

Frequently Asked Questions for Providers

**EXACT
SCIENCES**

The Falcon Registry Study and the Investigational Use Exact Sciences MCED Test



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Falcon Registry Study Details



- ▷ What is the Falcon Registry study?
- ▷ What is the study population?
- ▷ What are the inclusion and exclusion criteria?
- ▷ Will my patients be billed for this test or follow-up imaging?

Falcon Registry Study Details



What is the Falcon Registry study?

- The Falcon Registry study is a multi-site registry of patients receiving the Exact Sciences MCED test (MCED cohort) along with a comparison standard-of-care (SOC) cohort (SOC cohort) of patients who did not receive the test.
- The objective of the study is to characterize the course of clinical care in patients who receive multi-cancer early detection (MCED) testing and the psychological impact of receiving an MCED test.
- The Falcon Registry study will combine self-reported data collected via surveys (MCED cohort), as well as a set of pre-specified data elements, including medical images, extracted directly from each site's information systems (both cohorts).

Falcon Registry Study Details



What is the study population?

- The study population includes adult men and women who are deemed by their clinician to be appropriate candidates for MCED testing.
- Clinicians participating in this study will be advised that the study is only recruiting people who are 50 to 80 years of age with no history of a cancer diagnosis in the past 3 years.
- This study will enroll up to 25,000 participants across both cohorts.

Falcon Registry Study Details



What are the inclusion and exclusion criteria?

Inclusion Criteria	Exclusion Criteria
<ul style="list-style-type: none">■ Age 50-80■ Agree to receive the Exact Sciences MCED test and follow-up imaging■ Access to a suitable device, and willing to complete surveys digitally■ Able to provide informed consent	<ul style="list-style-type: none">■ Decline the Exact Sciences MCED test■ Personal history of an invasive malignancy in the past 3 years

The Exact Sciences MCED test is an investigational test for patients who have consented and enrolled in the Falcon Registry study. This study is being conducted under the Food and Drug Administration’s approval of an Investigational Device Exemption application.

Falcon Registry Study Details	Investigational Use: Product Details	Investigational Use: Intended Use Population	Test Ordering	Sample Collection	Shipping	Lab Processing/ Testing	Results and Follow-up
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Falcon Registry Study Details



Will my patients be billed for this test or follow-up imaging?

The cost of the Exact Sciences MCED test, diagnostic CT scan and the ¹⁸F-FDG PET-CT scan (if needed) are covered as part of the Falcon Registry study. The cost of specific alternative initial follow-up imaging or additional follow-up imaging following a positive result may be covered by Exact Sciences if certain requirements are met. However, the patient and/or their insurance company will be financially responsible for any other necessary medical procedures for the diagnosis or treatment of cancer and/or other routine care to include imaging not considered to be part of the initial follow-up.

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Investigational Use: Product Details



- ▷ What is the Exact Sciences MCED test?
- ▷ What are the performance characteristics of the Exact Sciences MCED test?

Investigational Use: Product Details



What is the Exact Sciences MCED test?

The Exact Sciences MCED test is a test for multi-cancer early detection (MCED) that is designed to help find cancer earlier. The test is a single blood test that detects multiple biomarkers associated with many types of cancer.

Investigational Use: Product Details



What are the performance characteristics of the Exact Sciences MCED test?

A stratified case-control clinical laboratory validation study of the Exact Sciences MCED test that included samples from 590 participants with 1 of 19 cancer types (excluding breast and prostate cancer[†]) and 2,434 participants with no cancer revealed an overall sensitivity of 56.8% (95% CI : 52.8%, 60.7%)* with an overall specificity of 98.5% (95% CI : 97.9%, 98.9%).¹ Individual cancer type sensitivities ranged from 15.4% to 80% for cancer types that had at least 10 cases in the study.^{1*} The test was not evaluated for the detection of pre-cancerous lesions.

Sensitivity: the proportion of people who test positive among all those who actually have the disease;

Specificity: the proportion of people who test negative among all those who actually do not have that disease.

*All data presented here was generated from a stratified 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. Real-world sensitivity may be lower compared to case-control data.

[†]Sensitivity in breast cancer: 34.1% (95% CI: 25%, 44.5%; n=88). Sensitivity in prostate cancer: 11.8% (95% CI: 5.5%, 23.4%; n=51).

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Investigational Use: Intended Use Population



- ▷ What is the intended use population?
- ▷ Who is not an appropriate patient for the Exact Sciences MCED test?

Investigational Use: Intended Use Population



What is the intended use population?

- Per the Investigational Device Exemption, the Exact Sciences MCED test is intended for adults of either sex, ages 50-84 years who have had no known cancer diagnosis within the preceding 3 years.
- The test is not indicated for screening of breast cancer and prostate cancer.

Investigational Use: Intended Use Population



Who is not an appropriate patient for the Exact Sciences MCED test?

