shield™

Multi-Cancer Detection

Developed by GUARDANT™

The Shield Multi-Cancer Detection (MCD) is a qualitative, laboratory developed test intended to detect cancer-derived methylation-based signals in cell-free DNA (cfDNA) from blood.

The Shield MCD test is intended to detect the following 10 cancers:[1]

Bladder	Breast	Colorectal	Esophageal	Stomach (Gastric)
Liver (Hepatocellular)	Lung	Ovarian	Pancreatic	Prostate

When a positive (abnormal) signal was detected, the Shield MCD test reports the top two cancer signal of origin (CSO) predictions.

Overall performance of the Shield MCD Test

60%
Overall Sensitivity (222/372)[1]

99%
Specificity (436/442)[1]

93%
Primary or secondary CSO accuracy[1,2]

73%
Sensitivity in cancers without average-risk, standard-of-care screening[1,3]
Includes bladder, esophageal, gastric, hepatocellular, lung, ovarian, and pancreatic cancers.

74%
Sensitivity in the 6 most aggressive cancers (defined as the shortest survival rates)[1,4]
Includes esophageal, gastric, hepatocellular, lung, ovarian, and pancreatic cancers.

Sensitivity: The ability of the test to correctly identify people who actually have the disease.
Specificity: The ability of the test to correctly identify people who do not have the disease.
Cancer Signal of Origin (CSO): The Predicted Cancer Signal of Origin (CSO) offers information about the tissue type or organ that may be associated with the positive result detected by this test.

Laboratory and test information:

The Shield MCD test is a Laboratory Developed Test (LDT) that was developed and its performance characteristics were determined by Guardant Health, Inc. This test may be used for clinical purposes and should not be regarded as investigational or for research only. Guardant Health's clinical laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high complexity clinical laboratory testing and accredited by the College of American Pathologists (CAP). The results should be interpreted in the context of other clinical information and laboratory, pathology, and imaging studies by a qualified medical professional prior to initiating or changing a patient's treatment plan. This test is not part of the Shield IVD and has not been cleared or approved by the United States Food and Drug Administration. For Export Use Only. Not for sale or use in the United States. The Shield MCD test is available by prescription only.

Important safety information:

The Shield MCD test (a laboratory developed test) is a qualitative test intended to detect cancer derived alterations in cell-free DNA from blood. The Shield MCD test is intended for multi-cancer screening in individuals age 45 or older, without a known diagnosis of cancer. The target cancers for the Shield MCD test include bladder, breast, colorectal, esophageal/ gastric (also called stomach), liver (also called hepatocellular), lung, ovarian, pancreatic, and prostate. The Shield MCD test is not indicated for use in pregnant women. Individuals with positive results should follow healthcare provider recommendations for diagnostic follow-up and evaluation. The Shield MCD test is intended to complement, not replace guideline recommended cancer screening tests. A negative result does not eliminate the possibility that cancer is present or will occur in the future. Individuals should continue to participate in age-appropriate guideline directed cancer screening programs. These findings should be interpreted in the context of other clinical information, and laboratory and imaging studies as clinically indicated by a qualified medical professional. The Shield MCD test is available by prescription only.

All information in this fact sheet is correct as of **April 2026**.

References:

1. He Y, Forouzmand E, Burke J, et al. Validation of a plasma cell-free DNA methylation-based multi-cancer detection test. *Abstract* 10550. Presented at: 2025 ASCO Annual Meeting; May 30-June 3, 2025; Chicago, IL.
2. Data on file. Guardant Health, Inc.
3. US Preventive Services Task Force. Published recommendations, cancer. Accessed August 14, 2025. https://www.uspreventiveservicestaskforce.org/uspstf/topic_search_results?topic_status=P&category%5B%5D=15&age_group%5B%5D=10&type%5B%5D=5&searchterm=
4. National Cancer Institute. Cancer stat facts: common cancer sites. Accessed August 14, 2025. https://seer.cancer.gov/statfacts/html/common.html.

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