Cancerguard™ Clinician Brochure

Test Information for Healthcare Providers

10/2025

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The Cancerguard test was developed, and the performance characteristics validated by Exact Sciences Laboratories following College of American Pathologists (CAP) and Clinical Laboratory Improvement Amendments (CLIA) regulations. This test has not been cleared or approved by the US Food and Drug Administration. The test is performed at Exact Sciences Laboratories. Exact Sciences Laboratories is accredited by CAP, certified under CLIA regulations, and qualified to perform high-complexity clinical laboratory testing.

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1 Indication for Use

The Cancerguard™ test is a qualitative in vitro diagnostic (IVD) for the detection of alterations in circulating tumor DNA and tumor-associated protein levels, which are commonly associated with cancer. It is performed on plasma derived from peripheral blood specimens. A positive Cancerguard test result means that the blood test identified a cancer signal that may indicate the presence of cancer. This result alone does not confirm the presence of cancer. Further clinical evaluation by a healthcare provider and follow-up imaging are needed to locate and confirm a diagnosis of cancer or determine that cancer is not present. While there are no established guidelines for imaging following a positive Cancerguard test result, there is a published follow-up workflow based on expert clinician opinion and results from an exploratory, prospective, interventional study.[1,2] The proposed workflow in the Kisiel *et al* publication includes an intravenous-contrast enhanced computed tomography (IV contrast CT of chest, abdomen/pelvis, and soft-tissue neck) and if necessary, positron emission tomography-computed tomography (18F FDG PET-CT) from the skull-base to mid-thigh. Alternative follow-up procedures (e.g., targeted imaging, endoscopic procedures, CT without IV-contrast) may be appropriate in the context of the patient's medical history and clinical evaluation.[2] The

Cancerguard test does not identify the type or location of the suspected cancer. The Cancerguard test is not a replacement for existing recommended cancer screening or diagnostic modalities for cancer. A negative Cancerguard test result alone does not rule out the presence of cancer of any type. This test is indicated for adults of either sex, ages 50-84 years, who have had no known cancer diagnosis within the preceding 3 years.

2 Warnings, Precautions, and Limitations

- The Cancerguard test does not detect all cancers and is not a replacement for existing recommended cancer screening or diagnostic modalities for cancer.
- The Cancerguard test is not recommended for patients with a history of adverse reactions to iodine based IV contrast, or women who are, could be, or intend to become pregnant because of the potential need for radiologic imaging.
- The Cancerguard test is not indicated for screening of breast and prostate cancer.
- The test was not evaluated for the detection of pre-cancerous lesions.
- Results should be interpreted in the context of a patient's medical history, clinical signs, and symptoms. A negative result does not rule out the presence of cancer of any type. A positive result does not confirm the presence of any cancer.
- The Cancerguard test may produce false negative or false positive results. A false positive result occurs when a test produces a positive result, even though the presence of cancer could not be identified clinically. A false negative result occurs when a test does not detect cancer even when cancer is identified clinically.
- The clinical performance data was generated from case-control studies of patients who were already known to have cancer or to be healthy (no active cancer or suspicion of cancer). The performance established may not accurately reflect the test performance in a clinical setting.
- This test has not been cleared or approved by the US Food and Drug Administration.
- The risks associated with using the LBgard® Blood Collection tubes are expected to be similar to those of routine phlebotomy.

3 Device Description

The Cancerguard test assesses biomarkers within the plasma from whole blood samples. The concentration of select protein biomarkers associated with cancer is measured in plasma by an immunoassay, while methylated cell-free DNA (cfDNA) in plasma is detected using real-time PCR following bisulfite conversion of DNA.

