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GUARDANT

shield™

Shield™ blood-based colorectal cancer screening test

A highly sensitive blood test to detect early-stage colorectal cancer

Today, 1 in 3 eligible adults do not complete recommended colorectal cancer screening because methods can be unpleasant, time-consuming and difficult to complete.1-6 Most patients prefer a blood test that can be completed at any doctor visit.7 The Shield test from Guardant Health offers an accurate, easy-to-complete, blood-based approach to cancer screening with the potential to improve screening rates and, ultimately, save more lives.

•The Shield blood test* uses a multimodal approach, integrating genomics, epigenomics and proteomics, to achieve high sensitivity and specificity in detecting early signs of colorectal cancer in average-risk adults age 45 and older.

•The technology is from Guardant Health, a leading precision oncology company that developed the first FDA-approved blood test for comprehensive genomic profiling across all solid cancers.

Patients who remain unscreened are at increased risk of death from colorectal cancer (CRC)

•CRC remains the second leading cause of cancer-related deaths in the U.S.8

•Each year, roughly 150,000 people are diagnosed with CRC in the U.S.8

•Cancer screening is a proven way to detect colorectal cancer early, when it's most treatable.9,10

•Over 75% of people who died from CRC between 2006 and 2012 were not up to date with screening. •5-[11]

year survival rates are improved when CRC is detected at earlier stages:10

- Early Stage (I-II): 90%
- Late Stage (IV): 14%

CRC screening compliance rates remain low despite current screening test options being offered to patients

•1 in 3 people in the U.S. today are not being screened for colorectal cancer in line with current guidelines.1

•Patients indicate that current screening methods—such as colonoscopy and stool-based methods—can be unpleasant, difficult to complete and time-consuming (prep through colonoscopy procedure can take 1-3 days).2-6

Blood-based CRC screening can help patients and healthcare providers overcome barriers and increase screening rates

•Guardant Health's market research found that 64% of patients prefer a blood-based screening test over all other screening methods, including colonoscopy or stool-based tests.7

•Blood-based screening is more convenient for patients and can help them break through barriers because it requires:12

- No special preparation
- No dietary changes
- No sedation
- No extra time away from family or work

•Blood testing can be done easily in most primary care healthcare professional practices.

Shield is a blood-based test that detects colorectal cancer with high accuracy

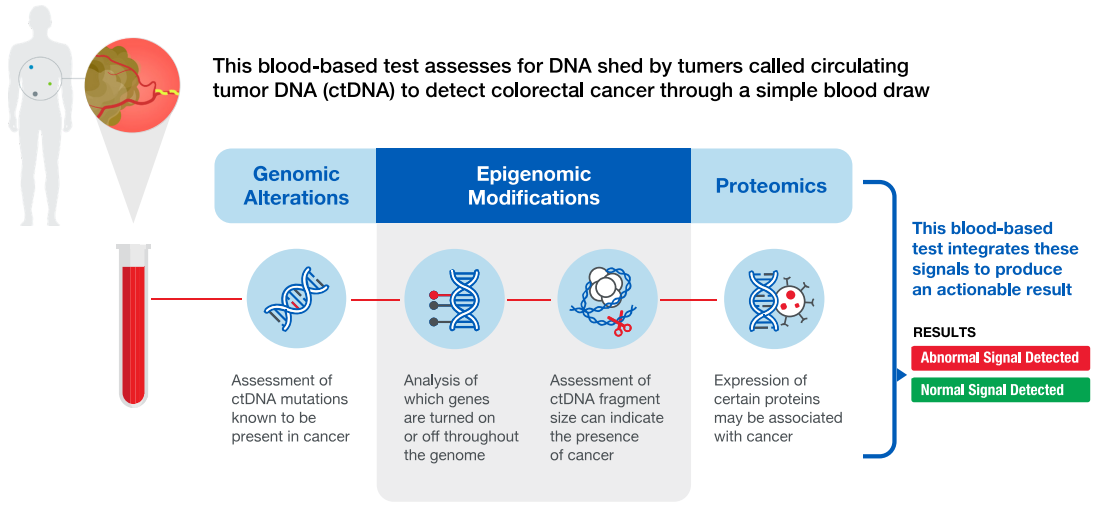
•The test uses a multimodal approach, integrating genomics, epigenomics and proteomics, to detect colorectal cancer signals in the bloodstream, including DNA that is shed by tumors, called circulating tumor DNA (ctDNA).

•Shield demonstrated sensitivity of 91% in colorectal cancer and 20% in advanced adenoma detection with 92% specificity (true negative rate) in normal cases in validation studies.

