

Performance of a Multi-Cancer Early Detection (MCED) Test Across Racial and Ethnic Groups: Descriptive Report from PATHFINDER 2

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INTRODUCTION

- Multi-cancer early detection (MCED) blood tests offer a single-test approach to screen for multiple cancer types, including many without established screening recommendations^{1,2}
- The commercially available Galleri® MCED test (GRAIL, Inc.) uses targeted methylation patterns in cell-free DNA to detect a shared cancer signal and predict cancer signal origin (CSO); this MCED test has demonstrated feasibility as a screening tool in large-scale clinical studies¹⁻³
- In the case-control Circulating Cell-free Genome Atlas study, the MCED test showed consistently high specificity and comparable sensitivity across racial and ethnic groups, though sample size and participant demographics limited interpretation of results in some subgroups⁴
- As MCED tests become more widely available, evaluation of MCED performance across diverse populations in large prospective studies is needed to ensure minimal disparities in cancer early detection⁵

OBJECTIVE

- To descriptively evaluate the performance of the MCED test across racial and ethnic groups in the prospective, interventional PATHFINDER 2 study, including in populations historically underrepresented in clinical cancer research

KEY RESULTS: MCED TEST PERFORMANCE WAS BROADLY CONSISTENT ACROSS RACIAL AND ETHNIC GROUPS, SUPPORTING APPLICABILITY OF MCED TESTING ACROSS DIVERSE POPULATIONS

Demographics and Baseline Characteristics

- PATHFINDER 2 enrolled 35,878 participants; 35,350 had analyzable data and 32,007 were included in analysis of MCED test performance²
- The analyzable participant cohort represented a diverse cross-section of the US population based on race (not mutually exclusive; self-reported) and ethnicity, including groups historically underrepresented in clinical cancer research
- Baseline demographics varied across racial and ethnic subgroups, providing important context for interpreting descriptive performance estimates (**Table 1**)

Table 1. Baseline Demographics and Clinical Characteristics in the PATHFINDER 2 Analyzable Participant Cohort.

Baseline Demographics	All Participants	Race ^a				Ethnicity ^b	
	N=35,350	American Indian or Alaska Native n=475	Asian, Native Hawaiian or Other Pacific Islander n=2371	Black or African American n=3211	White n=28,725	Hispanic or Latino n=2632	Not Hispanic or Latino n=32,274
Age, median (Q1, Q3), years	64.0 (58.0, 70.0)	62.0 (56.0, 70.0)	60.0 (54.0, 67.0)	63.0 (57.0, 69.0)	65.0 (59.0, 71.0)	60.0 (54.0, 67.0)	65.0 (59.0, 70.0)
Age Group, n (%)							
50-59 years	10,053 (28.4)	176 (37.1)	1165 (49.1)	1137 (35.4)	7245 (25.2)	1229 (46.7)	8704 (27.0)
60-69 years	15,549 (44.0)	178 (37.5)	807 (34.0)	1315 (41.0)	13,080 (45.5)	974 (37.0)	14,385 (44.6)
70-79 years	8764 (24.8)	110 (23.2)	358 (15.1)	668 (20.8)	7567 (26.3)	384 (14.6)	8257 (25.6)
≥80 years	984 (2.8)	11 (2.3)	41 (1.7)	91 (2.8)	833 (2.9)	45 (1.7)	928 (2.9)
Sex, n (%)							
Female	19,877 (56.2)	277 (58.3)	1393 (58.8)	2103 (65.5)	15,767 (54.9)	1643 (62.4)	17,996 (55.8)
BMI Category, n (%)							
<25 kg/m ²	11,738 (33.2)	110 (23.2)	1258 (53.1)	516 (16.1)	9767 (34.0)	561 (21.3)	11,040 (34.2)
25 to <30 kg/m ²	12,756 (36.1)	167 (35.2)	808 (34.1)	994 (31.0)	10,534 (36.7)	1015 (38.6)	11,582 (35.9)
≥30 kg/m ²	10,757 (30.4)	197 (41.5)	300 (12.7)	1692 (52.7)	8347 (29.1)	1045 (39.7)	9573 (29.7)
Missing	99 (0.3)	1 (0.2)	5 (0.2)	9 (0.3)	77 (0.3)	11 (0.4)	79 (0.2)
Smoking Status, n (%)							
Currently	1308 (3.7)	37 (7.8)	49 (2.1)	248 (7.7)	960 (3.3)	114 (4.3)	1171 (3.6)
Formerly	9550 (27.0)	142 (29.9)	355 (15)	714 (22.2)	8261 (28.8)	594 (22.6)	8831 (27.4)
Never	24,492 (69.3)	296 (62.3)	1967 (83)	2249 (70)	19,504 (67.9)	1924 (73.1)	22,272 (69)
Prior cancer history, ^c n (%)							
Yes	3264 (9.2)	27 (5.7)	141 (5.9)	315 (9.8)	2757 (9.6)	164 (6.2)	3060 (9.5)
No	32,086 (90.8)	448 (94.3)	2230 (94.1)	2896 (90.2)	25,968 (90.4)	2468 (93.8)	29,214 (90.5)