The Cancerguard test begins with collection of whole blood in LBgard Blood Tubes. The test is run in a single laboratory (Exact Sciences Laboratories located in Madison, WI). The blood is shipped from the collection site to the laboratory where it is processed to isolate plasma. An aliquot of plasma is subjected to a high-throughput immunoassay for quantification of multiple protein biomarkers associated with cancer. In parallel, cfDNA is extracted from the plasma using a qualified DNA extraction method and then subjected to bisulfite conversion. This process is followed by DNA quantification in assays that combine real-time PCR to perform specific amplification and detection of methylated target DNA. The data from the protein immunoassay and methylation assay (TELQAS: Target Enrichment Long-probe Quantitative Amplified Signal) are filtered through software and bioinformatics pipelines that include quality-control metrics. Final data from both assays are processed by a classifier to generate a positive or negative result for a cancer signal status. Controls are included to determine validity of the run and of each individual specimen for both the protein and methylation assays.

The Exact Sciences Specimen Collection Kit (kit) labeled with Cancerguard containing LBgard blood tubes for the collection, stabilization, transport, and storage of whole blood samples is investigational. Blood collection tubes are provided within each pre-packaged blood collection kit, which contains a pre-printed return label and FedEX clinical overpack. Kits must be used before the expiration date noted on the packaging. The kits must be stored and used in accordance with the instructions for use. Barcode labels will be used to identify the blood collection kit and the blood collection tubes. Blood collection kits will be provided by Exact Sciences.

4 Interpretation of Cancerguard Test Results

A negative result means that the blood test did not identify a cancer signal. A negative Cancerguard test result alone does not rule out the presence of cancer of any type. A test can also have a negative result that is incorrect (false negative). The patient should continue with recommended cancer screening procedures as directed by their healthcare provider.

A positive Cancerguard test result means that the blood test identified a cancer signal that may indicate

the presence of cancer. This result alone does not confirm the presence of cancer. A test can also have a positive result that is incorrect (false positive). Further clinical evaluation by a healthcare provider and follow-up imaging are needed to locate and confirm a diagnosis of cancer or determine that cancer is not present. While there are no established national guidelines for imaging following a positive Cancerguard test result, there is a published follow-up workflow based on expert clinician opinion and results from an exploratory, prospective, interventional study.[1,2] The proposed workflow in the Kisiel *et al* publication includes an intravenous-contrast enhanced computed tomography (IV contrast CT of chest, abdomen/pelvis, and soft-tissue neck) and if necessary, positron emission tomography-computed tomography (18F FDG PET-CT) from the skull-base to mid-thigh. Alternative follow-up procedures (e.g., targeted imaging, endoscopic procedures, CT without IV-contrast) may be appropriate in the context of the patient's medical history and clinical evaluation.[2]

In some instances, a quality control (QC) failure or insufficient clinical material in the sample leads to an invalid test (does not generate a result). In the case of an invalid test, a new specimen will need to be collected and tested to generate a valid result.

5 Test Development Study Results

Results from a test development, case-control study using peripheral blood samples from 729 individuals diagnosed with one of 21 types of cancer and 2,434 individuals without a cancer diagnosis are outlined below. Demographic characteristics of the study participants are shown in Table 5-1. The distribution of the 21 cancer types and stages selected for the 729 subjects with cancer is shown in Table 5-2.[3]

Table 5-1: Demographic Summary of Test Development Study Participants (N=3,163)

Characteristic	Cancer	Non-Cancer	Total
	n=729	n=2,434	N=3,163
Sex			
Female	388 (53.2%)	1,392 (57.2%)	1,780 (56.3%)
Male	341 (46.8%)	1,042 (42.8%)	1,383 (43.7%)
Age (years)			
Mean (SD)	66.3 (8.3)	64.9 (7.8)	65.2 (7.9)
(min, max)	(50, 84)	(50, 84)	(50, 84)
Race			
White	587 (80.5%)	2,009 (82.5%)	2,596 (82.1%)
Black or African American	67 (9.2%)	327 (13.4%)	394 (12.5%)
Asian	31 (4.3%)	55 (2.3%)	86 (2.7%)
American Indian or Alaska Native	7 (1%)	10 (0.4%)	17 (0.5%)
Mixed Race	1 (0.1%)	7 (0.3%)	8 (0.3%)
Native Hawaiian or Other Pacific Islander	1 (0.1%)	2 (0.1%)	3 (0.1%)
Unknown/Missing	35 (4.8%)	24 (1%)	59 (1.9%)
Ethnicity			
Not Hispanic/Latino	650 (89.2%)	2,077 (85.3%)	2,727 (86.2%)
Hispanic/Latino	49 (6.7%)	341 (14%)	390 (12.3%)
Unknown/Missing	30 (4.1%)	16 (0.7%)	46 (1.5%)

