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Early Real-World Experience With Repeat Multi-Cancer Early Detection (MCED) Testing

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Disclosure Information

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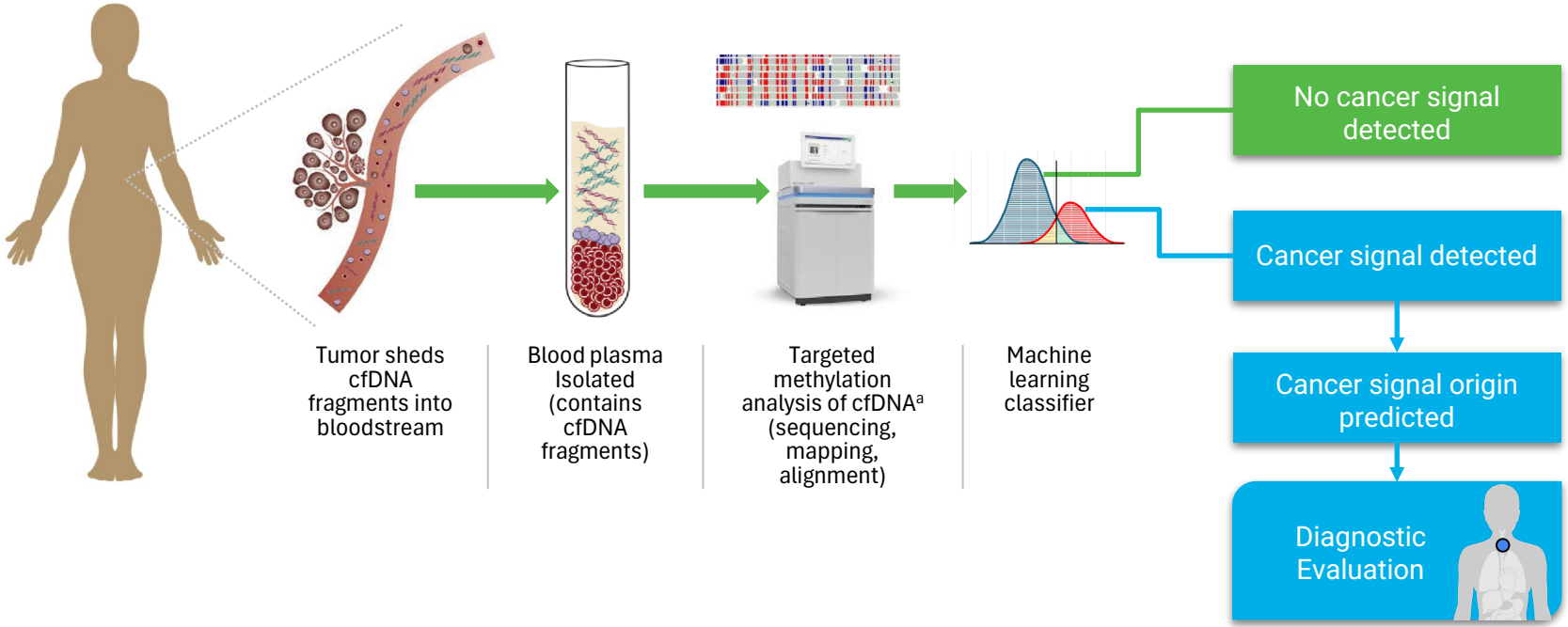
Dr. Ora Gordon

- Institutional research support from Grail
- Scientific Advisor Grail (within 24 months but not currently)
- Scientific Advisor, Genetic Technologies Corp

Multi-Cancer Early Detection With Galleri® Test



cfDNA, cell-free DNA.
[a]Bisulfite treatment; targeted probes pull out fragments matching regions of interest.
Adapted from Liu MC, et al. Ann Oncol. 2020;31(6):745-759. DOI:10.1016/j.annonc.2020.02.011.

