

Summary:

Detecting Cancers Earlier Through Elective mutation-based blood Collection and Testing (DETECT-A) Study

DATE OF SUMMARY

February 2024

THE FULL TITLE OF THIS MANUSCRIPT

Feasibility of blood testing combined with PET-CT to screen for cancer and guide intervention.

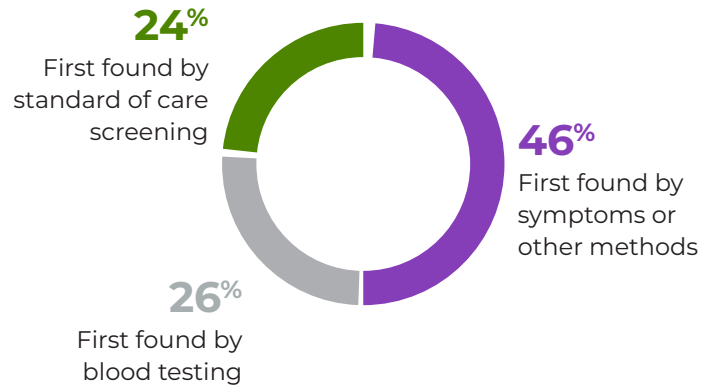
What does this summary describe?

- This summary provides an overview of the DETECT-A study and its key results.
- The DETECT-A study was designed to see if it is possible for a blood test plus diagnostic imaging scans to detect cancer.
- The study explored the use of a multi-cancer early detection (MCED): blood test plus full-body imaging with positron emission tomography-computed tomography (PET-CT) to detect cancer in multiple organs.

For more information on this study, click here: [View Scientific Manuscript](#)

What are the key takeaways from this study?

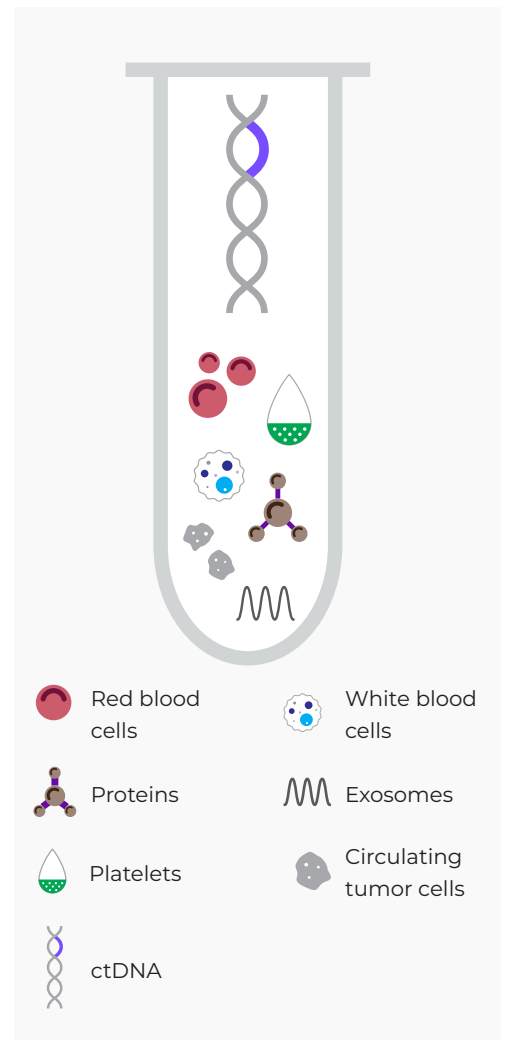
- MCED testing **doubled** the number of cancers first detected by standard-of-care screening.
- 62% of cancers detected were in early stages (localized or regional stage I-III).
- MCED testing can be safely use to detect cancer. And around half of the patients were treated with surgery meant to cure the cancer.



INTRODUCTION

What is the background of this study?

