



## PRESS RELEASE

### **Guardant Health Initiates New Study to Examine the Impact of Shield™ Blood Test to Increase Screening Compliance for Colorectal Cancer**

*Shield™ blood test will be used to evaluate whether blood test option improves adherence to colorectal cancer screening recommendations in medically underserved populations at Federally Qualified Health Centers*

**PALO ALTO, Calif.,** Feb. 15, 2023 -- Guardant Health, Inc. (Nasdaq: GH), a leading precision oncology company, announced the initiation of a new study to examine patient preference for Shield, Guardant Health's blood test to screen for colorectal cancer (CRC), and if having the option of a blood test improves patient adherence to screening. The study will be conducted by the Center for Asian Health Equity – University of Chicago Medicine (CAHE-UCM).

In this study, Understanding Patient Preference on Colorectal Cancer Screening Options (U-Screen), led by UChicago physician-scientist and colorectal cancer specialist, Dr. Karen Kim, patients receiving care at Federally Qualified Health Centers (FQHC) who fail to complete guideline recommended screening will have the option to complete their screening with a Shield blood test. Shield test performance was recently clinically validated by the ECLIPSE Study – one of the largest cancer screening studies of its kind – and achieved 83% sensitivity for the detection of CRC.<sup>1</sup>

Screening for colorectal cancer has been shown to improve survival rates, yet one in three adults have not completed the recommended CRC screening.<sup>2,3</sup> Adherence to CRC screening is particularly low among minority populations: only 59% of individuals aged 50 and older who are Hispanic and 65% of individuals who are Black/African American are up to date with recommended screenings.<sup>4</sup> Screening rates are even lower in FQHCs, where only 40% of eligible patients were screened for CRC in 2020.<sup>5</sup>

There are significant barriers associated with established CRC screening methods—such as a colonoscopy or a stool-based test—including patient preferences, time and difficulty to complete the procedure.<sup>6</sup> With a simple blood draw, the Shield test overcomes these barriers because it requires no special preparation, no sedation, no dietary changes, no extra time away from family or work, and it can be completed as part of any patient office visit.<sup>7</sup> Since the launch of the Shield test, it has shown approximately 90% adherence demonstrating the value of blood-based screening in a real-world clinical setting.<sup>8</sup>

“Failing to complete recommended screening is a significant factor contributing to the high rate of cancer-related deaths in underserved populations,” said AmirAli Talasaz, Guardant Health co-CEO. “We believe patient access to a highly accurate blood test can increase overall compliance to screening, which is critical to improving CRC outcomes, and we are excited to partner with CAHE-UCM on such an important study.”



According to Dr. Kim, the Sara and Harold Lincoln Thompson Professor of Medicine, Vice Provost for Research, and founder of the Center for Asian Health Equity – University of Chicago Medicine, “this study will use an implementation science approach to help us better understand patient and provider preferences for colorectal cancer screening so we can increase screening and reduce the unnecessary burden of colorectal cancer among all populations.”

### **About the U-Screen Study ([NCT05536713](#))**

The study will enroll people between the ages of 45 and 75 who are at average risk of developing CRC and have failed to complete guideline recommended screening. Up to 2,400 patients will be enrolled during the three-year study period at three Federally Qualified Health Centers (FQHC), which have multiple clinics in Illinois and Indiana and provide primary care services to racial/ethnic minority and low-income populations.

### **About the Shield™ Test**

The Shield test detects colorectal cancer signals in the bloodstream from DNA that is shed by tumors, called circulating tumor DNA (ctDNA). Specifically, the test uses a multi-modal approach to identify specific characteristics of the DNA that may indicate the presence of cancer.

The clinical performance of the Shield assay was validated using a analyzed set of over ten thousand patient samples in a screening study. The test demonstrated 83% sensitivity in detecting individuals with CRC. Specificity was 90% in both individuals without advanced neoplasia and in those who had a negative colonoscopy result. This test also demonstrated 13% sensitivity in detecting advanced adenomas.