Real World Evidence Cohorts

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Repeat-test Cohort

5,794 individuals

- ≥2 valid test results by 4Aug23
- First valid test result was "No Cancer Signal Detected"

First-test Cohort

47,016 individuals

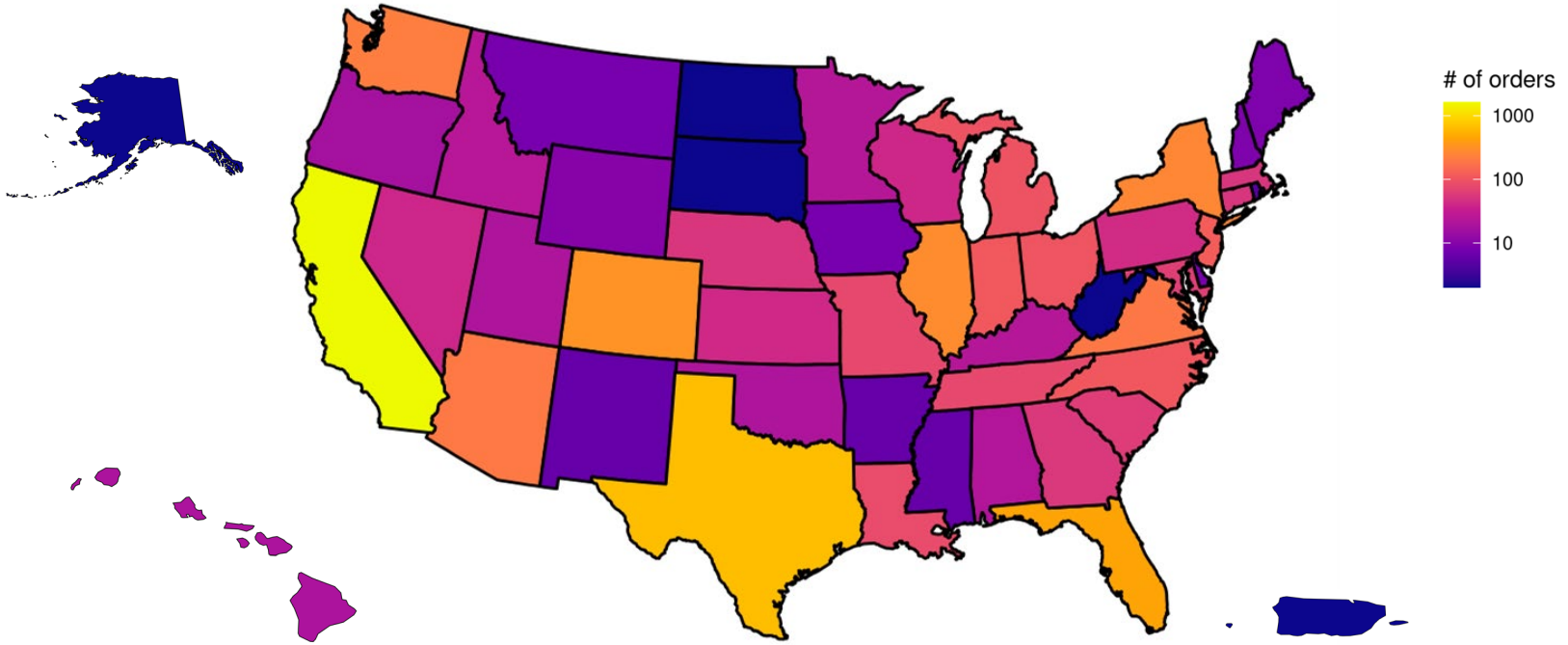
- First valid test result by 31Dec22
- Excludes individuals with repeat tests

Clinical outcomes collected as part of controlled Quality Assurance program are limited by availability of information provided

Both cohorts exclude clinical study participants and practices with contractual limitations

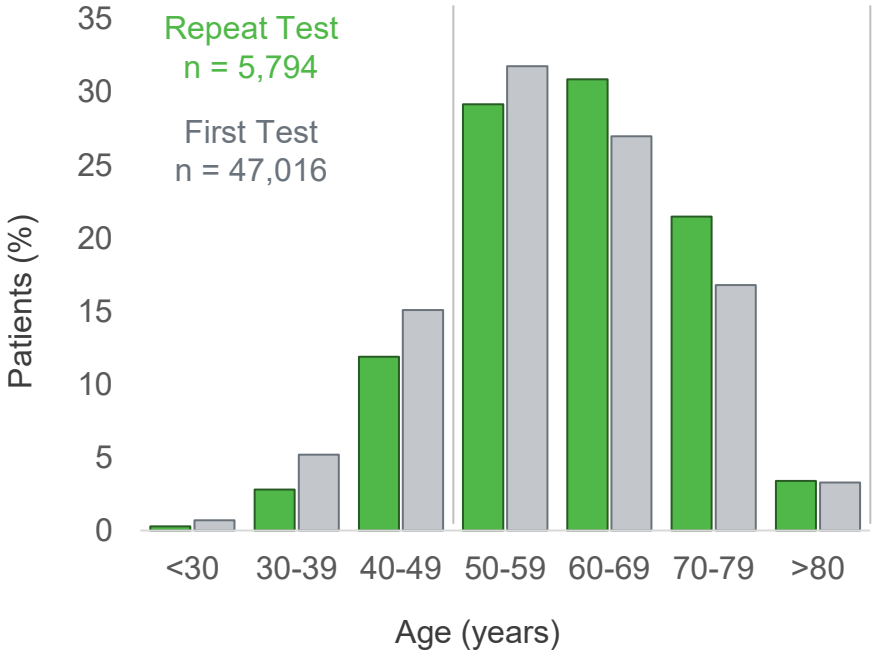
Repeat Testing Spanned The United States

