Corning and Exact Sciences Partner to Help Advance Noninvasive Colorectal Cancer Screening

Custom 100 mL pipet from Corning enables Exact Sciences to move forward with large-scale release of Cologuard® and advance colon cancer screening

Exact Sciences of Madison, Wisconsin is on a mission to eradicate colorectal cancer. A tall order, for sure, but within the realm of possibilities. In August 2014, the company received FDA approval for the first test of its kind, Cologuard, a noninvasive stool DNA-based colorectal cancer screening test that requires no prior bowel preparation or dietary restrictions. FDA approval followed a large-scale clinical trial, involving 10,000 patients, in which Cologuard found 92% of curable stage cancers, as well as 69% of high-risk pre-cancers—those most likely to develop into cancer.¹

Potential to greatly increase screening compliance

A screening test able to detect colon cancer at its earliest stage is critically important; most people understand that early detection saves lives. Yet many put off getting a screening colonoscopy despite knowing its importance. So what’s the best way to help people overcome their natural resistance?
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CARA TUCKER, SENIOR MANAGER, MARKETING COMMUNICATIONS, EXACT SCIENCES

Simple, make screening easy. And that, says Cara Tucker, Senior Manager, Marketing Communications, Exact Sciences, is one of the major advantages of Cologuard, which is used in the privacy of the patient’s own home. “Because Cologuard makes it easy to provide a sample for testing, it has the potential to dramatically increase the number of people getting screened for this highly preventable disease,” says Cara, who adds, “In fact, it’s the perfect test for patients of average risk, who are unwilling to get screened. And that’s significant, considering the high percentage of the population who don’t follow recommended screening guidelines.”

Enter Corning Life Sciences

But there was a major obstacle standing in the way of Exact Sciences’ ability to take the test from clinical trials into physician practices across the country and around the world. That’s where Corning Life Sciences came in. Working in close collaboration with the Research and Development team at Exact Sciences, Corning enabled the company to resolve a pesky problem in the sample collection transfer step that could have slowed down its ability to commercialize Cologuard.

A mixed bag of goods

The partnership story began in 2013, just as the clinical trial was wrapping up and just as Justin Krause joined Exact Sciences. The first day on the job as its Non-technical Manager of Clinical Laboratory Operations, Justin recalls walking into the lab where stool samples were being prepared for testing. “I immediately realized we had a big problem on our hands,” he says. As he explains, clinical trial participants were asked to collect the stool samples at home, then mail the kit back to Exact Sciences lab for analysis, where the samples were first homogenized to help ensure uniform consistency. But unlike testing blood, which comes in only three

Cologuard Detects Stool Sample DNA in Cells Associated with Cancer and Pre-cancer

Every day, millions of normal cells are shed from the colon wall into the stool stream. As these cells degenerate, they release DNA. All colon cancers start as polyps, and as those polyps develop, they also shed cells into the stool stream. Some of these cells contain altered DNA, reflecting acquired mutations found in precancerous adenomas and cancer.

Using the Cologuard kit, a patient collects a stool sample at home and mails it to Exact Sciences Laboratories using a prepaid and pre-addressed return label provided with the kit. The lab processes the sample through a series of sophisticated laboratory procedures to isolate specific DNA targets. The targeted DNA is then amplified and analyzed for molecular alterations associated with cancerous and precancerous conditions of the colon and rectum.

Cologuard is intended for the qualitative detection of colorectal neoplasia associated DNA markers and for the presence of occult hemoglobin in human stool. A positive result may indicate the presence of colorectal cancer or advanced adenoma and should be followed by a diagnostic colonoscopy. Cologuard is indicated to screen men and women 50 years or older, who are at typical average risk for colorectal cancer. Cologuard is not a replacement for diagnostic colonoscopy or surveillance colonoscopy in high risk individuals. Cologuard is available by prescription only.

Learn more about the efficacy and safety of Cologuard by visiting www.cologuardtest.com.
states, stool samples are a “mixed bag of goods, from very thin to extremely thick,” says Justin. “We tried using a standard pipet to transfer the samples for analysis, but it didn’t have a wide enough mouth to accommodate the range of specimens.”

Nail clipper workaround, far from “ideal”
Researchers at Exact Sciences came up with a temporary fix, using a sterile dog nail clipper to cut and widen the pipet tip. But the pipet would frequently lose suction. Multiple draws were often necessary to extract a sample for transfer, and the sample amount drawn was often finite.