Table 5-2: Summary of Cancer Types and Stages in the Test Development Study (n=729)

Cancer Type	Stage I	Stage II	Stage III	Stage IV	Unknown Stage
Lung and Bronchus (n=159)	46	23	48	39	3
Breast (n=88)	24	30	23	9	2
Colon and Rectum (n=88)	13	18	25	27	5
Prostate (n=51)	13	24	6	8	0
Uterus (n=39)	20	4	7	6	2
Pancreas (n=37)	7	8	7	14	1
Head and Neck (n=36)	10	5	11	10	0
Kidney and Renal Pelvis (n=32)	9	4	4	11	4
Stomach (n=30)	5	7	7	9	2
Urinary Bladder (n=28)	7	9	4	6	2
Esophagus (n=27)	6	5	8	7	1
Liver and Bile Duct (n=25)	5	6	8	5	1
Anus (n=16)	1	8	3	3	1
Ovary (n=14)	1	1	7	3	2
Vulva (n=13)	6	0	3	2	2
Cervix Uteri (n=13)	2	3	3	2	3
Thyroid (n=13)	4	4	0	4	1
Small Intestine (n=10)	0	3	4	3	0
Non-Hodgkin Lymphoma (n=7)	1	0	2	4	0
Testis (n=2)	2	0	0	0	0
Multiple Myeloma (n=1)	0	1	0	0	0
Total	182	163	180	172	32

6 Overall Performance Characteristics from Test Development Study

All data presented in this section were generated from a case-control, test development study of patients who were already known to have cancer or thought to be healthy (no active cancer or suspicion of cancer at the time of blood draw). Control participants were not followed for cancer status after the blood draw. These data therefore may not accurately reflect the test performance in a clinical setting with diagnostic follow-up.

Multiple analyses were completed to assess sensitivity of the Cancerguard test. The results from an analysis of 590 participants with one of 19 cancer types (excluding breast and prostate) are shown in Table 6-1. Additional results including sensitivity by cancer stage and type are shown in the tables to follow.[3]

The Cancerguard test is not intended for breast or prostate cancer screening; however, it may still detect these cancers. The test design relies on biomarkers that are commonly present across many cancer types and could potentially detect a cancer signal in cancers not specifically evaluated or validated during development. Accordingly, the Cancerguard test may yield a cancer signal for types beyond the 21 cancers included in the test development study. The performance characteristics for any additional cancer types that may be detected have not been established.

Table 6-1: Sensitivity Excluding Breast and Prostate Cancer (n=590), Specificity, and False Positive Rate

Sensitivity	95% Confidence Interval
64.1%	(60.1%, 67.8%)
Specificity	**95% Confidence Interval**
97.4%	(96.7%, 97.9%)
False Positive Rate	
2.6% *64 of 2,434 non-cancer participants had false positive results.*	

Table 6-2: Overall Sensitivity Analysis (all cancers including breast and prostate)

	Sensitivity	95% Confidence Interval
All Cancers (n=729)	57.8%	(54.1%, 61.3%)

Table 6-3: Sensitivity by Stage (excluding breast and prostate)

Stage	Sensitivity	95% Confidence Interval
Stage I (n=145)	24.8%	(18.5%, 32.4%)
Stage II (n=109)	57.8%	(48.4%, 66.6%)
Stage III (n=151)	81.5%	(74.5%, 86.8%)
Stage IV (n=155)	90.3%	(84.6%, 94.0%)
Unknown Stage (n=30)	53.3%	(36.1%, 69.8%)
Early Stage (Stage I and II)	39.0%	(33.2%, 45.1%)

