Pad
• Gauze Pad
• Bandage
• IBSchek Laboratory Requisition Form
• Prepaid Shipping Label

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Easy-to-Read Results Report

To complement the only quick and reliable blood test for IBS, Commonwealth Laboratories has developed an easy-to-read results report that will enhance the confidence of your diagnosis.

Antibodies—with reference ranges—are color coded, making it simple to interpret what your patient’s values mean

Results Interpretation clearly indicates if the levels of antibodies are consistent with a diagnosis of IBS...or if further investigation is required
IBS™ Is the Only Quick and Reliable Blood Test for a Confident Diagnosis of IBS*

✓ One Test
A simple blood test that requires just 3 cc of blood means that IBS is no longer a diagnosis of exclusion

✓ One Answer
Proprietary ELISA test based on 2 validated serum biomarkers—anti-CdtB and anti-vinculin

✓ In One Day
Results are reported back to the ordering healthcare provider within 24 hours after receipt of the specimen

For more information on IBSchek

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