

## Positive

The Exact Sciences MCED test found a cancer signal in your blood.

### What does a positive result mean?

**A positive result is not a cancer diagnosis.**

The Exact Sciences MCED test looks for a cancer signal that is common to multiple cancer types. A positive result means that the test found a signal in your blood that may indicate the presence of cancer.

This test result alone is not enough to confirm a cancer diagnosis. **It's an indication that you should have further testing.** You will need to have follow-up imaging scans and possibly other medical tests to obtain more information that will allow your healthcare provider to make a diagnosis.

## What are my next steps?

### Talk to your healthcare provider

Your healthcare provider should complete a clinical evaluation and will order imaging scans that create detailed images of your body to look for cancer. This may include CT scans with IV contrast of your neck, chest, and abdomen/pelvis.

If the CT scans are negative for cancer or unclear, your doctor may also order a test called a PET-CT. A PET-CT may find a possible cancer that was not found by the initial imaging scans.

Sometimes, depending on your medical history, your doctor may recommend alternative or additional imaging scans or other medical tests. The results of the imaging scans will help determine next steps.

### Get additional support from your Care Navigation team

**Your Care Navigation team is here to help and they will reach out to you in the coming days. Here are a few ways they can assist you if needed:**

- 1** Work directly with your healthcare provider
- 2** Help coordinate your appointments, including imaging (radiology) scans
- 3** Assist you with appointment logistics
- 4** Provide emotional support and educational resources





## FAQs

### Does this positive result mean that I have cancer?

A positive Exact Sciences MCED test result means that the blood test identified a cancer signal that may indicate the presence of cancer. It is not a diagnosis and does not confirm that you have cancer. Imaging scans (such as CT scans and possibly a PET-CT scan) and other medical tests are typically required to locate and confirm a cancer diagnosis.

### Does the Exact Sciences MCED test show the type or stage of cancer?

No. This test does not confirm the presence, type, or stage of cancer. After a positive Exact Sciences MCED test, follow-up imaging scans and other medical tests can be used to locate and confirm the presence of cancer. If cancer is present, further evaluation may be needed to determine the type and stage.

### What types of imaging (radiology) scans may be used after a positive test?

Your healthcare provider may order imaging scans like IV contrast CT scans that create a 3D picture of the body to confirm the presence and find the location of a possible cancer. Your provider may order other imaging tests based on your medical history. If the initial scans don't locate any cancer, a whole-body PET-CT scan may be used to take a closer look.

### What happens if follow-up imaging scans or other medical tests indicate signs of cancer or other significant findings?

If follow-up imaging tests or other medical tests find cancer or other significant findings, your healthcare team will work with you on next steps and help create a treatment plan that makes sense for your specific situation.





## What happens if follow-up imaging scans or other medical tests do **not** show cancer or other significant findings?

If follow up tests do not show cancer or other significant findings, you should continue to follow the care plan and advice of your healthcare provider. Since the Exact Sciences MCED test can detect early cancer signals, you and your healthcare provider may want to make this test part of your routine screening plan.

## What do I tell my loved ones?

Though cancer signals have been found, you have not been diagnosed. Further testing is required to confirm the presence of cancer. We understand that this can be a stressful time. As you undergo further medical testing, taking care of your emotional and mental health is important – seek support when you feel you need it.

## Should I continue with other cancer screening tests?

Yes. It is important to keep up to date with your other routine cancer screening tests. Tests like mammograms, colonoscopies, or stool-based colorectal cancer screening tests look for cancer in a single organ. The Exact Sciences MCED test looks for cancer signals for multiple cancer types. Using the Exact Sciences MCED test and other routine cancer screening tests together may help increase the chance that cancer is found if it is present.<sup>1</sup>

## Can false positive results occur?

Yes. If the Exact Sciences MCED test found a cancer signal in your blood sample, but you don't actually have cancer, that's called a "false positive."

### You're not alone

We encourage you to talk to your provider and work with your Care Navigation team that will reach out to you shortly, but if you have questions and would like to talk to someone sooner, you can reach out to us at **888-303-6233**.



<sup>1</sup> Lennon AM, Buchanan AH, Kinde I, et al. Feasibility of blood testing combined with PET-CT to screen for cancer and guide intervention. *Science*. 2020;369(6499):eabb9601.



# Disclaimer

**CAUTION:** The Exact Sciences MCED test is an investigational device/limited by Federal (or United States) law to investigational use. The test is for patients who have consented and enrolled in the Falcon Registry Study. It has not been cleared or approved by the US Food and Drug Administration or other notified regulatory authority.

The Exact Sciences MCED test is intended for use in adults ages 50-84 with no known cancer diagnosis in the last three years. It detects alterations in circulating tumor DNA and tumor-associated protein levels which are commonly associated with cancer. The test does not detect all cancers and is not a replacement for existing recommended cancer screening or diagnostic modalities for cancer. The test is not indicated for screening of breast and prostate cancer. The test is not recommended for patients with a history of adverse reactions to iodine based IV contrast, or women who are, could be, or are looking to get pregnant.

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. A positive Exact Sciences MCED test result may indicate the presence of cancer and should be followed by a clinical evaluation by a health care provider and radiological imaging including intravenous-contrast media computed tomography (IV contrast CT) and, if necessary, positron emission tomography-computed tomography (18F FDG PET-CT). False positive and false negative test results can occur.

The Exact Sciences MCED test was developed, and its performance characteristics validated by Exact Sciences Laboratories following College of American Pathologists (CAP) and Clinical Laboratory Improvement Amendments (CLIA) regulations. 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.

