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**NOW FDA APPROVED** FOR COLORECTAL CANCER (CRC) SCREENING

## **Educational resources**

Here is more information to educate your patients and the rest of your practice about the benefits of the Shield<sup>™</sup> blood test and the importance of early CRC screening.

Instructional videosPeer testimonialsPreventive health education	



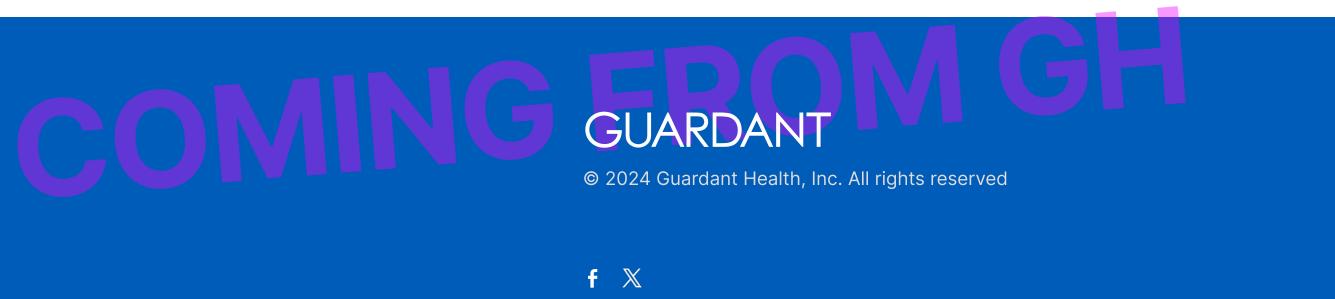
## **Intended Use**

- The Shield test is a qualitative in vitro diagnostic test intended to detect colorectal cancer derived alterations in cell-free DNA from blood collected in the Guardant Shield Blood Collection Kit.
- Shield is intended for colorectal cancer screening in individuals at average risk of the disease, age 45 years or older. Patients with an
  "Abnormal Signal Detected" may have colorectal cancer or advanced adenomas and should be referred for colonoscopy evaluation. Shield is
  not a replacement for diagnostic colonoscopy or for surveillance colonoscopy in high-risk individuals. This test is performed at Guardant
  Health, Inc.

## Important Safety Information

- The Shield test is not indicated for an individual who:
- Has a personal history of colorectal cancer (CRC) or family history of CRC
- Has a known hereditary/germline risk of CRC (for example, Lynch syndrome or Hereditary Non-Polyposis CRC, or Familial Adenomatous Polyposis) or known diagnosis of inflammatory bowel disease
- Patients with an Abnormal Signal Detected result should be referred for colonoscopy evaluation.
- A Normal Signal Detected Shield test result does not preclude the presence of colorectal neoplasia, and patients should continue
  participating in guideline-recommended screening programs.
- False positives and false negatives do occur. 10% of patients without colorectal cancer or advanced adenomas received a positive result (false positive) and 17% of patients with cancer received a negative result (false negative).
- The Shield test should be considered alongside other CRC screening modalities like colonoscopy and is not a replacement for diagnostic colonoscopy or surveillance colonoscopy of high-risk individuals.
- Shield has limited ability to detect advanced adenomas.
- Screening for CRC is recommended for people over 45 years old and providers should discuss the most appropriate test to use with patients depending on their medical history and individual preferences and circumstances.

Please consult the instructions for use included in the Guardant Shield BCK for Cancer Screening (LBL-000324) for warnings and precautions specific to the collection and shipping of blood samples.



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