5794 total people had repeat testing as of Aug 2023



Most MCED Test Patients Are 50–70 Years Old

Age distribution was similar between repeat- and first-test cohorts, but significantly higher % of repeat test participants were ≥50



Age	Repeat Test	First Test
<50	871 (15%)	9,877 (21%)
≥50	4,923 (85%)	37,139 (79%)
p value < 0.0001		

Male
n = 3,367 (58%)
Median Age: 61.3 years
Range: 24-89

Female
n = 2,427 (42%)
Median Age: 60.5 years
Range: 23-89

Most Repeat Test Were Taken Within 2 Months Of Annual Cadence

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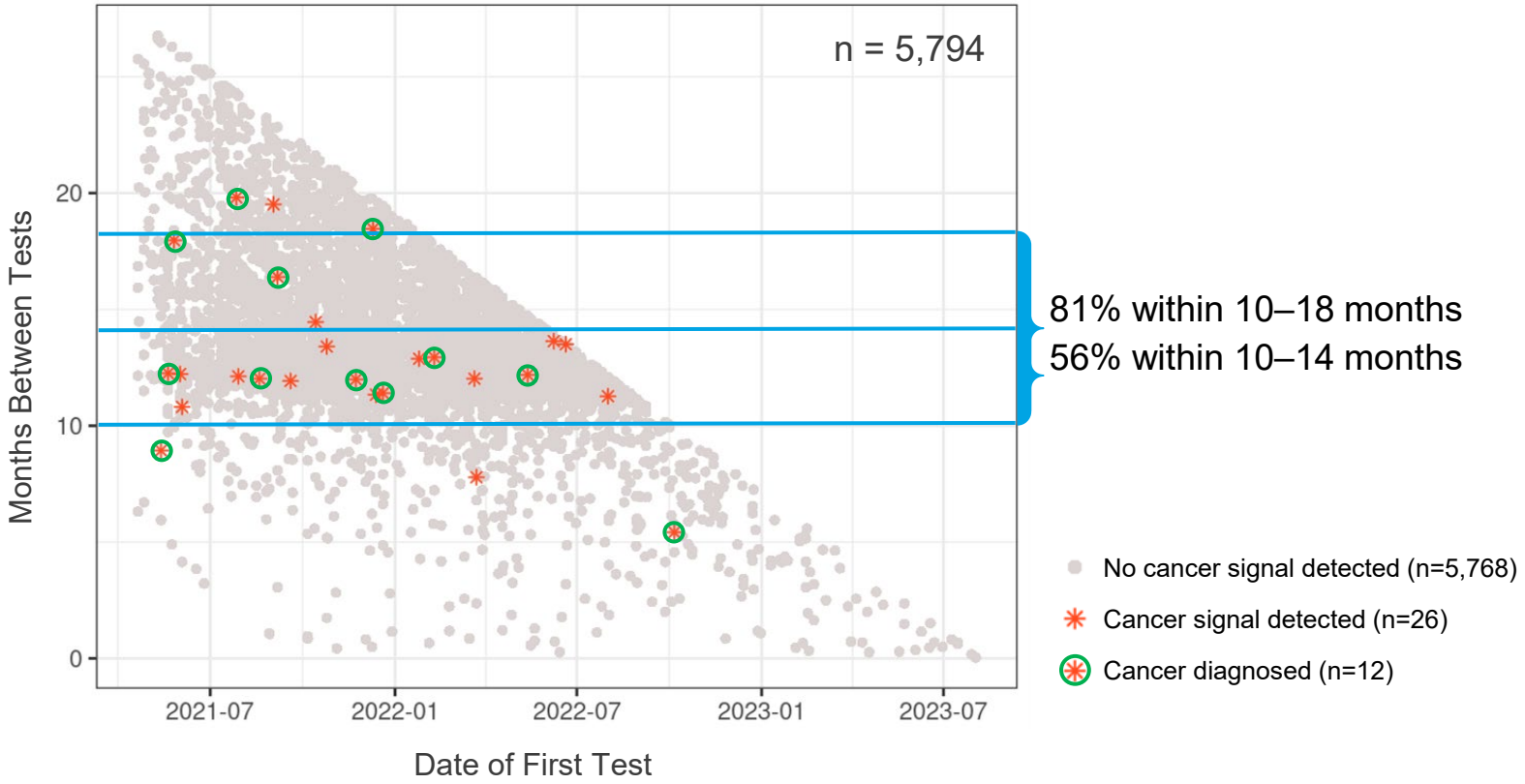

