for early detection of cancers™

Cancer Screening for Firefighters

March 2019

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Overview of Presentation

- **Cancer Among U.S. Firefighters—*Findings of U.S. Government Study***
- **Limitations of current recommended screening approaches for firefighters**
- **Our *OneTest*™ Solution**
  - Product Overview
  - *OneTest* Biomarkers & High Incidence Cancers in Firefighters
  - The Added Benefit of the *OneTest* Algorithms
    - The Power of Machine Learning & Yearly Testing
    - Special Algorithm for Fire Exposure
  - 20/20's History with and Commitment to the Fire Service

Cancer Among U.S. Firefighters

5-year study of ~30,000 U.S. fire fighters by NIOSH ending in 2015 found that

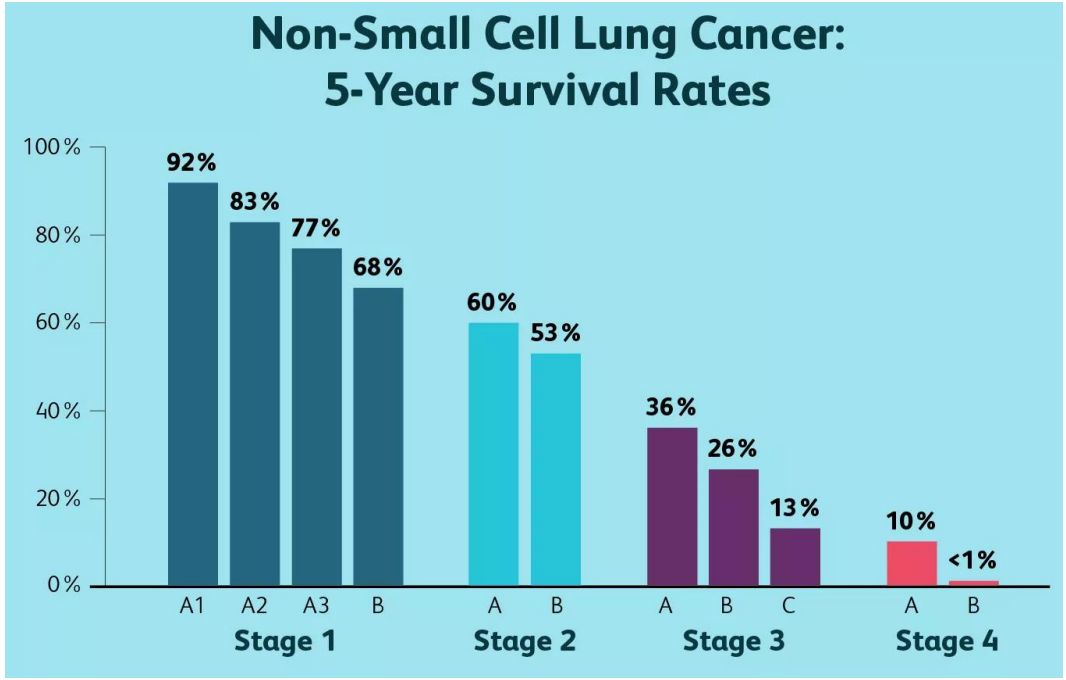
- Firefighters proportionately had a **greater number of cancer diagnoses and cancer-related deaths** than the general U.S. population.
- Mostly **digestive, oral, respiratory, and urinary cancers.**
- More cases of certain cancers among **younger fire fighters** (e.g. bladder & prostate)
- The chance of **lung cancer** diagnosis or death increased with amount of time spent at fires.