Table 6-4: Sensitivity by Cancer Type

Cancer Type	Sensitivity	95% Confidence Interval
Lung and Bronchus (n=159)	62.9%	(55.2%, 70.0%)
Breast (n=88)	42.0%	(32.3%, 52.5%)
Colon and Rectum (n=88)	76.1%	(66.3%, 83.8%)
Prostate (n=51)	11.8%	(5.5%, 23.4%)
Uterus (n=39)	38.5%	(24.9%, 54.1%)
Pancreas (n=37)	78.4%	(62.8%, 88.6%)
Head and Neck (n=36)	69.4%	(53.1%, 82.0%)
Kidney (n=32)	46.9%	(30.9%, 63.6%)
Stomach (n=30)	73.3%	(55.6%, 85.8%)
Bladder and Urinary (n=28)	67.9%	(49.3%, 82.1%)
Esophagus (n=27)	63.0%	(44.2%, 78.5%)
Liver and Bile Duct (n=25)	80.0%	(60.9%, 91.1%)
Anus (n=16)	68.8%	(44.4%, 85.8%)
Ovary (n=14)	71.4%	(45.4%, 88.3%)
Thyroid (n=13)	23.1%	(8.2%, 50.3%)
Vulva (n=13)	46.2%	(23.2%, 70.9%)
Cervix Uteri (n=13)	76.9%	(49.7%, 91.8%)
Small Intestine (n=10)	40.0%	(16.8%, 68.7%)
Non-Hodgkin Lymphoma (n=7)	57.1%	(25.0%, 84.2%)
Testis (n=2)	50.0%	(9.5%, 90.5%)
Multiple Myeloma (n=1)	0.0%	(0.0%, 79.3%)

Table 6-5: Sensitivity by Cancer Type/Stage

Cancer Type	Sensitivity (95% Confidence Interval)				
	Stage I	**Stage II**	**Stage III**	**Stage IV**	**Unknown Stage**
Lung and Bronchus (n=159	19.6% (10.7%, 33.2%) n=46	52.2% (33.0%, 70.8%) n=23	83.3% (70.4%, 91.3%) n=48	92.3% (79.7%, 97.3%) n=39	100.0% (43.9%, 100.0%) n=3
Colon and Rectum (n=88)	23.1% (8.2%, 50.3%) n=13	61.1% (38.6%, 79.7%) n=18	88.0% (70.0%,95.8%) n=25	96.3% (81.7%,99.3%) n=27	100.0% (56.6%,100.0%) n=5
Breast (n=88)	8.3% (2.3%, 25.8%) n=24	40.0% (24.6%,57.7%) n=30	60.9% (40.8%,77.8%) n=23	100.0% (70.1%,100.0%) n=9	0.0% (0.0%, 65.8%) n=2
Prostate (n=51)	7.7% (1.4%,33.3%) n=13	0.0% (0.0%, 13.8%) n=24	0.0% (0.0%, 39.0%) n=6	62.5% (30.6%,86.3%) n=8	-
Uterus (n=39)	15.0% (5.2%, 36.0%) n=20	25.0% (4.6%, 69.9%) n=4	71.4% (35.9%,91.8%)) n=7	83.3% (43.6%,97.0%) n=6	50.0% (9.5%, 90.5%) n=2
Pancreas (n=37)	42.9% (15.8%,75.0%) n=7	75.0% (40.9%,92.9%) n=8	100.0% (64.6%,100.0%) n=7	92.9% (68.5%,98.7%) n=14	0.0% (0.0%, 79.3%) n=1
Head and Neck (n=36)	60.0% (31.3%,83.2%) n=10	60.0% (23.1%,88.2%) n=5	72.7% (43.4%,90.3%) n=11	80.0% (49.0%,94.3%) n=10	-
Kidney (n=32)	0.0% (0.0%, 29.9%) n=9	75.0% (30.1%,95.4%) n=4	50.0% (15.0%,85.0%) n=4	90.9% (62.3%,98.4%) n=11	0.0% (0.0%, 49.0%) n=4
Stomach (n=30)	40.0% (11.8%,76.9%) n=5	57.1% (25.0%,84.2%) n=7	85.7% (48.7%,97.4%) n=7	100.0% (70.1%,100.0%) n=9	50.0% (9.5%, 90.5%) n=2
Urinary Bladder (n=28)	28.6% (8.2%,64.1%) n=7	66.7% (35.4%,87.9%) n=9	100.0% (51.0%,100.0%) n=4	100.0% (61.0%, 100.0%) n=6	50.0% (9.5%,90.5%) n=2
Esophagus (n=27)	33.3% (9.7%,70.0%) n=6	40.0% (11.8%,76.9%) n=5	75.0% (40.9%,92.9%) n=8	85.7% (48.7%,97.4%) n=7	100.0% (20.7%,100.0%) n=1