Cancer Signal Detection Rate Is 0.45% In Repeat Test Cohort

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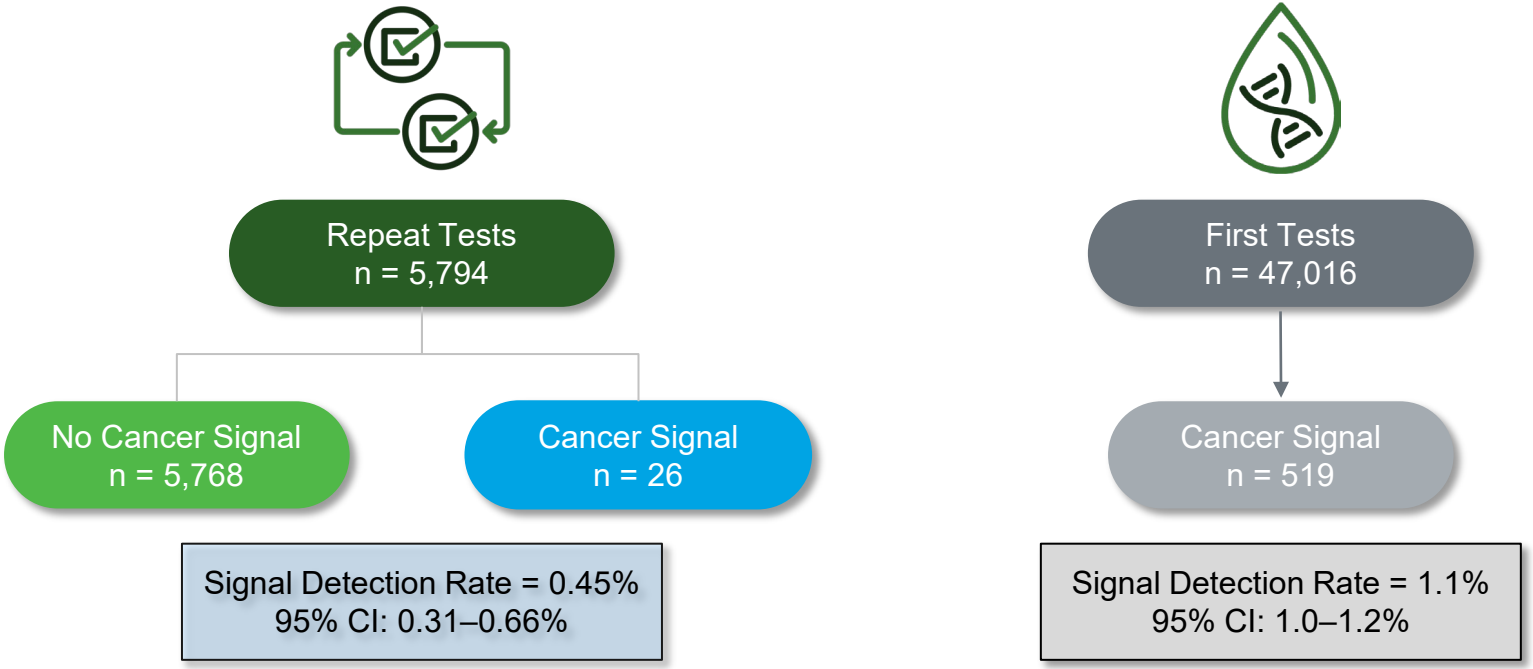

Over 70% of CSOs With Repeat Testing Contain Cancers Without Current Screening Options