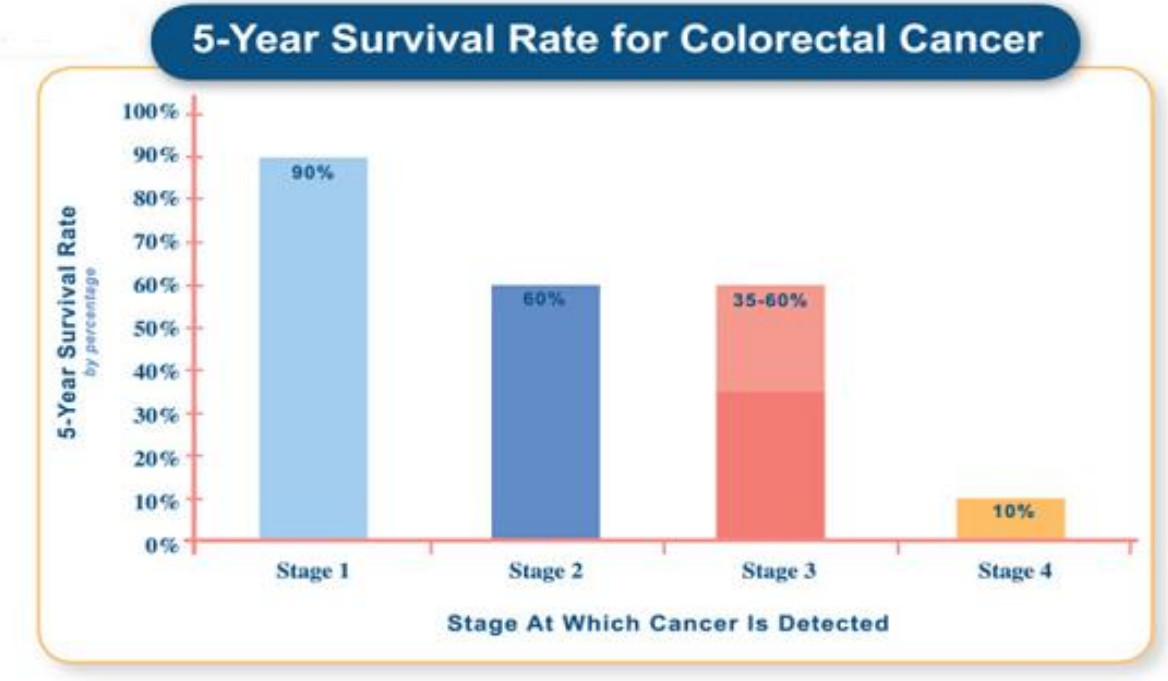
National Institute for Occupational Safety and Health
NIOSH

CDC
Centers for Disease Control and Prevention

See https://www.cdc.gov/niosh/pgms/worknotify/pdfs/ff-cancer-factsheet-final.pdf

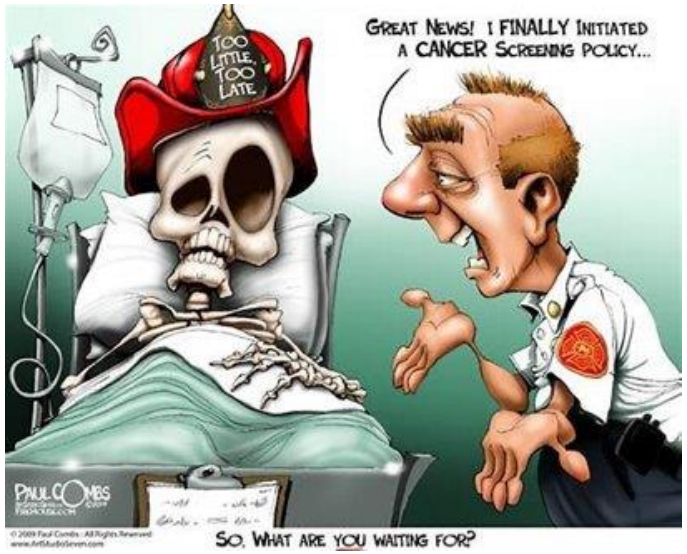
The Case for Early Detection





Limitations of Recommended Cancer Screening Guidelines for Firefighters

- About 97% of firefighters are men (NFPA)
- The recommended cancer screening guidelines (for men) of the U.S. Preventative Services Task Force, American Cancer Society, and other leading medical groups fail to adequately address many cancers which firefighters are shown to be at increased risk at younger ages:
  - Lung (especially mesothelioma)
  - Stomach
  - Esophagus
  - Intestines
  - Kidney
  - *others*