- Screening tests are recommended for four common cancers. Not everyone gets their recommended screening tests. Most cancers do not have a screening test.
- There is a need for tests, like the MCED test, that can detect more cancer types early and lower the number of people who get sick or die from advanced cancer.
- Today's recommended screening tests work well. Therefore, a new MCED should complement and not replace them and should not discourage people from getting screened.
- Using MCED testing as a complement to recommended screening is the best way to increase the number of cancer cases found early.
- The MCED test in this study uses multiple biomarkers to detect cancer.
 - Biomarkers used in this MCED include:
 - Proteins in the blood associated with cancer.
 - ctDNA (or circulating tumor DNA) biomarkers that are released into the bloodstream from tumor cells.
- This clinical trial sought to determine if an MCED test could identify cancers earlier, when they are more treatable. It also sought to detect cancers in organs that do not have routine screening (like ovarian, pancreatic, and others).



Researchers wanted to find out....

1. Can an MCED test find cancer in someone who has never had cancer before?
2. Can such a test be included in routine clinical care without discouraging patients from getting recommended screenings?
3. Can such a test be used to enable therapy with the intent to cure?
4. Can such a test be performed safely without introducing unnecessary and potentially harmful follow-up tests?

STUDY DETAILS

- The DETECT-A study was the first prospective, interventional study of a MCED blood test.
→ Prospective, interventional studies test a medicine or medical device in a population to determine how effective and safe the medicine or device is.
- Participants from 18 clinical sites across the Geisinger Health System were enrolled between September 2017 and May 2019.
- This study aimed to evaluate the effectiveness and safety of the test under investigation.

Who took part in this study?



10,006 **women** (9,911 tested)

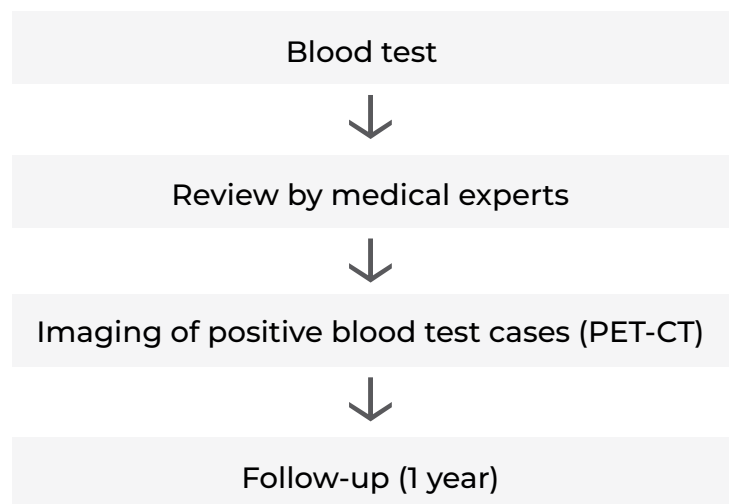


Age range **65-75** years old



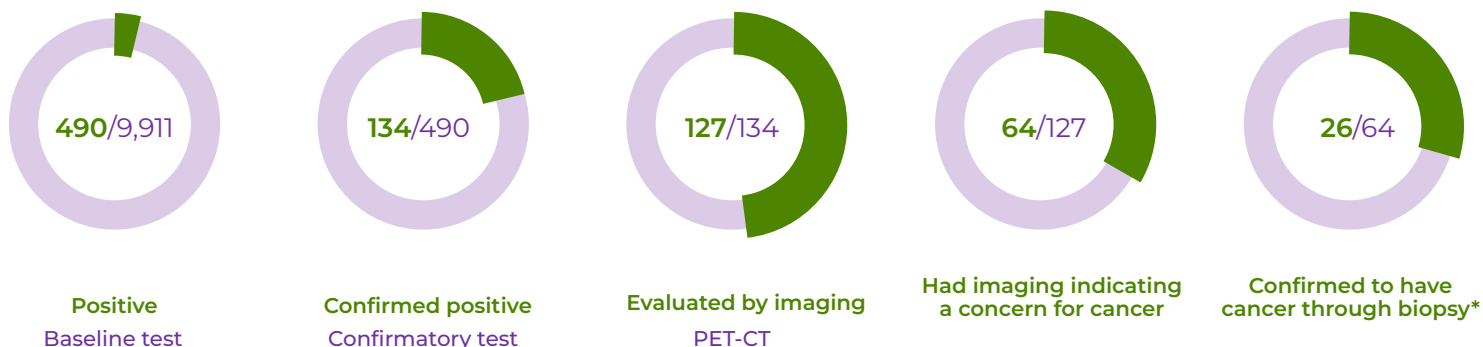
No history of cancer at the time of study entry

