

# Abbott's Cologuard Plus® Receives CE Mark For Colorectal Cancer Screening In Europe

- Cologuard Plus is a noninvasive, stool-based DNA screening test designed to detect both colorectal cancer and advanced precancerous lesions
- In the pivotal BLUE-C study, Cologuard Plus demonstrated 95% sensitivity for colorectal cancer at 94% specificity in the screened population
- CE Mark is an important regulatory milestone as Abbott prepares to introduce Cologuard Plus in select European markets, with timing and availability varying by country

ABBOTT PARK, Ill., Oct. 20, 2026 /PRNewswire/ -- Abbott, a global healthcare leader, announced today that the Cologuard Plus® test has received CE Mark under the European Union's In Vitro Diagnostic Medical Devices Regulation (IVDR), marking an important step toward making the noninvasive colorectal cancer screening test available in Europe.

Cologuard Plus is a DNA test designed to detect both colorectal cancer and advanced precancerous lesions. The test analyzes DNA markers and blood in stool associated with colorectal cancer and precancer and does not require bowel preparation, dietary restrictions or sedation.

The CE Mark represents an important regulatory milestone in Abbott plans to bring Cologuard Plus to people in Europe. Abbott plans to introduce the test in select European markets, with the timing and availability varying by country based on local healthcare pathways, reimbursement and operational readiness.

"Screening is one of the most powerful tools we have in the fight against colorectal cancer, but it only works when people complete it," said Jake Orville, senior vice president of Abbott's cancer diagnostics business. "Cologuard has helped transform colorectal cancer screening in the United States by giving people an effective, convenient option they can complete at home. With Cologuard Plus, we've built on that experience with even stronger performance. Receiving CE Mark is an important step toward bringing this option to more people and helping address unmet screening needs across Europe."

## Addressing a significant cancer burden in Europe

Colorectal cancer is one of the most commonly diagnosed cancers in Europe. In 2022, approximately 538,000 people across Europe were diagnosed with the disease.<sup>1</sup> Within the European Union, colorectal cancer accounted for more than 356,000 new cases, or approximately 13% of all new cancer diagnoses.<sup>2</sup>

Screening can identify colorectal cancer earlier, when treatment may be more effective, and can also identify certain precancerous lesions before they progress to cancer. Yet participation in colorectal cancer screening varies considerably across Europe. In 2022, an average of 42% of people in the target age group across reporting EU countries participated in colorectal cancer screening within the previous two years.<sup>3</sup>

"Colorectal cancer remains a major public-health challenge in Europe, and increasing participation in screening is an important part of addressing it," said Dr. Cesare Hassan, Full Professor of Gastroenterology at Humanitas University, Milan, Italy. "Expanding access to accurate, noninvasive screening options that people are willing to complete could help identify more cancers earlier and detect advanced precancerous lesions before they progress."

## How Cologuard Plus screens for colorectal cancer

Cologuard Plus uses a stool sample that patients collect at home. The test analyses multiple DNA markers and blood in the stool associated with colorectal cancer and advanced precancerous lesions. For the sample-collection process, patients do not need bowel preparation, dietary changes, sedation, or time away from work or other activities.

## Clinical performance demonstrated in the BLUE-C study

Cologuard Plus was evaluated in BLUE-C, a prospective, multicentre study of more than 20,000 participants and one of the largest prospective studies of colorectal cancer screening.

Among the U.S. screening population, Cologuard Plus demonstrated:

- 95% sensitivity for colorectal cancer detection at 94% specificity<sup>4</sup>
- 43% sensitivity for advanced precancerous lesions<sup>4</sup>
- 74% sensitivity for high-grade dysplasia, the type of precancerous lesion most likely to progress to cancer<sup>4</sup>
- Up to a 40% reduction in false-positive results compared with the original Cologuard test<sup>5</sup>

Results from the BLUE-C study were published in the *New England Journal of Medicine*.

Cologuard Plus incorporates novel biomarkers and improvements to laboratory processes and sample stability, building on more than a decade of experience with the original Cologuard test.

## About the Cologuard and Cologuard Plus tests

Developed in collaboration with Mayo Clinic, Cologuard® and Cologuard Plus® are noninvasive, stool-based colorectal cancer

screening tests. Cologuard Plus detects colorectal neoplasia-associated DNA markers and occult blood in stool. The test is indicated to screen adults aged 45 years or older who are at average risk for colorectal cancer and uses a stool sample collected at home.

A positive Cologuard Plus result may indicate the presence of colorectal cancer or advanced precancerous lesions and should be followed by a colonoscopy. Cologuard Plus is not a replacement for diagnostic colonoscopy or surveillance colonoscopy in high-risk individuals.

The first version of the Cologuard test was launched in the United States in 2014 and has been used for more than 23 million screenings. Cologuard Plus builds on this experience with enhanced clinical performance and additional improvements to the testing process.

#### **About Abbott:**

Abbott is a global healthcare leader that helps people live more fully at all stages of life. Our portfolio of life-changing technologies spans the spectrum of healthcare, with leading businesses and products in diagnostics, medical devices, nutritionals and branded generic medicines. Our 122,000 colleagues serve people in more than 160 countries.

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1. Ferlay J, et al. Global Cancer Observatory: Cancer Today. International Agency for Research on Cancer. GLOBOCAN 2022.
2. European Commission, European Cancer Information System. Colorectal cancer prevention: prevalence and incidence in the European Union.
3. OECD/European Commission. Health at a Glance: Europe 2024: State of Health in the EU Cycle. Cancer screening. 2024. [OECD – Health at a Glance: Europe 2024](#)
4. Cologuard Plus Clinician Brochure. Exact Sciences Corporation.
5. Data on file. Exact Sciences Corporation.

\*94% specificity was determined among adults with no colorectal neoplasia and age-weighted to the U.S. population.

NOTE: Cologuard and Cologuard Plus are trademarks of the Abbott group of companies

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