

In the News

ISSUE: AUGUST 2015 | VOLUME: 66:8

Colitis Monitoring May Soon Start at Home

Like diabetics check their blood sugar, IBD patients will test for inflammation

by David Wild

Imagine having a cheap fecal calprotectin test that can be conducted anywhere and that spits out results within 12 minutes. In Europe, gastroenterologists no longer need to wait for such a test. They have access to the *IBDoc* (BÜHLMANN Laboratories), a device that allows patients to conduct fecal calprotectin testing at home.

If such a device were approved in the United States, experts believe it would profoundly change how inflammatory bowel disease (IBD) is managed.

“I think that an at-home test that can allow us to tightly control inflammation the way that endocrinologists aim to tightly control glucose levels has the potential to improve IBD outcomes,” said Peter Higgins, MD, director of the IBD program at the University of Michigan, in Ann Arbor. Dr. Higgins does not have a financial interest in the device.

How It Works

The *IBDoc* includes a stool collection and extraction kit consisting of flushable stool collection paper and a sampling pin (Figure). A collected stool sample is applied to the device’s “rapid test cassette,” which uses a technology similar to pregnancy tests to display a band of color with an intensity that matches calprotectin concentrations (www.youtube.com/watch?v=38p0zuQUCWY).

Using a smartphone and a proprietary application (CalApp), the user photographs the image produced by the cassette, and the application uploads the results to the company’s online database (*IBDoc* Portal) through a secure Internet connection. The results are immediately



available to the patient's authorized provider. The entire process of determining and displaying calprotectin levels takes 12 minutes, according to the manufacturer.

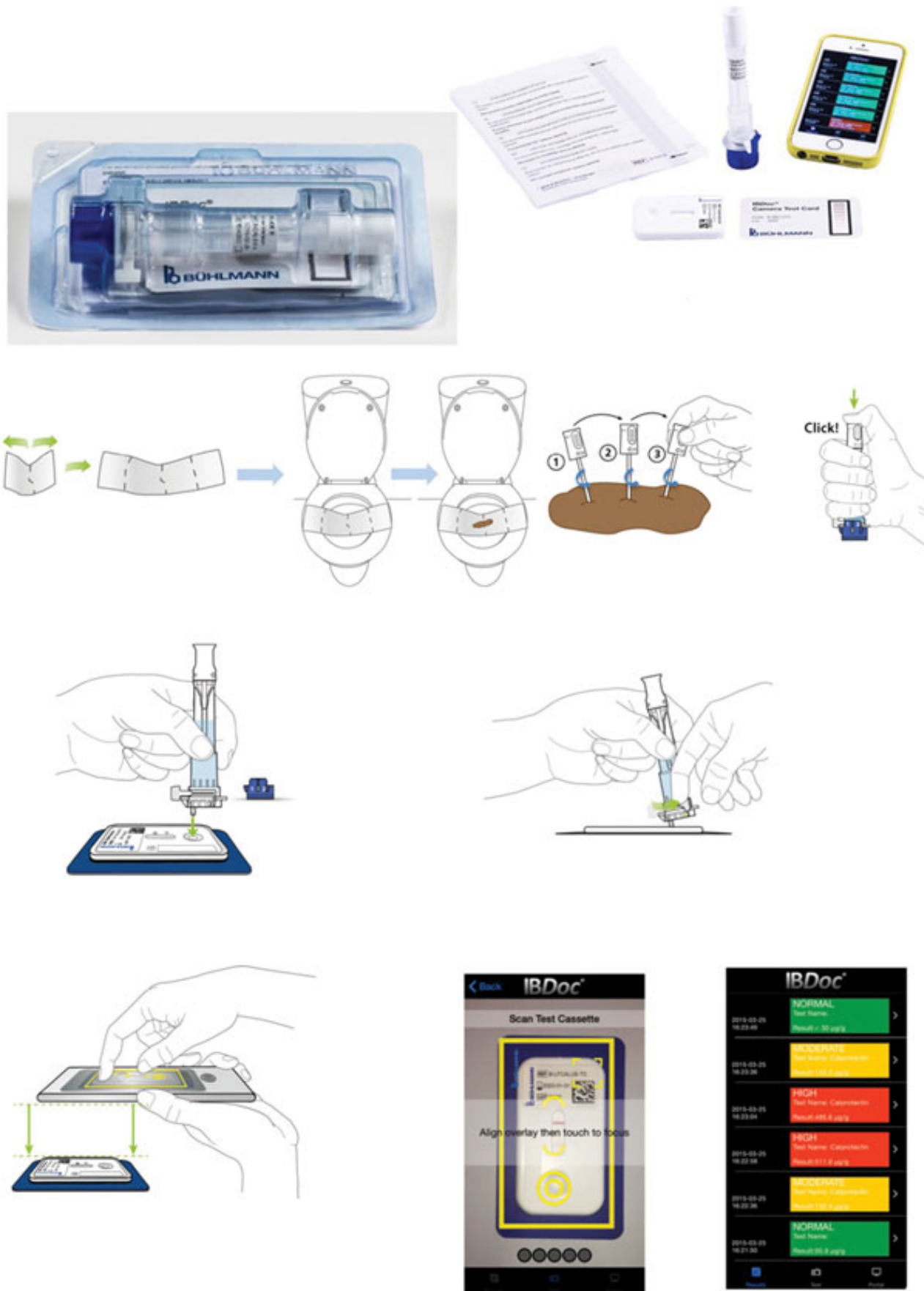


Figure. The IBDoc calprotectin home test kit.