What were the steps involved in this MCED test?



What were the results of the DETECT-A study?

A: The multi-cancer blood testing and diagnostic results



- Among the 9,911 participants, 96 cancers were found within 12 months of enrollment.
- The MCED test detected 26/96 cancers.
- Recommended standard-of-care screening detected 24/96 cancers (20 breast, 3 lungs, 1 colorectal).
- About 1 in 100 participants had a positive blood test, and no cancer was found on imaging.
- About 1 in 500 participants had to have an invasive procedure before cancer was ruled out.

I: Performance of the multi-cancer blood test (baseline and confirmation test)

27.1%
 Sensitivity**
 A sensitivity of 27.1% means that the test detected about 1/4 of the cancers that were present.

98.9%
 Specificity***
 A specificity of 98.9% means that 98.9% of people without cancer got a negative test result.

II: Performance of the multi-cancer blood test with imaging

27.1%
 Sensitivity**
 A sensitivity of 27.1% means that the test detected about 1/4 of the cancers that were present.

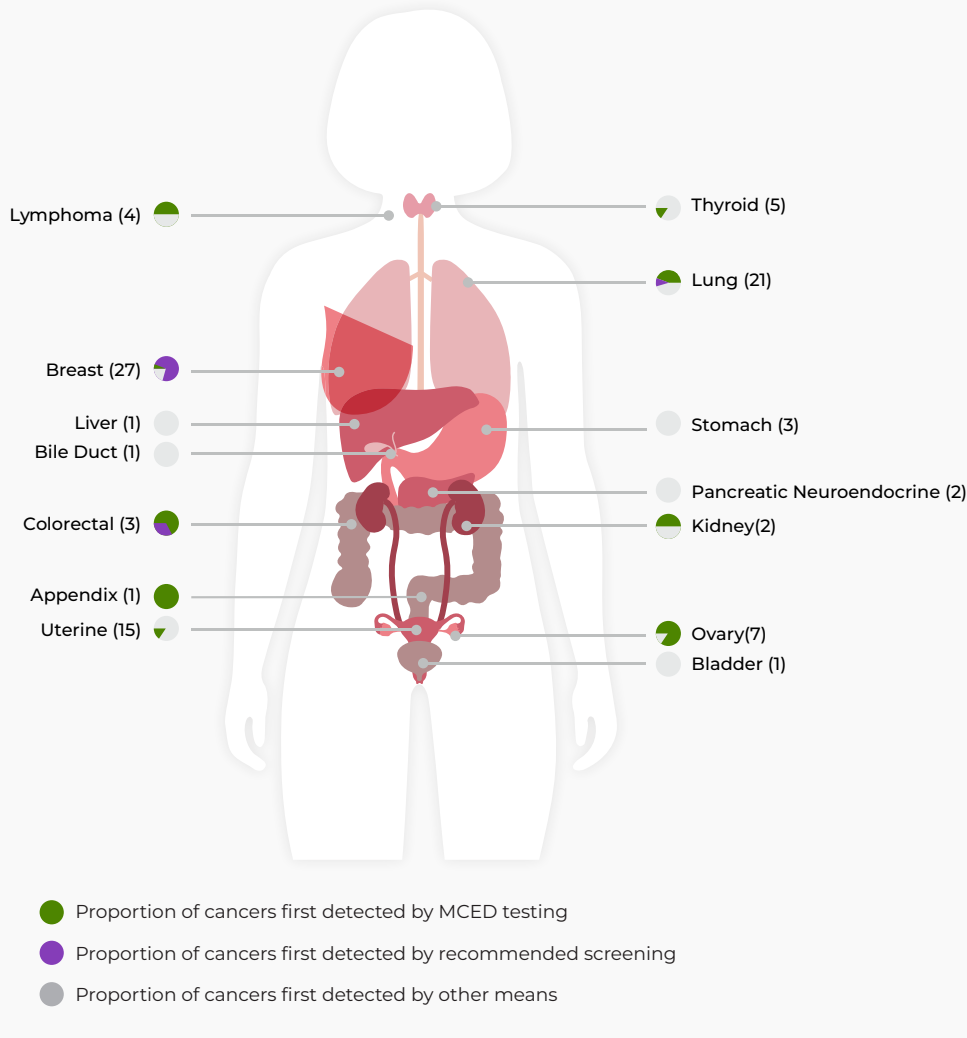
99.6%
 Specificity***
 A specificity of 99.6% means that 99.6% of people without cancer got a negative test result.