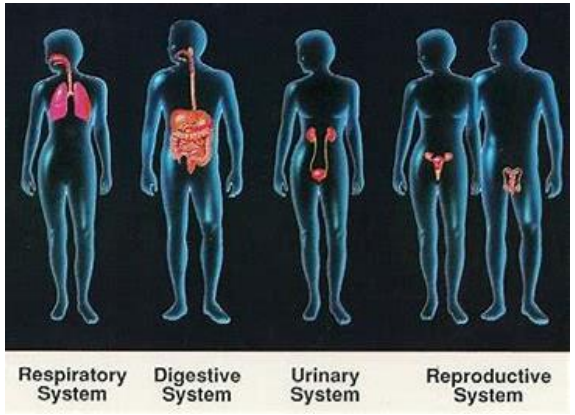


Introduction to *OneTest*™

- Blood test (venipuncture) for early detection of multiple cancers (lung, liver, esophagus, pancreatic, stomach, prostate, + others)
- Measures panel of 6 biomarkers (tumor antigens) and captures clinical factors; uses machine learning
- Intended for healthy (asymptomatic) population
- Consumer self-pay: ~$189 for general public; **$99 for firefighters** (**8% of on-line orders from firefighters**)
- Based on testing paradigm very popular in East Asian "Health Check Centers"
- Developed by 20/20 GeneSystems, Inc., Rockville, MD www.2020gene.com the developer of the *BioCheck*® suspicious powder screening kits, popular with hundreds of fire departments worldwide

Our Newest Solution

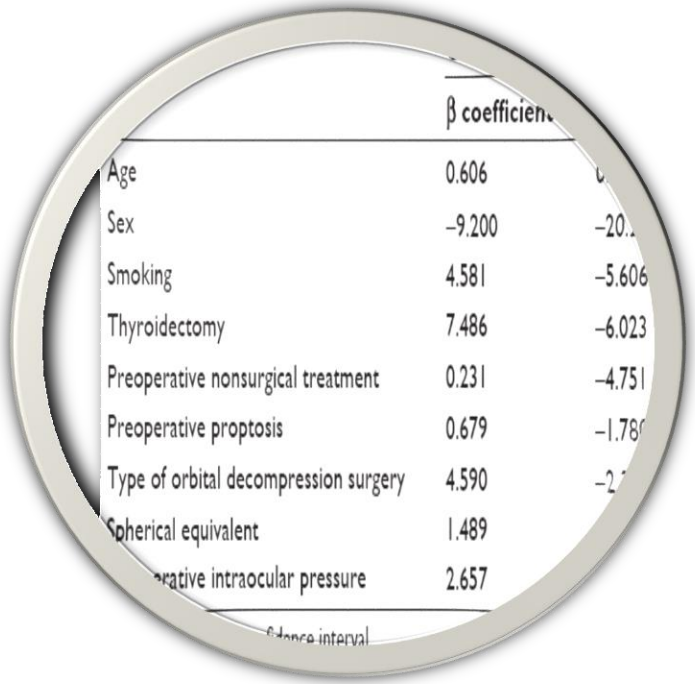
AI powered Early Cancer Screening Blood Test System for Multiple Cancers



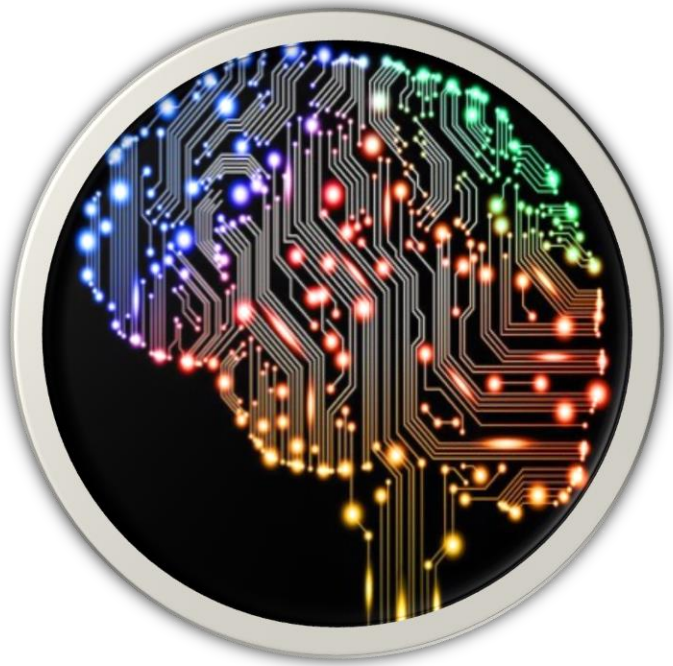
Liver, Lung, Stomach, Prostate, Pancreas, Colon, *+ more*

Core Elements
(Patents issued & pending)