^aRace was self-reported, and not mutually exclusive. In n=1043 participants, race was not reported. ^bEthnicity was self-reported. In n=444 participants, ethnicity was not reported. ^cNon-metastatic basal cell carcinoma and squamous cell carcinoma of the skin were not included. BMI, body mass index.

MCED Performance Across Racial and Ethnic Subgroups

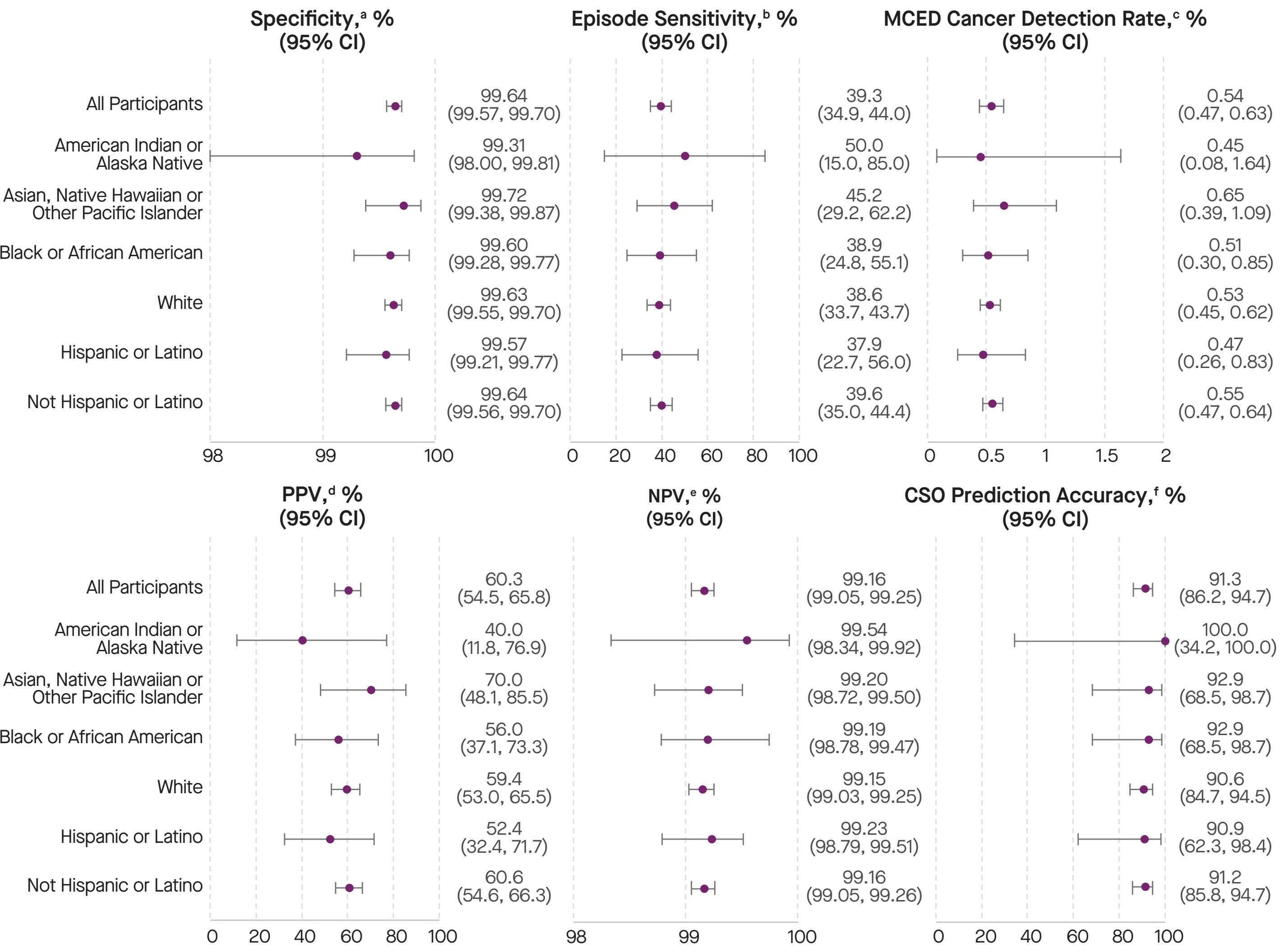
- Positive MCED test results and diagnosed cancers were observed across racial and ethnic subgroups (**Table 2**)
 - MCED-detected cancers included multiple cancer types; however, subgroup counts were too small to assess differences in cancer-type distribution (**Table S1 via QR code**)
- Specificity was ≥99.3%, PPV was ≥40%, and CSO1/2 prediction accuracy was >90% across all racial and ethnic subgroups (**Figure 1**)
- Performance estimates in smaller subgroups showed more numerical variation and wider confidence intervals, as expected; this was consistent with small numbers of positive MCED test results and diagnosed cancers in some subgroups (**Table 2; Figure 1**)
 - Subgroup analyses were descriptive and sample size was limited; comparisons of performance between subgroups should be interpreted cautiously
- Overall, MCED test performance was broadly consistent across all racial and ethnic subgroups and comparable to overall performance (**Figure 1**)