Cancer Type	Sensitivity (95% Confidence Interval				
	Stage I	Stage II	Stage III	Stage IV	Unknown Stage
Liver and Bile Duct (n=25)	40.0% (11.8%,76.9%) n=5	83.3% (43.6%,97.0%) n=6	100.0% (67.6%,100.0%) n=8	100.0% (56.6%,100.0%) n=5	0.0% (0.0%, 79.3%) n=1
Anus (n=16)	0.0% (0.0%, 79.3%) n=1	75.0% (40.9%,92.9%) n=8	66.7% (20.8%,93.9%) n=3	100.0% (43.9%,100.0%) n=3	0.0% (0.0%, 79.3%) n=1
Ovary (n=14)	0.0% (0.0%, 79.3%) n=1	0.0% (0.0%, 79.3%) n=1	85.7% (48.7%,97.4%) n=7	66.7% (20.8%,93.9%) n=3	100.0% (34.2%,100.0%) n=2
Vulva (n=13)	16.7% (3.0%,56.4%) n=6	-	66.7% (20.8%,93.9%) n=3	100.0% (34.2%,100.0%) n=2	50.0% (9.5%, 90.5%) n=2
Thyroid (n=13)	0.0% (0.0%, 49.0%) n=4	0.0% (0.0%, 49.0%) n=4	-	75.0% (30.1%,95.4%) n=4	0.0% (0.0%, 79.3%) n=1
Cervix Uteri (n=13)	100.0% (34.2%,100.0%) n=2	66.7% (20.8%,93.9%) n=3	100.0% (43.9%,100.0%) n=3	100.0% (34.2%,100.0%) n=2	33.3% (6.1%, 79.2%) n=3
Small Intestine (n=10)	-	66.7% (20.8%,93.9%) n=3	25.0% (4.6%, 69.9%) n=4	33.3% (6.1%, 79.2%) n=3	-
Non-Hodgkin Lymphoma (n=7)	0.0% (0.0%, 79.3%) n=1	-	50.0% (9.5%,90.5%) n=2	75.0% (30.1%,95.4%) n=4	-
Testis (n=2)	50.0% (9.5%, 90.5%) n=2	-	-	-	-
Multiple Myeloma (n=1)		0.0% (0.0%, 79.3%) n=1	-	-	-

Table 6-6: Sensitivity in Cancer Subgroups

Subset Definition	n/N	Sensitivity	95% CI
Sensitivity in cancers that contribute to approximately ¾ of cancer deaths: lung, colorectal, pancreas, breast, prostate, liver, non-Hodgkin lymphoma, bladder, esophagus, and kidney/renal pelvis	314 / 542	57.9%	(53.7%, 62.0%)
Sensitivity in cancers with recommended screening: breast, colorectal, lung, prostate, and cervical	220 / 399	55.1%	(50.2%, 59.9%)
Sensitivity excluding cancer types with recommended screening: excluding breast, lung, colorectal, prostate, and cervical	201 / 330	60.9%	(55.5%, 66.0%)
Sensitivity excluding cancer types with recommended screening other than lung: e.g., excluding breast, colorectal, prostate, and cervical	301 / 489	61.6%	(57.2%, 65.8%)
Sensitivity of the 6 most aggressive cancer types with the shortest 5-year survival rate: pancreatic, esophagus, liver, lung, stomach, and ovarian	198 / 292	67.8%	(62.2%, 72.9%)