Widely Used Tumor Biomarkers

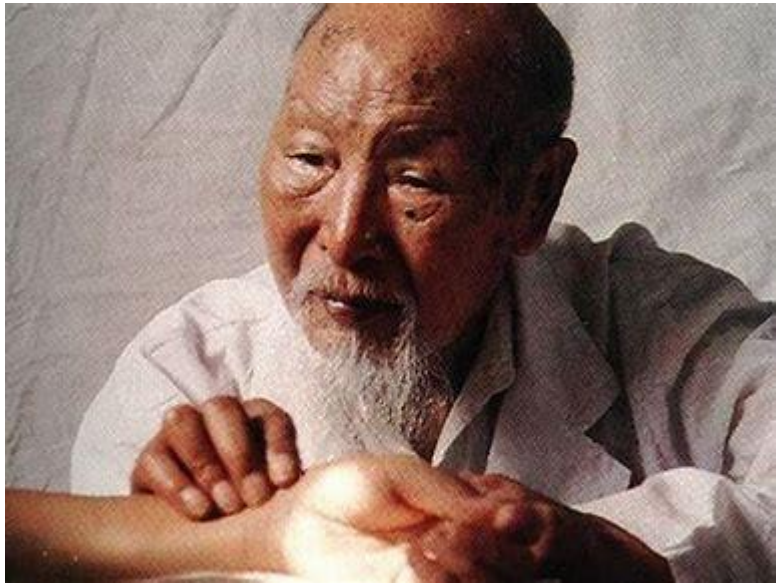


Clinical Factors



Machine Learning AI

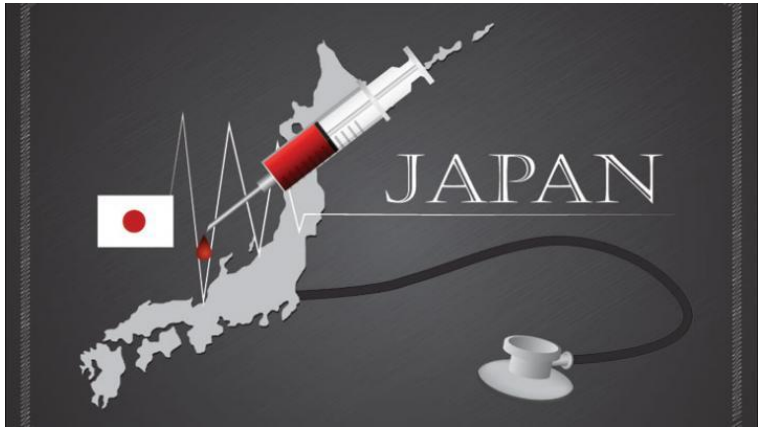
Foundations of *OneTest*



Disclaimer: These statements reflect management's current views and are meant for illustrative purposes. They do not represent guarantees of future results, levels of activity, performance, or achievements, all of which cannot be made.

Foundations of *OneTest*

- Tens of thousands of "Health Check Centers", mostly in East Asia (Japan, Korea, China, Taiwan) as well as in Europe test panels tumor antigens on tens of millions of healthy individuals each year
- These tests are overwhelmingly self-pay (or employer paid); not covered by national insurance programs
- Approach proven effective in detecting early stage cancer based on large scale real-world evidence study from largest hospital in Taiwan published in 2015



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Core Elements

- Tumor biomarkers tested:
  - *Male: AFP, CEA, CA19-9, CYFRA21-1, CA-125, PSA*
  - *Female: AFP, CEA, CA19-9, CYFRA21-1, CA125, CA15-3*
- Utilize FDA approved immunoassay analyzers (Roche Diagnostics) and detection kits
- Include machine learning algorithms powered by data from tens of thousands of asymptomatic individuals ("Gold standard") wherein cancers were diagnosed w/ in one year after biomarker tests tested.
- Collect and integrate into algorithms clinical factors that potentially contribute to false -/+
- One-year outcome data continually collected from users for ongoing accuracy improvement and machine learning.

Accuracy of Biomarkers Alone (no algorithm)

Cancer Type	Sensitivity (%)	Specificity (%)
Liver	92	89%
Lung	75	
Prostate	100	
Pancreas	89	
Colon	77	
Average	87%	

Data source:
Chang Gung Memorial Hospital (published in 2015)
Based on Real World data from 40,000 individuals tested **before** being diagnosed with cancer w/ in one year (Gold Standard).
(Consistent w/ results from an independent data set from Korean collaborators)

20/20 GeneSystems, Inc.