* Biopsy: Biopsy is removal of cells or tissues for examination by a pathologist.

** Sensitivity of test: Percentage of people **WITH** cancer that MCED test correctly identified.

*** Specificity of test: Percentage of people **WITHOUT** cancer that MCED test correctly identified.

B: Cancers detected



C. Feasibility and safety

- No major adverse events (unwanted effects) linked to the MCED test were reported during the study.
- Study participants did not skip recommended mammograms as a result of getting an MCED test.

STUDY CONCLUSION

Researchers found out...

- The MCED test was able to detect multiple cancer types. This includes those with no recommended screening in patients without any history of the disease.
- It is possible to detect cancer in its early stages. This makes it possible to initiate therapy meant to cure cancer.
- Blood testing can be incorporated into routine medical care without discouraging patients from having other forms of screening.
- This kind of testing can be done safely. There isn't much chance that unnecessary follow-up tests will be done.

Who sponsored this study?

This work was supported by The Marcus Foundation; Lustgarten Foundation for Pancreatic Cancer Research; The Virginia and D.K. Ludwig Fund for Cancer Research; The Sol Goldman Center for Pancreatic Cancer Research; Susan Wojcicki and Dennis Troper; the Rolfe Foundation; The Conrad R. Hilton Foundation; The John Templeton Foundation; Burroughs Wellcome Career Award For Medical Scientists; ancillary support to investigators was provided by National Institutes of Health grants and contracts CA06973, U01-CA152753, U01-CA230691, P50-CA62924, R44CA203350, R37CA230400, T32-GM007309, and HHSN261201600034C.

Further research by Exact Sciences is building upon this study to develop an MCED test. The technology is under development and has not been cleared or approved by the US Food and Drug Administration or any other national regulatory authority. The features describe current development goals, and claims have yet to be established.

[Authors thank DETECT-A participants for their courage and generosity.](#)

Reference

Lennon AM, Buchanan AH, Kinde I, Warren A, Honushefsky A, Cohain AT, Ledbetter DH, Sanfilippo F, Sheridan K, Rosica D, Adonizio CS, Hwang HJ, Lahouel K, Cohen JD, Douville C, Patel AA, Hagmann LN, Rolston DD, Malani N, Zhou S, Bettegowda C, Diehl DL, Urban B, Still CD, Kann L, Woods JI, Salvati ZM, Vadakara J, Leeming R, Bhattacharya P, Walter C, Parker A, Lengauer C, Klein A, Tomasetti C, Fishman EK, Hruban RH, Kinzler KW, Vogelstein B, Papadopoulos N. Feasibility of blood testing combined with PET-CT to screen for cancer and guide intervention. *Science*. 2020 Jul 3;369(6499):eabb9601. doi: 10.1126/science.abb9601. Epub 2020 Apr 28. PMID: 32345712; PMCID: PMC7509949.