7 Independent Clinical Validation Study

The clinical performance of the Cancerguard test was also evaluated in an independent case control clinical validation study using peripheral blood samples from 324 individuals diagnosed with one of 19 types of cancer and 800 individuals without a cancer diagnosis or suspicion of cancer. Cancer samples were selected to achieve balanced representation across stages I-IV (excluding breast and prostate cancer) for estimation of stage-specific performance. Within stage, the distribution of 17 cancer types (excluding breast and prostate) was chosen to reflect 2021 incidence reported by the Surveillance, Epidemiology, and End Results (SEER) Program. For breast and prostate cancer, we selected 50 samples each, ensuring the stage distribution mirrored 2021 SEER incidence. Non-cancer samples were chosen so that the distribution of age groups, sex, and race (White, Black, Other) mirrored the demographics reported in the 2021 Census.

The purpose of this study was to provide an independent evaluation of the clinical performance of the Cancerguard test, using a set of samples selected with consideration to the characteristics of the intended use population.

Demographic characteristics of the study participants are shown in Table 7-1. The distribution of the 19 cancer types and stages selected for the 324 subjects with cancer is shown in Table 7-2.[4]

Table 7-1: Demographic Summary of Clinical Validation Study Participants (N=1,124)

Characteristic	Cancer	Non-Cancer	Total
	n=324	n=800	N=1,124
Sex			
Female	160 (49.4%)	415 (51.9%)	575 (51.2%)
Male	164 (50.6%)	385 (48.1%)	549 (48.8%)
Age (years)			
Mean (SD)	66.9 (8.2)	63.7 (8.9)	64.6 (8.8)
(Min, Max)	(50, 84)	(50, 84)	(50, 84)
Race			
White	284 (87.7%)	657 (82.1%)	941 (83.7%)
Black or African American	30 (9.3%)	91 (11.4%)	121 (10.8%)
Asian	2 (0.6%)	10 (1.3%)	12 (1.1%)

Characteristic	Cancer	Non-Cancer	Total
	n=324	n=800	N=1,124
American Indian or Alaska Native	2 (0.6%)	6 (0.8%)	8 (0.7%)
Native Hawaiian or Other Pacific Islander	1 (0.3%)	1 (0.1%)	2 (0.2%)
More than one race	1 (0.3%)	6 (0.8%)	7 (0.6%)
Unknown	4 (1.2%)	29 (3.6%)	33 (2.9%)
Ethnicity			
Hispanic/Latino	11 (3.4%)	155 (19.4%)	166 (14.8%)
Not Hispanic/Latino	302 (93.2%)	636 (79.5%)	938 (83.6%)
Unknown	11 (3.4%)	7 (0.9%)	18 (1.6%)
Missing	0	2	2

Table 7-2: Summary of Cancer Types and Stages in the Clinical Validation Study

Cancer Type	Stage I	Stage II	Stage III	Stage IV
Prostate (n=51)	12	21	11	7
Breast (n=50)	38	6	4	2
Lung (n=57)	11	11	14	21
Colorectal (n=38)	7	10	13	8
Kidney (n=19)	8	3	5	3
Uterus (n=17)	9	2	4	2
Head and Neck (n=17)	4	6	3	4
Pancreas (n=17)	2	5	3	7
Bladder (n=12)	3	6	2	1
Liver (n=12)	3	4	3	2
Thyroid (n=5)	4	1	0	0
Stomach (n=7)	2	2	1	2
Ovary (n=7)	1	1	3	2
Esophagus (n=6)	1	2	1	2
Small Intestine (n=3)	0	1	0	2
Cervix Uteri (n=2)	0	1	1	0
Anal (n=2)	0	1	1	0
Vulva (n=1)	1	0	0	0
Testis (n=1)	0	0	1	0
Total	106	83	70	65

8 Overall Performance Characteristics from Independent Clinical Validation Study

Multiple analyses were completed to assess sensitivity of the Cancerguard test. The results from an analysis of 223 participants with one of 17 cancer types (excluding breast and prostate) are shown in Table 8-1. Additional results including sensitivity by cancer stage and type are shown in the tables to follow.[4]

The Cancerguard test is not intended for breast or prostate cancer screening; however, it may still detect these cancers. The test design relies on biomarkers that are commonly present across many cancer types and could potentially detect a cancer signal in cancers not specifically evaluated or validated during development. Accordingly, the Cancerguard test may yield a cancer signal for types beyond the 19 cancers included in the independent clinical validation study. The performance characteristics for any additional cancer types that may be detected have not been established.