•Results from ECLIPSE, a registrational study of more than 12,750 patients designed to further validate this technology in detecting early signs of CRC in average-risk adults, are expected in 2022.

•Shield is a Laboratory Developed Test (LDT) that is intended to be complementary to and not a replacement for current recommended CRC screening methods.

A multimodal approach for accurate and early detection of colorectal cancer



Transforming cancer care at all stages of the disease through the power of blood tests and data

Guardant Health's vision is to transform cancer care across all stages of the disease through the power of blood. The continuum of care includes patients with early-stage and advanced cancer, as well as asymptomatic individuals.

Founded in 2012, the company introduced the Guardant360® test* for advanced cancer patients in 2014. It was the first liquid biopsy to comprehensively sequence a patient's cancer to reveal actionable mutations for precision medicine treatment decisions. The blood test overcame challenges of tissue biopsy to enable faster, easier, more complete genomic testing. In 2020, the Guardant360 CDx test became the first FDA-approved comprehensive liquid biopsy.

In 2021, the introduction of the Guardant Reveal™ test* for residual disease and recurrence monitoring of early-stage cancer marked the next important step along the cancer care contiuum. The innovative test promises to transform management of early-stage cancer for millions of patients. Studies are currently underway to validate the clinical utility of the Guardant Reveal test (COBRA Escalation Trial, ACT-III Escalation Trial, PEGASUS De-Escalation Trial) as well as the Shield test* for early-stage CRC detection and screening (ECLIPSE trial).

* Guardant Reveal, Guardant360 TissueNext, Guardant360 Response, Guardant360 and Shield tests were developed, and their performance characteristics determined, by the Guardant Health Clinical Laboratory in Redwood City, CA USA, which is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high complexity clinical testing. Guardant360 refers to Guardant360 Laboratory Developed Test (LDT). These tests have not been cleared or approved by the U.S. FDA.

References

1 Centers for Disease Control and Prevention. Use of Colorectal Cancer Screening. https://www.cdc.gov/cancer/colorectal/statistics/use-screening-tests-BRFSS.htm. Accessed May 1, 2022.

2 Centers for Disease Control and Prevention. Cost-effectiveness of colorectal cancer interventions. Updated August 18, 2021. Accessed December 7, 2021. https://www.cdc.gov/chronicdisease/programs-impact/pop/colorectal-cancer.htm

3 Liles EG, Coronado GD, Perrin N, et al. Uptake of a colorectal cancer screening blood test is higher than of a fecal test offered in clinic: a randomized trial. Cancer Treat Res Comm. 2017;10:27-31. doi:10.1016/j.ctarc.2016.12.004

4 Denberg TD, Melhado TV, Coombes JM, et al. Predictors of nonadherence to screening colonoscopy. J Gen Intern Med. 2005;20(11):989-995. doi:10.1111/j.1525-1497.2005.00164.x

5 Parks P. Innovation in colorectal cancer screening - there has to be a better way. Am J Manag Care. Published October 9, 2017. Accessed September 17, 2021. https://www.ajmc.com/view/innovation-in-colorectal-cancer-screening-there-has-to-be-a-better-way

6 American Society of Clinical Oncology. Colonoscopy. Cancer.net website. Updated December 2019. Accessed December 7, 2021. https://www.cancer.net/navigating-cancer-care/diagnosing-cancer/tests-and-procedures/colonoscopy

7 Proportion ranking LUNAR-2 as top CRC screening preference*, Overall N=299, GH Internal LUNAR2 Patient Research.

8 www.cancer.org/cancer/colon-rectal-cancer/about/key-statistics.html Accessed online Feb 5, 2021.

9 Chakrabarti S, Peterson C, Sriram D, Amit Mahipal A, et al. Early stage colon cancer: Current treatment standards, evolving paradigms, and future directions. World J Gastro Oncol. 2020 Aug 15; 12(8): 808–832.

10 American Cancer Society: Colorectal Cancer Facts & Figured 2020-2022. Available at: https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/colorectal-cancer-facts-and-figures/colorectal-cancer-facts-and-figures-2020-2022.pdf. Accessed online Feb 5, 2021.

11 Rich T, Raymond V, Lang K. Where are we today? Efforts to understand strategies and barriers to physician issuance of a recommendation for colorectal cancer screening: a systematic review. Gastroenterology. 2020;158(6 suppl 1): S-918. doi:10.1016/S0016-5085(20)32981-4.

12 Doubeni CA, Fedewa SA, Levin TR, et al. Modifiable failures in the colorectal cancer screening process and their association with risk of death. Gastroenterology. 2019;156(1):63-74. doi:10.1053/j.gastro.2018.09.040.