Shield is commercially available for eligible individuals by prescription only through healthcare professionals. This LDT (Laboratory Developed Test) is intended to be complementary to, and not a replacement for, current recommended CRC screening methods. A negative result does not rule out the presence of cancer. Patients with an abnormal blood-based screening result should be referred for a diagnostic colonoscopic evaluation.

More information about the Shield test is available at [bloodbasedscreening.com](http://bloodbasedscreening.com).

### **About Guardant Health**

Guardant Health is a leading precision oncology company focused on helping conquer cancer globally through use of its proprietary tests, vast data sets and advanced analytics. The Guardant Health oncology platform leverages capabilities to drive commercial adoption, improve patient clinical outcomes and lower healthcare costs across all stages of the cancer care continuum. Guardant Health has commercially launched Guardant360<sup>®</sup>, Guardant360<sup>®</sup> CDx, Guardant360 TissueNext<sup>™</sup>, Guardant360 Response<sup>™</sup>, and GuardantOMNI<sup>®</sup> tests for advanced-stage cancer patients, and Guardant Reveal<sup>™</sup> for early-stage cancer patients. The Guardant Health screening portfolio, including the Shield<sup>™</sup> test, aims to address the needs of individuals eligible for cancer screening. For more information, visit [guardanthealth.com](http://guardanthealth.com) and follow the company on [LinkedIn](#) and [Twitter](#).



### **About CAHE-UCM**

The Center for Asian Health Equity – University of Chicago Medicine provides a central location for the comprehensive evaluation of the health issues and diverse healthcare needs of immigrants and communities of color. Established in 2015, CAHE is a partnership between the University of Chicago Medicine and the Asian Health Coalition, bringing together the assets of a world class research institution and a respected non-profit organization to investigate health disparities that disproportionately affect Asian American, Native Hawaiian, Pacific Islander (AANHPI), African, and other communities of color. The center takes a multidisciplinary, collaborative approach to addressing gaps in clinical medicine and public health through a comprehensive program for research, health education, training, community engagement, policy, and information dissemination. CAHE-UCM is the first of its kind in the Midwest housed within an academic research institution and one of only four in the nation. For more information, visit [asianhealth.uchicago.edu](http://asianhealth.uchicago.edu) and follow the organization on [LinkedIn](#) and [Twitter](#).

### **Guardant Health Forward-Looking Statement**

This press release contains forward-looking statements within the meaning of federal securities laws, including statements regarding the potential utilities, values, benefits and advantages of Guardant Health’s liquid biopsy tests or assays, which involve risks and uncertainties that could cause the actual results to differ materially from the anticipated results and expectations expressed in these forward-looking statements. These statements are based on current expectations, forecasts and assumptions, and actual outcomes and results could differ materially from these statements due to a number of factors. These and additional risks and uncertainties that could affect Guardant Health’s financial and operating results and cause actual results to differ materially from those indicated by the forward-looking statements made in this press release include those discussed under the captions “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operation” and elsewhere in its Annual Report on Form 10-K for the year ended December 31, 2021 and in its other reports filed with the Securities and Exchange Commission. The forward-looking statements in this press release are based on information available to Guardant Health as of the date hereof, and Guardant Health disclaims any obligation to update any forward-looking statements provided to reflect any change in its expectations or any change in events, conditions, or circumstances on which any such statement is based, except as required by law. These forward-looking statements should not be relied upon as representing Guardant Health’s views as of any date subsequent to the date of this press release.

### **References**

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## **Guardant Health Contacts**

### **Investor Contact:**

Alex Kleban  
investors@guardanthealth.com  
+1 657- 254-5417

### **Media Contact:**

Breen Weir  
press@guardanthealth.com  
+1 843-384-0095

## **CAHE-UCM Contacts**

### **Media Contact:**

Jeremy Chia  
jchia1@bsd.uchicago.edu