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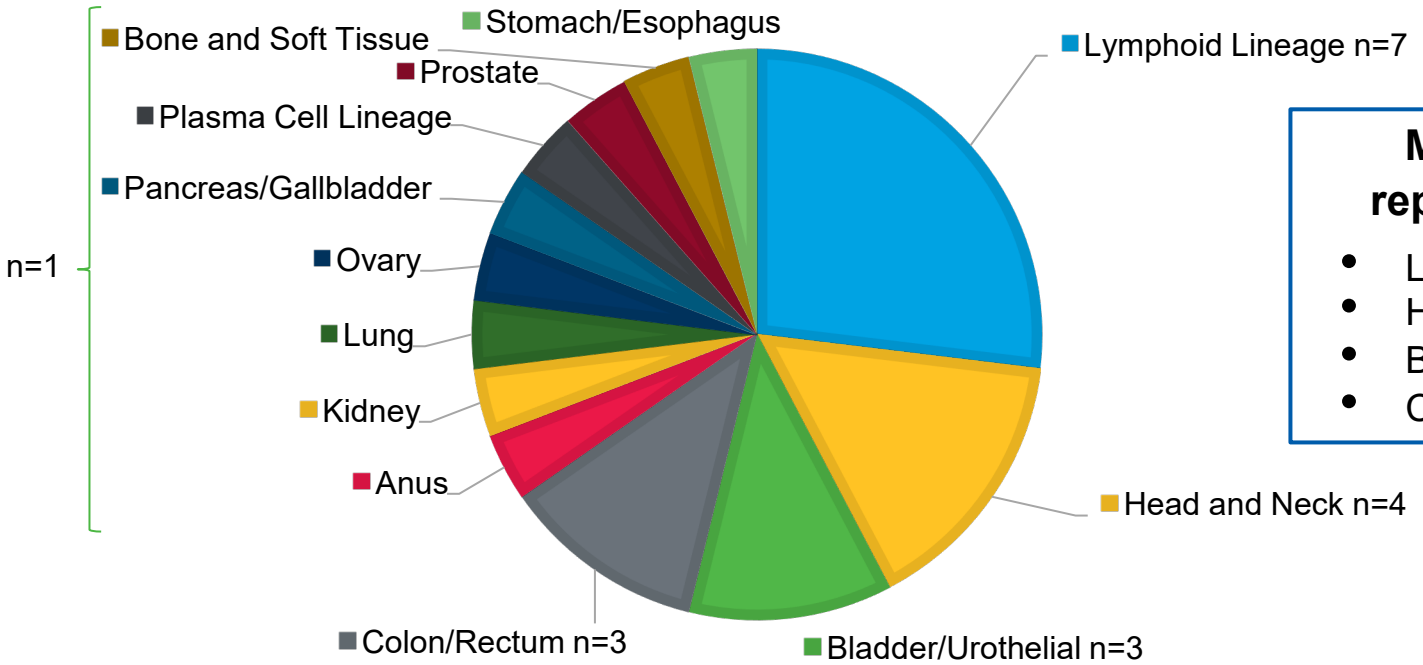
Cancer Signal Origin (n = 26)



Most common repeat-test CSOs

- Lymphoid lineage
- Head and neck
- Bladder, urothelial
- Colon, rectum

CSO, cancer signal origin.

Repeat Testing Reveals Potential Shift Towards Cancers Without Recommended Screening