There are important limitations to consider when interpreting the results from this study. First, due to sample availability the size of this study was limited, with 9 cancer types having fewer than 10 cases. As a result, many confidence intervals are wide and sensitivity estimates, particularly for cancer types with few cancers, should be viewed with caution. Second, all data presented in this section were generated from a case-control, clinical validation study of patients who were already known to have cancer or to be healthy (no active cancer or suspicion of cancer). These sensitivity numbers may not accurately reflect the test performance in a clinical setting.

Table 8-1: Sensitivity Excluding Breast and Prostate Cancer (n=223), Specificity, and False Positive Rate

Sensitivity	**95% Confidence Interval**
55.6%	(49.0%, 62.0%)
Specificity	**95% Confidence Interval**
97.4%	(96.0%, 98.3%)
False Positive Rate	
2.6% *21 of 800 non-cancer participants had false positive results.*	

Table 8-2: Overall Sensitivity Analysis (All Cancers including breast and prostate)

	Sensitivity	**95% Confidence Interval**
All Cancers (n=324)	41.4%	(36.1%, 46.8%)

Table 8-3: Sensitivity by Stage (excluding breast and prostate)

Stage	**Sensitivity**	**95% Confidence Interval**
Stage I (n=56)	26.8%	(17.0%, 39.6%)
Stage II (n=56)	42.9%	(30.8%, 55.9%)
Stage III (n=55)	63.6%	(50.4%, 75.1%)
Stage IV (n=56)	89.3%	(78.5%, 95.0%)
Early Stage (Stage I and II)	34.8%	(26.6%, 44.0%)

Table 8-4: Sensitivity by Cancer Type

Cancer Type	**Sensitivity**	**95% Confidence Interval**
Prostate (n=51)	3.9%	(1.1%, 13.2%)
Breast (n=50)	16.0%	(8.3%, 28.5%)
Lung (n=57)	59.6%	(46.7%, 71.4%)
Colorectal (n=38)	60.5%	(44.7%, 74.4%)
Kidney (n=19)	26.3%	(11.8%, 48.8%)
Head and Neck (n=17)	58.8%	(36.0%, 78.4%)
Pancreas (n=17)	70.6%	(46.9%, 86.7%)
Uterus (n=17)	17.6%	(6.2%, 41.0%)
Liver (n=12)	91.7%	(64.6%, 98.5%)
Bladder (n=12)	16.7%	(4.7%, 44.8%)
Ovary (n=7)	100.0%	(64.6%, 100%)

Cancer Type	Sensitivity	95% Confidence Interval
Stomach (n=7)	57.1%	(25%, 84.2%)
Esophagus (n=6)	66.7%	(30.0%, 90.3%)
Thyroid (n=5)	20.0%	(3.6%, 62.4%)
Small Intestine (n=3)	100.0%	(43.9%, 100%)
Anal (n=2)	100.0%	(34.2%, 100%)
Cervix Uteri (n=2)	50.0%	(9.5%, 90.5%)
Vulva (n=1)	100.0%	(20.7%, 100%)
Testis (n=1)	100.0%	(20.7%, 100%)