Supporting Data

A study of 146 patients with ulcerative colitis showed calprotectin levels that were measured using a technology identical to that in the IBDoc correlated well with endoscopically confirmed mucosal inflammation (*Inflamm Bowel Dis* 2013;19:1034-1042).

A trial of 25 healthy volunteers presented at the 2015 annual congress of the European Crohn's and Colitis Organisation (abstract A-1621) demonstrated that the device is user-friendly, with almost all participants performing the test successfully after one training session and 21 individuals saying they felt comfortable using a smartphone for medical testing.

Christian Moore, PhD, chief product officer at BÜHLMANN Laboratories, in Schönenbuch, Switzerland, said physicians and patients are free to determine the frequency of testing, but the research has shown that fecal calprotectin levels rise roughly three months prior to a disease exacerbation (*J Crohns Colitis* 2015;9:1-3), so the company recommends testing every three months.

Getting Ahead of Disease Relapses

Tracking fecal calprotectin at home “has a high potential to improve disease outcomes by allowing physicians and patients to get ahead of the disease before relapses occur,” said Gary Lichtenstein, MD, professor of medicine in the Division of Gastroenterology at the Hospital of the University of Pennsylvania, and director of the IBD Center at the University of Pennsylvania's Perelman School of Medicine, both in Philadelphia.

Moreover, physicians could use the technology for other clinical applications, Dr. Lichtenstein said, pointing to data indicating that fecal calprotectin levels predict disease recurrence following intestinal resection (*Gastroenterology* 2015;148:938-947). “Physicians could use the test at the point of care to identify patients who might benefit from introduction of a new medical therapy or intensification of their current medical therapy postoperatively.”

A rapid point-of-care fecal calprotectin test could also help guide the diagnostic workup in patients presenting with diarrhea and who could have irritable bowel syndrome (IBS) or IBD, Dr. Lichtenstein added.

Knowing which patients should undergo endoscopic evaluation is particularly important in the pediatric population, since caregivers are more reluctant to put children through endoscopic procedures, he said.

“In the future, in addition to fecal calprotectin testing, one can envision a panel of at-home tests that includes other markers of inflammation, like C-reactive protein, as well as assays for measuring drug levels,” he said.

Whether or not point-of-care and at-home inflammation monitoring would lead to more

efficient health care needs to be studied, Dr. Higgins said.

“In terms of reducing the need for more costly colonoscopies, I don’t know if monitoring and screening with calprotectin or a similar inflammatory marker would really change the overall number of procedures we perform, but it would help us target these procedures [in] those patients who really need it,” he said.

Empowering Patients ... With Limits

Along with the potential for better disease management, at-home tests such as the *IBDoc* can also carry hazards, Dr. Lichtenstein said.

“What we don’t want is for patients to see that their calprotectin levels have gone up and decide on their own to take the prednisone they have in their medicine cabinet,” he said. “We should empower our patients, but not to the extent that they are making clinical decisions on their own, without appropriate guidance.”

Dr. Moore said BüHLMANN Laboratories has taken steps to reduce the likelihood of these scenarios occurring by requiring that physicians initiate use of the device.

“A provider needs to create the account, define the calprotectin thresholds they are classifying as normal, moderate or high, and select the frequency of testing in collaboration with patients,” Dr. Moore said. “The device allows patients to adopt an active role in their care while operating under the guidance and support of their health care professional.”

Patient education can further mitigate the risk of patients misinterpreting their calprotectin levels, Dr. Higgins said. He said the prospect of improved IBD care outweighs the cost required to create any necessary safeguards.

“Employing devices that stand to improve disease outcomes is the right thing to do,” Dr. Higgins said. “Our decades of experience with glucose monitoring in diabetic patients has proven tight control is a huge benefit to patients. And while prospective studies are needed to show that tight control of inflammation leads to savings in net health care costs, our experience in diabetes suggests that this could be the case.”

Dr. Moore said BüHLMANN Laboratories has started pilot studies in the United States. However, he said, “as with all FDA approvals, obtaining approval can be a long process, especially for a new product category like the smartphone-based diagnostic tests. But we do hope to launch in the United States for routine applications in the next two or three years.”

Dr. Moore said the per-use cost of the *IBDoc* will likely be below \$45. That is in sharp contrast with the price tag for the two fecal calprotectin tests currently approved in the United States—Genova Diagnostics’ Calprotectin PhiCal ELISA and Inova Diagnostics’ QUANTA Lite Calprotectin—Dr. Higgins noted.

“It’s disappointing that physicians currently need to send out a stool sample for testing, and the test costs \$200 and requires 10 days to receive the results,” Dr. Higgins said, adding that

fecal calprotectin testing is currently approved only for differentiating IBS from IBD.

“It’s unfortunate too, since affordable at-home monitoring makes absolute sense under an accountable care landscape that stresses low-cost approaches to achieve better patient outcomes,” he said.

Dr. Higgins has received research funding from BüHLMANN Laboratories. Dr. Moore is chief product officer at BüHLMANN Laboratories. Dr. Lichtenstein reported no relevant financial conflicts of interest; he is a member of the editorial board of Gastroenterology & Endoscopy News.