“Using a dog clipper in a lab environment to modify a standard pipet was far from ideal. It was extremely time-consuming; you couldn’t always get a clean clip. There was a lot of waste, added costs, and it could have opened us up to safety and contamination concerns,” explains Justin, who adds: “The process was adequate for testing samples during the clinical trial phase, when volume and time pressures aren’t a huge concern. But the nail clipper workaround was simply not practical, sustainable, or scalable for large-scale commercialization.”

No standard off-the-shelf solution
The Exact Sciences Research and Development team reached out to several manufacturers to see if an off-the-shelf pipet existed that would resolve its liquid handing challenges. The ideal pipet would need a wide enough orifice for thick samples, while being able to provide sufficient suction to draw thin samples. They found nothing in the market that would work for the spectrum of stool specimen thicknesses.

Through the grapevine, the team heard that Corning Life Sciences has a knack for solving difficult production issues by partnering with customers to design custom products. As Justin emphasizes, “Without Corning’s willingness to work with us to come up with a viable solution, we wouldn’t be where we are today.”

Not too narrow, not too wide—“just right”
It took about six months—and multiple iterations—to develop a pipet that was “just right—not too narrow, not too wide,” Justin recalls. “We got to be Goldie Locks in the story. We’d say, there’s not enough pressure to pick up volume, and Corning would go back at it again.” And Justin notes, “At the time, we were just a small lab in Madison with a big dream. We weren’t nearly as well known and hadn’t yet gotten FDA approval. We also knew that the custom pipet would be a niche product, making it less economically attractive for suppliers to manufacture.”

In fact, as Justin points out, “Every time we place a new order, Corning has to shut down its production line, then rework it to accommodate us. That speaks volumes about them; they care enough about supporting their customers, they were willing to get into the trenches with the little guy from Wisconsin before we had even secured FDA approval.”

Corning sets Exact Sciences up for high throughput screening
Once the prototype was finalized, Corning delivered its first batch of 40,000 custom 100 mL pipets. "Corning is exceptionally honored to be part of Exact Sciences’ mission to eradicate colorectal cancer. When it comes to cancer screening, it’s all about advancing early detection, and that’s what Cologuard is all about.”

ROBERT CURRY, PRODUCT MANAGER, LIQUID HANDING, CORNING LIFE SCIENCES

Cologuard Offers Clinically Proven Sensitivity in a Noninvasive Colorectal Cancer Screening Test

In a clinical study published in the New England Journal of Medicine, Cologuard was found to have 92% sensitivity in detecting cancer stages I-IV (compared with about 74% for FIT) and to be 94% sensitive in detecting early-stage colorectal cancer (stage I-II). To view all of the data, visit www.nejm.org.
pipets in the Fall of 2014, helping Exact Sciences establish a highly-automated, state-of-the-art clinical laboratory to streamline the sample transfer process and increase its high throughput capabilities. Says Justin: “Corning set us up so that we could commercialize and scale up using a lean and clean process.”

**Accelerating Adoption**

Today, Cologuard is being adopted by such major healthcare providers as Mayo Clinic Health System, along with more than 10,000 independent physicians. As of June 2015, Exact Sciences had already screened a large number of samples and expects that number to continue to quickly accelerate over the coming months.

Exact Science also has a 24/7 customer support center, which Cara says is key to increasing patient compliance with guidelines, which specify colorectal cancer screening beginning at age 50. Marcia Mullins, colon cancer survivor-advocate, said it best when she told the FDA advisory panel during its review of Cologuard: “All of this, the life-threatening danger of this cancer, the fear, the pain, the incredible expense, the impact on my family, all of this could have been avoided if I’d only gotten screened on time.”

**Ready to deliver to meet demands**

Corning stands ready to deliver the volume of pipets required to keep pace with demand.

As Robert Curry, Product Manager, Liquid Handling, Corning Life Sciences, says: “Corning is exceptionally honored to be part of Exact Sciences’ mission to eradicate colorectal cancer. We have no doubt that Cologuard will transform colon cancer screening, as more and more people hear about the technology and begin routinely asking their doctors about Cologuard. When it comes to cancer screening, it’s all about advancing early detection, and that’s what Cologuard is all about.”

**Reference**


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