Table 2. MCED Test Results and Cancer Status Across Racial and Ethnic Subgroups Among Participants in the Performance Analyzable Cohort.

Race/Ethnicity ^a	Cancer Diagnosis	No Cancer Diagnosis	Total
American Indian or Alaska Native			
n	4	436	440
Positive MCED test result, n	2	3	5
Negative MCED test result, n	2	433	435
Asian, Native Hawaiian or Other Pacific Islander			
n	31	2112	2143
Positive MCED test result, n	14	6	20
Negative MCED test result, n	17	2106	2123
Black or African American			
n	36	2718	2754
Positive MCED test result, n	14	11	25
Negative MCED test result, n	22	2707	2729
White			
n	360	25,885	26,245
Positive MCED test result, n	139	95	234
Negative MCED test result, n	221	25,790	26,011
Hispanic or Latino			
n	29	2329	2358
Positive MCED test result, n	11	10	21
Negative MCED test result, n	18	2319	2337
Not Hispanic or Latino			
n	404	28,845	29,249
Positive MCED test result, n	160	104	264
Negative MCED test result, n	244	28,741	28,985

^aRace categories were not mutually exclusive.

Figure 1. Performance of the MCED Test Was Broadly Consistent Across Racial and Ethnic Subgroups.



Subgroup population sizes, MCED test results, and cancer status counts are provided in **Table 2**; denominators vary by performance measure. ^aSpecificity is the proportion of participants with a negative MCED test result out of all participants with no cancer diagnosis within the 12-month follow-up period: TN/(FP+TN). ^bEpisode sensitivity is the ability of a screening test to detect cancers that are diagnosed during a specified follow-up period after a screening test. 12-month episode sensitivity is the proportion of participants with a positive MCED test result out of all participants with a cancer diagnosis within the 12-month follow-up period: TP/(TP+FN). ^cMCED cancer detection rate is the proportion of participants with a positive MCED test result and a cancer diagnosis (TP) out of all participants in the performance analysis set: TP/(TP+FP+FN+TN). ^dPPV is the proportion of participants with a cancer diagnosis out of all participants with a positive MCED test result: TP/(TP+FP). ^eNPV is the proportion of participants with no cancer diagnosis out of all participants with a negative MCED test result: TN/(FN+TN). ^fCSO prediction accuracy is the proportion of participants with a correct first or second CSO (CSO1/2) prediction (ie, CSO prediction matching the diagnosed cancer type) among participants with TP MCED test results. CSO, cancer signal origin; FN, false negative; FP, false positive; MCED, multi-cancer early detection; NPV, negative predictive value; PPV, positive predictive value; TN, true negative; TP, true positive.