Table 8-5: Sensitivity by Cancer Type / Stage

Cancer Type	Sensitivity (95% Confidence Interval)			
	Stage I	Stage II	Stage III	Stage IV
Prostate (n=51)	0% (0%, 24.2%) n=12	0% (0%, 15.5%) n=21	0% (0%, 25.9%) n=11	28.6% (8.2%, 64.1%) N=7
Breast (n=50)	5.3% (1.5%, 17.3%) n=38	33.3% (9.7%, 70%) n=6	50% (15%, 85%) n=4	100% (34.2%, 100%) n=2
Lung (n=57)	27.3% (9.7%, 56.6%) n=11	45.5% (21.3%, 72%) n=11	64.3% (38.8%, 83.7%) n=14	81% (60%, 92.3%) n=21
Colorectal (n=38)	14.3% (2.6%, 51.3%) n=7	60% (31.3%, 83.2%) n=10	61.5% (35.5%, 82.3%) n=13	100% (67.6%, 100%) n=8
Kidney (n=19)	0% (0%, 32.4%) n=8	0% (0%, 56.1%) n=3	40% (11.8%, 76.9%) n=5	100% (43.9%, 100%) n=3
Head and Neck (n=17)	50% (15%, 85%) n=4	33.3% (9.7%, 70%) n=6	100% (43.9%, 100%) n=3	75% (30.1%, 95.4%) n=4
Pancreas (n=17)	100% (34.2%, 100%) n=2	20% (3.6%, 62.4%) n=5	66.7% (20.8%, 93.9%) n=3	100% (64.6%, 100%) n=7
Uterus (n=17)	11.1% (2%, 43.5%)	50% (9.5%, 90.5%)	0% (0%, 49%)	50% (9.5%, 90.5%)

Cancer Type	Sensitivity (95% Confidence Interval)			
	Stage I	Stage II	Stage III	Stage IV
	n=9	n=2	n=4	n=2
Liver (n=12)	66.7% (20.8%, 93.9%) n=3	100% (51%, 100%) n=4	100% (43.9%, 100%) n=3	100% (34.2%, 100%) n=2
Urinary Bladder (n=12)	33.3% (6.1%, 79.2%) n=3	0% (0%, 39%) n=6	0% (0%, 65.8%) n=2	100% (20.7%, 100%) n=1
Ovary (n=7)	100% (20.7%, 100%) n=1	100% (20.7%, 100%) n=1	100% (43.9%, 100%) n=3	100% (34.2%, 100%) n=2
Stomach (n=7)	0% (0%, 65.8%) n=2	50% (9.5%, 90.5%) n=2	100% (20.7%, 100%) n=1	100% (34.2%, 100%) n=2
Esophagus (n=6)	0% (0%, 79.3%) n=1	50% (9.5%, 90.5%) n=2	100% (20.7%, 100%) n=1	100% (34.2%, 100%) n=2
Thyroid (n=5)	25% (4.6%, 69.9%) n=4	0% (0%, 79.3%) n=1	-	-
Small Intestine (n=3)	-	100% (20.7%, 100%) n=1	-	100% (34.2%, 100%) n=2
Anal (n=2)	-	100% (20.7%, 100%) n=1	100% (20.7%, 100%) n=1	-
Cervix Uteri (n=2)	-	0% (0%, 79.3%) n=1	100% (20.7%, 100%) n=1	-
Vulva (n=1)	100% (20.7%, 100%) n=1	-	-	-
Testis (n=1)	-	-	100% (20.7%, 100%) n=1	-

Table 8-6: Sensitivity in Cancer Subgroups

Subset Definition	n/N	Sensitivity	95% CI
Sensitivity in cancers that contribute to approximately ¾ of cancer deaths*: lung, colorectal, pancreas, breast, prostate, liver, bladder, esophagus, and kidney/renal pelvis	101 / 262	38.5%	(32.9%, 44.6%)
Sensitivity in cancers with recommended screening: breast, colorectal, lung, prostate, and cervical	68 / 198	34.3%	(28.1%, 41.2%)
Sensitivity excluding cancer types with recommended screening: excluding breast, lung, colorectal, prostate, and cervical	66 / 126	52.4%	(43.7%, 60.9%)
Sensitivity excluding cancer types with recommended screening other than lung: e.g., excluding breast, colorectal, prostate, and cervical	100 / 183	54.6%	(47.4%, 61.7%)
Sensitivity of the 6 most aggressive cancer types with the shortest 5-year survival rate: pancreatic, esophagus, liver, lung, stomach, and ovarian	72 / 106	67.9%	(58.5%, 76.0%)

* Non-Hodgkin lymphoma was listed in the study protocol within this cancer subgroup; however, due to lack of availability, there were no Non-Hodgkin lymphoma samples tested in the study.

9 References

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