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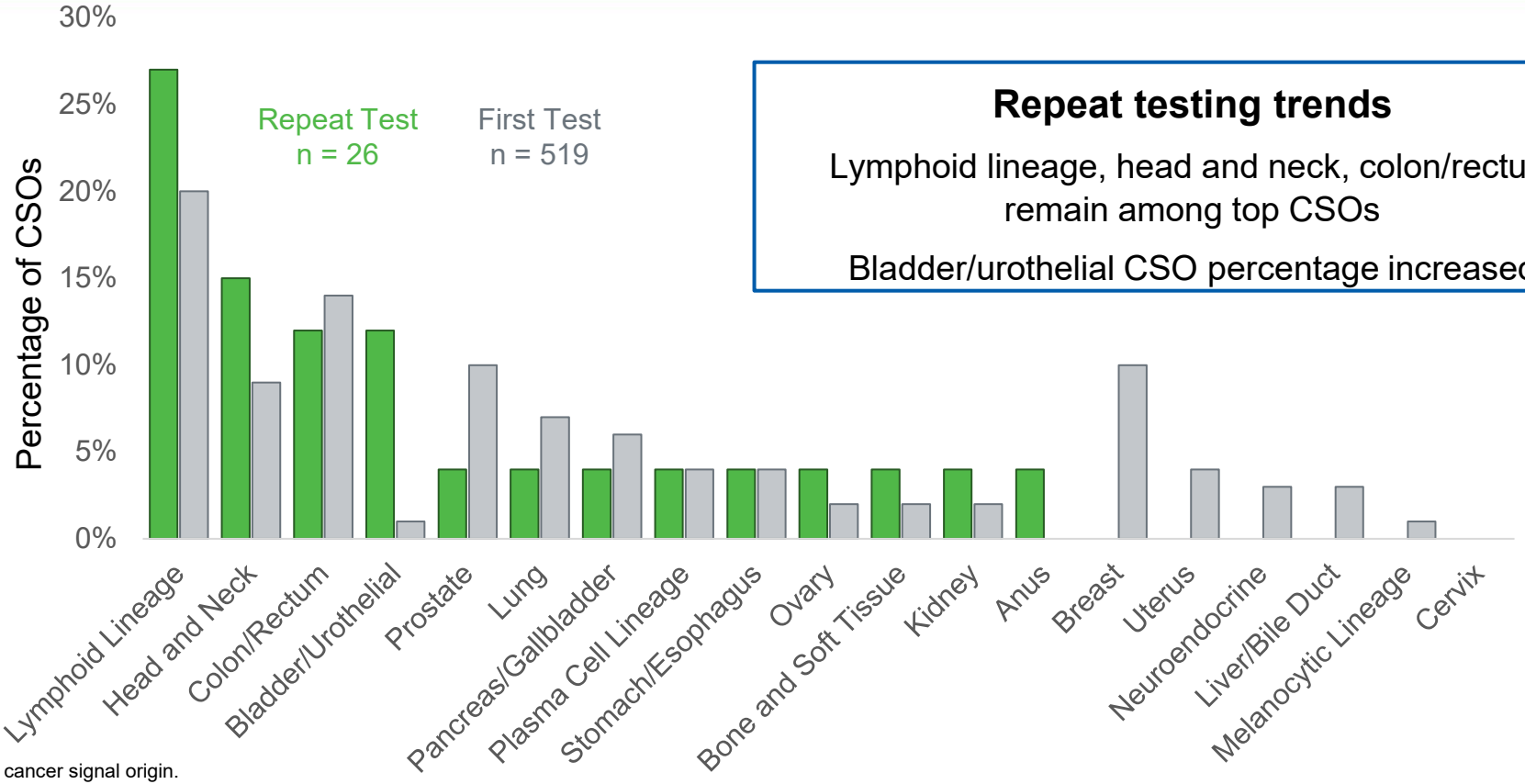

Repeat testing trends

Lymphoid lineage, head and neck, colon/rectum remain among top CSOs

Bladder/urothelial CSO percentage increased

CSO, cancer signal origin.

More Than 50% Of Patients With Known Clinical Outcomes Were Diagnosed With Cancer

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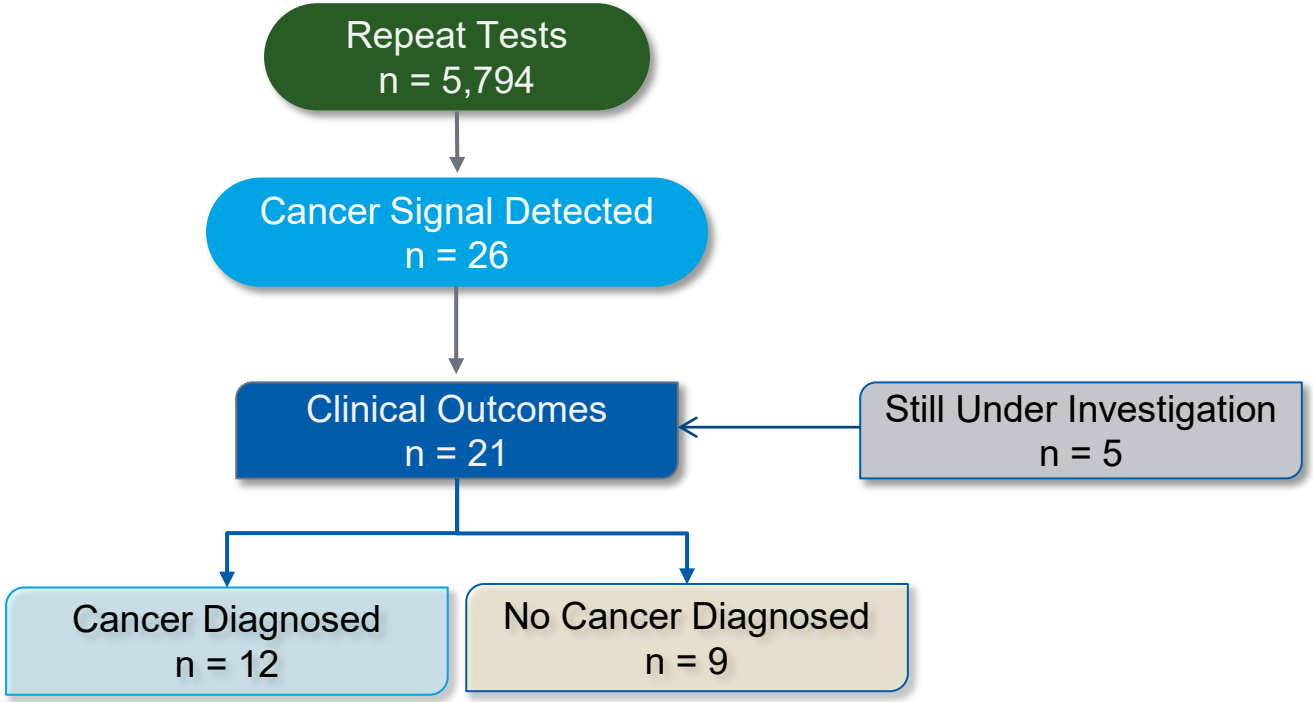