CONCLUSIONS

- In the large, diverse PATHFINDER 2 population, MCED test performance was broadly consistent across racial and ethnic groups, with specificity ≥99.3% across all subgroups
- These findings support the applicability of MCED testing across diverse populations

References

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Disclosures

Study funded by GRAIL, Inc. **MJD** holds stock in Agenus; has received honoraria from AADI, White Hawk Therapeutics, Crinetics Pharmaceuticals, Loxo/Lilly, and Corcept Therapeutics; has served in a consulting/advisory role for Loxo/Lilly, Orphagen, Bayer, TD2, Theralink, OnCusp, Pfizer, Boehringer Ingelheim, and Crinetics Pharmaceuticals. **CHM** has served in a consulting/advisory role with GRAIL. **DK** is an employee of HCA Healthcare with stock in the company. **KVG** has served in a consulting/advisory role for Lilly, Onvov, Novartis, Medscape, Clinical Education Alliance, Quantum Leap Healthcare Collaborative, GRAIL, Conexant, and Association for Molecular Pathology and received travel expenses from GRAIL. **NMA** is an employee of Ochsner Health; has served in a consulting/advisory role for AstraZeneca and Tempus; and has served on a speakers' bureau for Bristol Myers Squibb, AstraZeneca, Merck, Eisai, Genentech, Janssen, Exelixis, Seagen, and Daiichi Sankyo/Lilly. **JT** holds stock in Novo Nordisk and Vertex. **JWL** holds patents with Chinook Therapeutics (a Novartis company). **VG** has served in a consulting/advisory role with Genentech, Hologic, Puma, Daiichi Sankyo, Novartis, AstraZeneca, Bayer, Gilead, Lilly, Pfizer; has ownership interest in 3rdEyeBio, AmunBio, Novilla, Ozette.ai, TempusAI, XTRemisBio; and has funding from Lilly, **DG, AK**, and **MMc** are or were employees of GRAIL at time of study. **NN** has served a consulting/advisory role with Exact Sciences and Grail and received honoraria from Roche Diagnostics and MJH Life Sciences. **RHK, DS, DC, JJ, RC, ST, TT** and **JKT** have nothing to disclose.

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METHODS

- PATHFINDER 2 (NCT05155605) is a multicenter, prospective, interventional study that enrolled participants aged ≥50 years without clinical suspicion of cancer or cancer diagnosis/treatment in the past 3 years²
- Enrollment targets for race/ethnicity were established from 2020 National Center for Health Statistics data⁶; sex and age targets (enriched for the 60-69 years and 70-79 years age groups) relative to the US population were based on 2020 Census data⁷
- Data on baseline demographics (age, sex, race/ethnicity) were collected at enrollment (race and ethnicity were self-reported; racial groups were not mutually exclusive)

- A blood sample was drawn from each participant for MCED testing; for those with a positive MCED test result (ie, cancer signal detected), 1 or 2 CSOs were predicted
- MCED test performance at 12 months was analyzed in participants with a completed 12-month cancer status assessment
- All endpoints reported in this analysis were designed to be descriptive; no prespecified success criteria or formal hypothesis testing were applied



**Supplementary Table S1.
MCED-Detected Cancer Types by
Race and Ethnicity.**



Digital Poster

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Table S1. MCED-Detected Cancer Types by Race and Ethnicity.

Cancer Type	American Indian or Alaska Native n=2	Asian, Native Hawaiian or Other Pacific Islander n=14	Black or African American n=14	White n=139	Hispanic or Latino n=11	Not Hispanic or Latino n=160
Anus	0	0	0	5	0	5
Bladder, Urothelial Tract	0	1	0	1	1	2
Bone or Soft Tissue Sarcoma	0	0	0	1	0	1
Breast	0	2	4	13	1	18
Colon/Rectum	0	1	2	15	0	18
Esophagus	0	0	0	3	0	3
Head and Neck	0	2	0	16	0	18
Kidney	0	0	2	3	1	4
Liver, Intrahepatic Bile-Duct	1	1	1	14	1	16
Lung	0	0	0	10	1	9
Lymphoid Lineage	0	3	1	23	1	27
Myeloid Lineage	0	0	0	0	0	0
Ovary or Fallopian Tubes	0	0	0	4	3	2
Pancreas, Extrahepatic Bile-Duct, Gallbladder	0	1	0	11	1	12
Plasma Cell Lineage	0	1	3	1	0	5
Prostate	0	1	0	7	1	7
Skin ^a	0	0	0	0	0	0
Stomach	1	0	0	2	0	2
Thyroid	0	0	0	0	0	0
Uterus	0	0	0	4	0	4
Other ^b	0	1	1	6	0	7

^aSkin cancers excluding basal cell carcinoma and squamous cell carcinoma. ^bOther cancer types include Testis (N = 2), Thymus (N = 2), Ampulla of Vater (N = 1), Brain and Spinal Cord (N = 1), cancer of unknown primary origin (N = 1), Small Intestine (N = 1), Uveal Melanoma (N = 1).