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Detecting Cancer Signals With A Single Blood Draw Using a Multi-Cancer Early Detection (MCED) Test

Circulating Cell-free Genome Atlas (CCGA) Substudy 3: Clinical Validation[1]

15,254 participants from 142 sites[2]
56% with cancer
44% without cancer

Blood samples
All participants

Tissue samples
Cancer participants only

MCED Test result

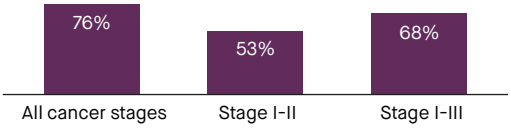
Follow-up
for 5 years
(vitals & cancer status)

Cancer Signal Detection

Specificity 99.5%
(95% CI: 99.0–99.8%)
0.5% false-positive rate

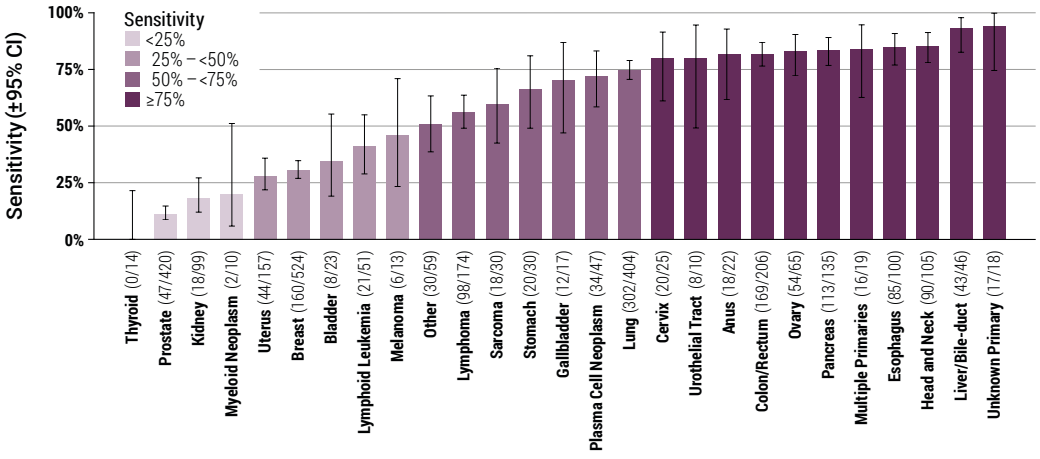
PPV 44.4%*
(95% CI: 28.6–79.9%)
*Estimated value (adjusted to SEER cancer incidence and stage distribution in the 50-79 y age group)[3,a]

Sensitivity 51.5%
(95% CI: 49.6–53.3%)
Sensitivity of 12 prespecified cancers that account for ~2/3 of US cancer deaths[4,b]



Diversity of Cancer Signals Detected

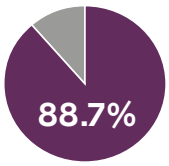
MCED Test Sensitivity[c]



>50 AJCC cancers[5]

including those without common screening options

High Accuracy of Predicted Cancer Signal Origin



(95% CI: 87.0–90.2%)

High rate of correctly identified Cancer Signal Origins across multiple cancer types, which can help direct diagnostic evaluation

Clinical validation supports use of this MCED test in a clinical setting as a complement to existing single-cancer screening tests in **adults with elevated cancer risk**

Adverse Events

0 serious AEs
related to blood draw

0.4%
participants (20/5309) with AEs related to blood draw

Participants by highest-grade AE

Overview of CCGA Substudies

Samples divided among 3 pre-specified CCGA substudies[1]

CCGA 1

Discovery[6]

Whole Genome Methylation identified as method for further development (of 3 methods evaluated)

Training: n=1785
Validation: n=1015

CCGA 2

Assay Refinement and Initial Validation[7]

Targeted Methylation identified key informative methylation regions

Training and validation of the machine-learning classifier to differentiate cancer vs non-cancer and predict signal origin

Training: n=3133
Validation: n=1354

CCGA 3

Further Assay Refinement and Clinical Validation[1]

Further refined for use as screening tool

Clinical validation supporting Galleri product launch

n=4077 confirmed status analysis set (cancer=2823; non-cancer=1254)

The Galleri® test is recommended for use in adults with an elevated risk for cancer, such as those aged 50 or older. The Galleri test should be used in addition to guideline-recommended cancer screenings such as **mammography, colonoscopy, PSA, or cervical cancer screening.** The Galleri test does not detect all cancers and all cancers cannot be detected in the blood. False positive results and false negative results do occur. **Visit Galleri.com/safety-information** for Important Safety Information.

[a]Estimated PPV value was adjusted using SEER 2016 to 2017 cancer incidence data, as PPV is impacted by population incidence and specificity. PPV in the PATHFINDER study was 40.4%.

[b]Anus, Bladder, Colon/rectum, Esophagus, Head and neck, Liver/bile duct, Lung, Lymphoma, Ovary, Pancreas, Plasma cell neoplasm, Stomach.

[c]The graph shows 24 cancer classes plus 3 additional classes (other, unknown primary, and multiple primaries). The 24 cancer classes plus the"other" class used for sensitivity reporting correlate with the >50 AJCC cancer types.

[d]17 participants with 19 mild AEs: dizziness (n=8), bruising (n=2), hematoma and bruising (n=1), lightheaded (n=2), lightheaded and nausea (n=1), feeling warm (n=1). syncope (n=1), multiple attempts for blood draw (n=1).

[e]3 participants with 3 moderate As: syncope (n=2) and vasovagal reaction (n=1); 1 participant with syncope also reported a mild AE of vomiting.

Abbreviations: AE: adverse event; AJCC: American Joint Committee on Cancer; CCGA: The Circulating Cell-free Genome Atlas study (1, 2. and 3 indicate substudies); CI: confidence interval; MCED: multi-cancer early detection test; PPV: positive predictive value; PSA: prostate specific antigen; SEER: Surveillance, Epidemiology. and End Results Program.

References
1. Klein EA, et al. Ann Oncol. 2021;32(9):1167-1177. DOI: 10.1016/j.annonc.2021.05.806.
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3. SEER Stat Database: Incidence - SEER 18 Regs Research Data, Nov 2017 Sub.Includes persons aged 50+ diagnosed 2006-2015.
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5. Amin MB, et al. CA Cancer J Clin. 2017;67(2):93-99. DOI: 10.3322/caac.21388.
6. Jamshidi A, et al. Cancer Cell. 2022;40(12):1537-1549.e12. DOI: 10.1016/j.ccell.2022.10.022.
7. Liu MC, et al. Ann Oncol. 2020;31(6):745-759. DOI: 10.1016/j.annonc.2020.02.011.

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