Cancers Diagnosed After Repeat Testing Were Mostly Early Stage And Without Screening Options

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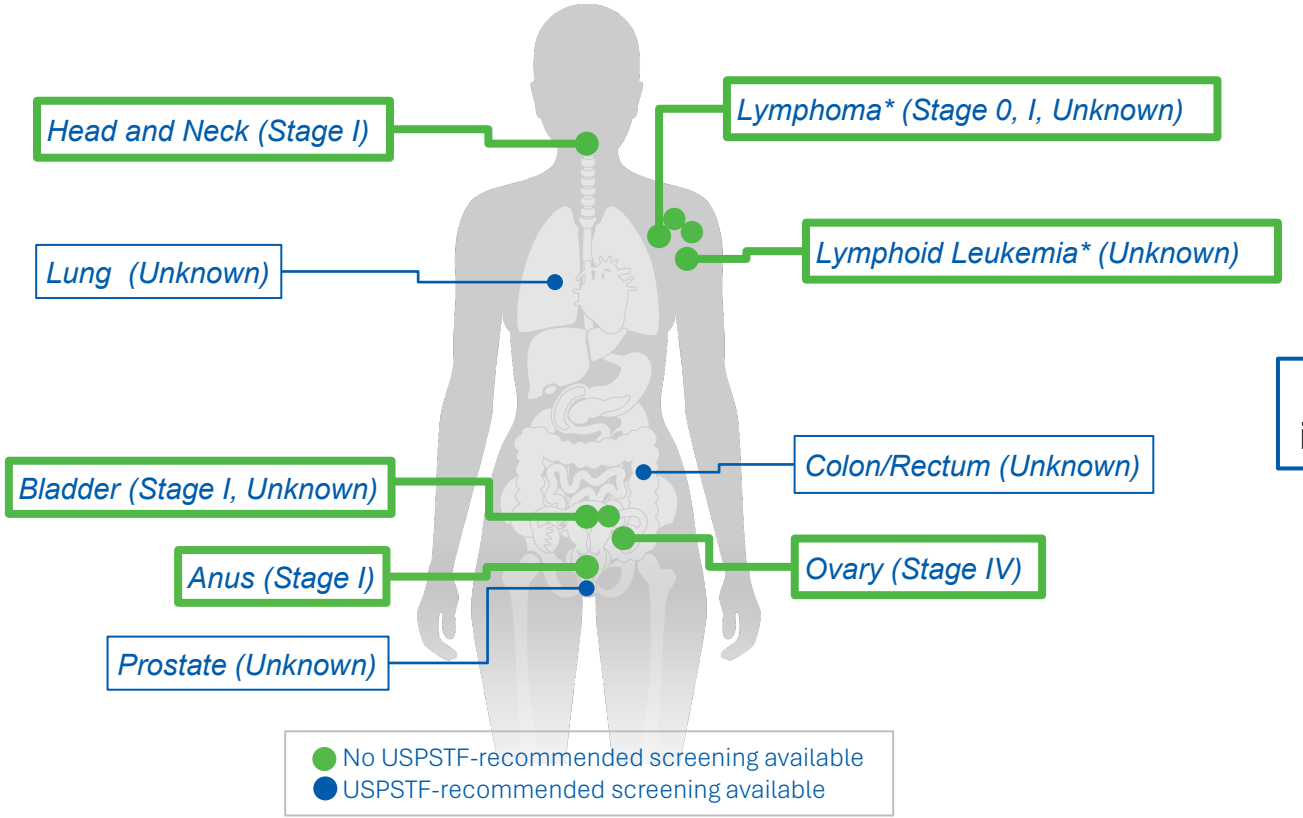

*Rai staging used for lymphomas.