OneTest Biomarkers Demonstrated to be Elevated in Cancers w/ Higher Incidence or Mortality among U.S. Firefighters

Cancer Type	Increase in Mortality / Cancer Incidence	OneTest Biomarkers Elevated	Sources (citations at end)
Mesothelioma	100% / 129%	Cyfra 21-1, CEA	1-7
Esophagus	39% / 62%	CA 19-9, CEA, Cyfra 21-1	44-46
Intestines	30% / 21%	CA 19-9, CEA	8-24
Rectum	45% / 11%	CA 19-9, CEA	
Stomach	10% / 15%	CA 19-9, CEA, CA125	25-32
Lung	10% / 12%	Cyfra 21-1, CEA, CA125	33-43
Prostate	9% / 3%	PSA	47-50
Bladder	0%/12%	Cyfra 21-1	51-56

Algorithm improvements over Standard Biomarker Testing

- Compares patterns of biomarkers and clinical factors to reference set of over 25,000 individuals (asymptomatic) previously screened with same biomarker set for whom one year cancer outcomes are known.
- Demonstrated to help (i) detect some cancers that may be otherwise missed with biomarker measurements alone and (ii) reduce false positives and alarm
- Studies show algorithm helps detect 2x more cancers in males 4x more cancers in females than biomarker levels alone
- Continued year-over-year sensitivity improvements anticipated due to (i) growth of database, and (ii) value of serial tracking.

Algorithm improvements over Standard Biomarker Testing—*Real World Example 1*

Gender: Male

Age: 60

Tumor Markers Above Standard Cut-Offs: **None**

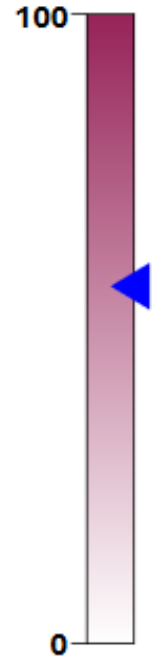
Subsequent Diagnosis: **Liver Cancer Stage I**

Algorithm Benefit: OneTest correctly classified this individual as having an increased probability of having a Gastro-Intestinal (GI) cancer within one year of the test (5 out of 100) despite otherwise normal biomarkers levels.

Multi-Cancer Analyzer Results

Case Number:	CASE-00033	Patient Visit Date:	
Account Number:	XXX	Acount Name:	
First Name:		Last Name:	
Gender:	Male	Date of Birth:	25-Apr-1950

OneTest Score	Explanation
57	Approximately 5 out of 100 males who have scored at or above your score (in the population used to develop the algorithm) were diagnosed with cancer within one year of having these biomarkers tested. *Please carefully review the interpretation section for the use, limitations and strengths of this scoring algorithm.*



Test Name	Result	Exception	Normal Range
CEA	4.34 ng/mL		0 - 4.7
AFP	2.68 ng/mL		0 - 8.3
CA 19-9	12.18 U/mL		0 - 35
CYFRA 21-1	2.65 ng/mL		0.5 - 3.3
PSA	0.66 ng/mL		0 - 4.0
SCC	0.9 ng/mL		0 - 2.5

Cancer Type	Probability	Explanation
GI	100	
Chest	0	
Derma	0	

Algorithm improvements over Standard Biomarker Testing—*Real World Example 2*

Gender: Male

Age: 79

Tumor Markers Above Standard Cut-Off: None

Subsequent Diagnosis: Bladder Cancer Stage 1

Algorithm Benefit: OneTest correctly classified this individual as having a high probability of Genito-Urinary (GU) cancer within one year of test (12 out of 100) despite all biomarkers being at normal levels.

Multi-Cancer Analyzer Results

Case Number:	CASE-00035	Patient Visit Date:	
Account Number:	XXX	Acount Name:	
First Name:		Last Name:	
Gender:	Male	Date of Birth:	15-Sep-1931

OneTest Score	Explanation
86	Approximately **12 out of 100** males who have scored at or above your score (in the population used to develop the algorithm) were diagnosed with cancer within one year of having these biomarkers tested. *Please carefully review the interpretation section for the use, limitations and strengths of this scoring algorithm.*

Test Name	Result	Exception	Normal Range
CEA	3.9 ng/mL		0 - 4.7
AFP	2.8 ng/mL		0 - 8.3
CA 19-9	9.1 U/mL		0 - 35
CYFRA 21-1	1.81 ng/mL		0.5 - 3.3
PSA	2.69 ng/mL		0 - 4.0
SCC	0.8 ng/mL		0 - 2.5

