Diagnostic Tests

What Physicians Need to Know

IBSchek for Irritable Bowel Syndrome

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IBSchek is a blood test marketed to assist in the diagnosis of irritable bowel syndrome with predominant diarrhea (IBS-D) or with mixed bowel habits (IBS-M) in adults.

Test	Indication	Population	Cost*
IBSchek	Diagnosis of IBS-D or IBS-M	Adults suspected of having IBS-D or IBS-M	$199

IBS-D = irritable bowel syndrome with predominant diarrhea; IBS-M = irritable bowel syndrome with mixed bowel habits.

*—Payment rate according to Commonwealth Diagnostics International.

Accuracy

The diagnosis of IBS-D or IBS-M is made using Rome IV criteria, which include the presence of certain symptoms, the absence of alarm symptoms, and negative screening blood test results (complete blood count, C-reactive protein, fecal calprotectin, and celiac serologies).[1,2] The type of IBS is categorized based on the predominant type of stool using the Bristol stool scale: IBS-D, IBS with predominant constipation, IBS-M, and IBS unclassified.

IBSchek detects antibodies against cytolethal distending toxin B (anti-CdtB) and the cell adhesion protein vinculin (antivinculin). These serum biomarkers are thought to be involved in the pathophysiology of postinfectious IBS.[3] Studies have demonstrated a six- to sevenfold increase in the odds of developing IBS after an episode of gastroenteritis.[4,5]

The initial study of these biomarkers included 2,681 adults between 18 and 65 years of age. Of these participants, 2,375 had IBS-D using Rome III criteria, 121 had celiac disease, 142 had inflammatory bowel disease, and 43 were healthy. Anti-CdtB optical densities were highest in patients with IBS-D (2.53 ± 0.69). Patients with IBS-D were differentiated from those with inflammatory bowel disease using an anti-CdtB optical density of 2.80 or greater (specificity = 91.6%; sensitivity = 43.7%; positive likelihood ratio [LR+] = 5.2; negative likelihood ratio [LR–] = 0.6) or an antivinculin optimal density of 1.68 or greater (specificity = 83.8%; sensitivity = 32.6%; LR+ = 2.0; LR– = 0.8).[3] An additional study using Rome III criteria also showed that patients with IBS-D or IBS-M have high positivity rates of these biomarkers when compared with healthy patients.[6] However, these case-control studies overestimate true test accuracy.

Benefit

The manufacturer recommends using IBSchek to assist with the diagnosis of postinfectious IBS and in the assessment of patients with persistent symptoms consistent with IBS despite negative results on the limited screening tests described in the Rome IV criteria. However, no prospective data on diagnostic accuracy support these indications. There is also no evidence that the test improves disease management or patient-oriented outcomes.

Harms

Because of low test sensitivity, a negative result on IBSchek cannot rule out IBS-D and IBS-M. Use of this test may be challenging in some practices because it is performed only in one laboratory. Finally, patients with comorbidities commonly seen in primary care (HIV, history of diabetes mellitus, known pancreatic disease, unstable thyroid disease, chronic opioid use, bowel surgeries except cholecystectomy, and appendectomy) were excluded during initial validation of the test, raising concerns about its generalizability to these populations.

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Cost

IBSchek costs $199.[7] This test is currently not reimbursed in the 2020 Centers for Medicare and Medicaid Services' clinical laboratory fee schedule.[8]

Bottom Line

Preliminary data from studies with suboptimal designs suggest that IBSchek may have promise in the diagnosis of IBS-D and IBS-M, particularly in patients with suspected postinfectious IBS. Until further studies are performed, however, there is insufficient evidence to recommend the use of this test in clinical practice.

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