CSO accuracy was 100% in the 12 diagnosed cancers

High Percentage Of Stage I Diagnoses With Repeat Testing

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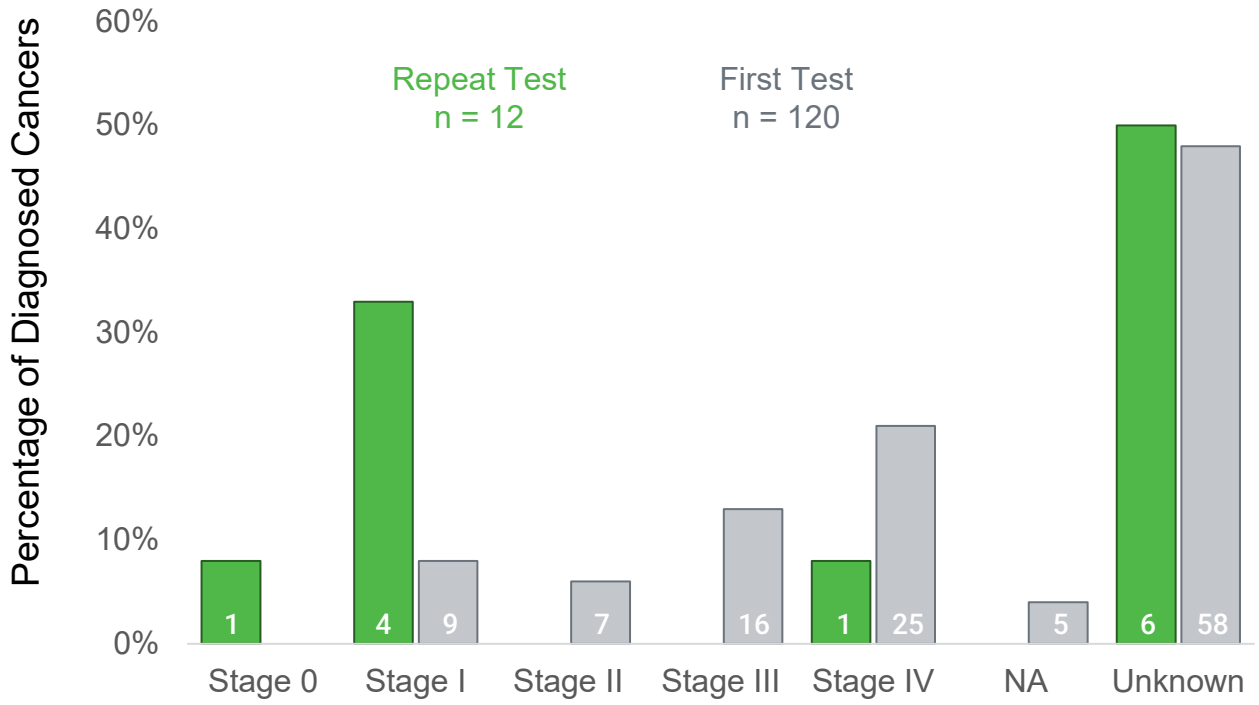

N values shown at bottom of each column. NA, not applicable or no AJCC/Rai stage expected. Patients for whom the practice has not reported cancer staging are captured as Unknown.

Strengths And Limitations

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- The strength of real-world evidence is that it provides insight into how a test is being used in a clinical practice setting and improves generalizability of data
- Limitations include limited data availability and timing of reporting between practices
- The population who have had repeat MCED testing may also be unusually health conscious
  - "Healthy volunteer effect" is well documented in cancer screening trials
- The data presented here are preliminary and descriptive in nature, signifying early trends that will need to be confirmed

Conclusions

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- ✅ Cancer Signal Origin accuracy was 100%
  - CSO is a unique feature of this MCED test and helps direct diagnostic work up
- ✅ Among the 6 confirmed cancers with known stage, 5/6 were stage 0 or 1
  - 1 was stage 0: chronic lymphocytic leukemia
  - 4 were stage I: head and neck, anus, lymphoma, bladder
  - 1 was Stage IV: ovarian
- ✅ Repeat testing may improve early detection of multiple cancer types, including those currently without USPSTF-recommended screening

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We gratefully acknowledge the contributions to this effort of the patients, staff, and healthcare providers who provided clinical data