Cancer Type	Probability	Explanation
GI	75	
GU	25	
Chest	0	

Ongoing Machine Learning

- Seek to screen 20,000+ American firefighters yearly by 2021 (2% of firefighters)
- To collect expanded health + fire fighting history
- Residual serum specimens to be used for research into novel biomarkers (e.g. cell-free DNA)

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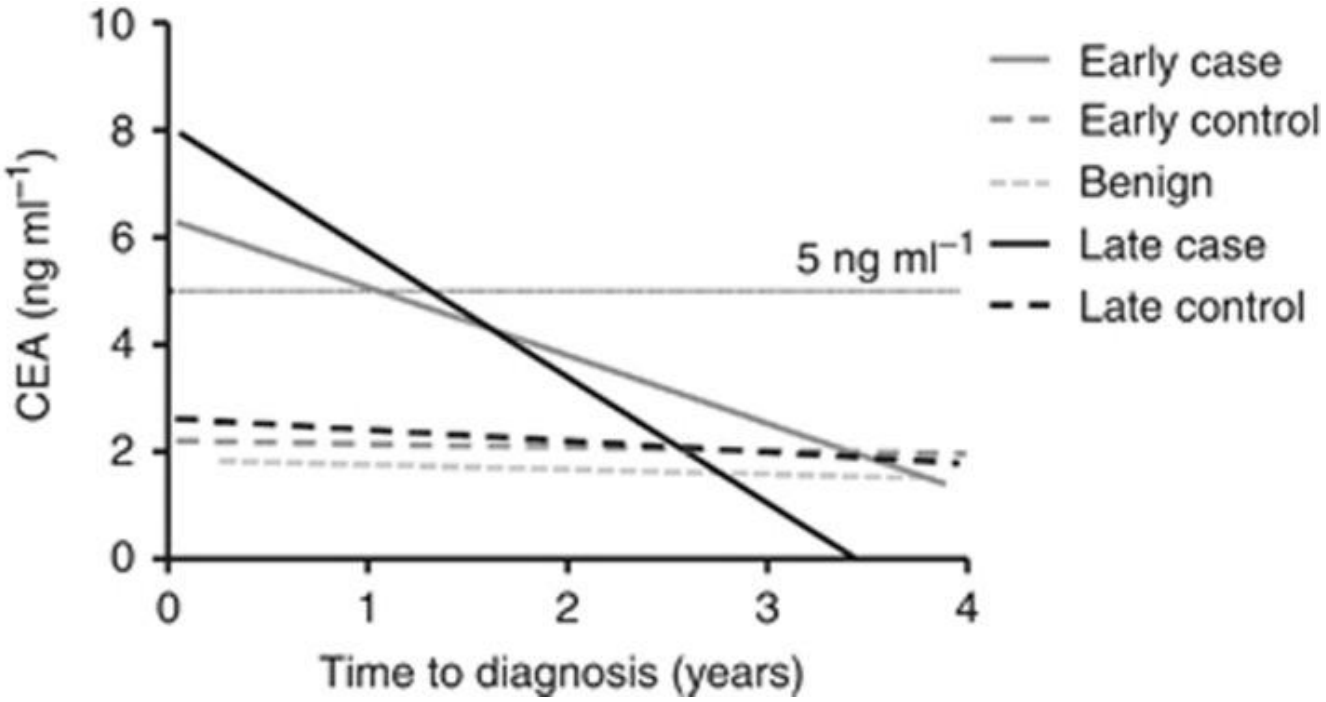
The Detection Sensitivity Improves with Yearly (Serial) Testing

In a study in the United Kingdom, CEA levels increased towards diagnosis in a significant proportion (1/3) of colorectal cancer (CRC) cases (half of late-stage cases), whereas longitudinal profiles were static in both benign and non-cancer controls.

Combining CEA with other biomarkers (e.g. CA-19.9) further improves detection capabilities for CRC according to various studies.

Other published studies support the value of yearly (serial) testing with *OneTest* biomarkers in pancreatic, ovarian, and liver cancers.



Br J Cancer. 2015 Jul 14; 113(2): 268–274

Our Longstanding Commitment to the Fire Service

- 20/20 Founder and CEO is a former volunteer firefighter
- Hundreds of Fire Departments use our very popular *BioCheck*® kits for screening suspicious powders (see www.BioCheckInfo.com)
- Offering generous product discount of $99 for firefighters (limited time only)

For More Information Visit

www.OneTestforCancer.com

Fire Department Inquiries:

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Endnotes

Mesothelioma

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End Notes , continued

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Prostate cancer

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