- Per the Investigational Device Exemption, the Exact Sciences MCED test is not intended for adults with a history of invasive cancer or hematological malignancy in the last 3 years.
- Given the potential for follow-up imaging (radiology) scans for positive results and the potential need for a CT with iodine-based IV contrast, patients with a history of adverse reactions to iodine-based IV contrast may not be appropriate candidates for this testing.
- Consideration should be given to women who are, could be, or are looking to get pregnant as a positive Exact Sciences MCED test may be followed up by imaging scans that may use ionizing radiation.
- It is important to use your clinical discretion when identifying the right patients for testing.

Test Ordering



- ▶ How do I order the Exact Sciences MCED test for my patients participating in the Falcon Registry study?

Test Ordering



How do I order the Exact Sciences MCED test for my patients participating in the Falcon Registry study?

In the Falcon Registry study, orders for the Exact Sciences MCED test are placed via your electronic medical record (EMR) system. If you have additional questions about the test ordering process, please contact the Customer Care Center at **1-888-303-MCED (6233)**.

Sample Collection



- ▶ What is needed to collect specimens for the Exact Sciences MCED test as part of the Falcon Registry study?
- ▶ How much blood is required to do the testing?
- ▶ Should the blood be drawn on a particular day of the week during the Falcon Registry study?
- ▶ Where can patients get their blood drawn during the Falcon Registry study?

Sample Collection



What is needed to collect specimens for the Exact Sciences MCED test as part of the Falcon Registry study?

- The Exact Sciences MCED test requires an Exact Sciences Blood Collection Kit labeled as Multi-Cancer Early Detection (Kit) for collection and transport of blood specimens to the performing laboratory.
- The kit contains the appropriate blood collection tubes and packing materials needed for specimen collection and shipment.
- Each kit is a single unit. Tubes from other kits should not be used.

Sample Collection



How much blood is required to do the testing?

- To ensure that enough blood is available to complete the Exact Sciences MCED test during the Falcon Registry study, six (6) LBgard® Blood Tubes must be collected.
- Each LBgard Blood Tube must be completely filled with 8.5 ml of blood per tube (total 51 ml).
- Please fill each LBgard Blood Tube to the black line marked on the label or until the vacuum has been exhausted.
- It is important to prioritize filling tubes completely to the black line marked on the label or until the vacuum has been exhausted. Do not underfill multiple blood tubes to draw some blood in all 6 tubes.
- If there is an issue with completely filling all 6 tubes, the lab may be able to perform the test with 4 or 5 completely filled tubes. You can send the kit back to the lab and the lab will try to perform the test. This is not guaranteed, and a redraw may be needed.

Sample Collection



Should the blood be drawn on a particular day of the week during the Falcon Registry study?

- Yes. Since the blood specimen must be processed within 72 hours, patients should have their blood drawn for the Exact Sciences MCED test Monday through Friday only.
- For Friday collections, check with FedEx to find out the last pickup time in your area prior to collecting. Ensure blood is collected prior to the last pickup time.
- Please ship kits to the laboratory the same day specimens are collected using FedEx Priority Overnight delivery.
- Do not collect and ship specimens on weekends and on observed holidays.

Sample Collection



Where can patients get their blood drawn during the Falcon Registry study?

- Patients should have their blood drawn at a laboratory/phlebotomy location associated with your clinic or healthcare system.
- Patients should NOT go to a third-party laboratory location for blood collection.
- For patients requiring a redraw due to a canceled or invalid test, mobile phlebotomy services may be arranged by Exact Sciences at no additional cost to the patient. Please call our Customer Care Center at **1-888-303-MCED (6233)** to check availability and to arrange for mobile phlebotomy.

Shipping



- ▶ When can I ship specimens to the laboratory?

Shipping



When can I ship specimens to the laboratory?

- Since blood specimens must be processed within 72 hours of the blood draw, they should be shipped to the laboratory on the same day as collected, Monday through Friday, and not during holidays.
- For Friday collections, check with FedEx to find out the last pickup time in your area prior to collecting.
- The laboratory can receive specimens for the Exact Sciences MCED test Monday through Saturday.
- The laboratory cannot receive specimens on Sundays or holidays.

Lab Processing/Testing



- ▷ What happens if the specimen cannot be processed, or a valid result is not obtained?

Lab Processing/Testing



What happens if the specimen cannot be processed, or a valid result is not obtained?

- If the specimen cannot be processed or a valid result is not obtained, you will be notified via your EMR.
- If you still wish to have the test performed, you will be required to submit a new order for testing, and specimens will need to be recollected.
- Mobile phlebotomy services may be available in some areas for specimen recollection at no additional cost to the patient. Please call our Customer Care Center at **1-888-303-MCED (6233)** to check availability and to arrange for mobile phlebotomy.

Results and Follow-up



- ▶ What results does the Exact Sciences MCED test provide?
- ▶ How do I receive the Exact Sciences MCED test results during the Falcon Registry study?
- ▶ What is the expected turnaround time to receive results?
- ▶ Will I receive results before the patient during the Falcon Registry study?
- ▶ What does a positive Exact Sciences MCED test result mean?

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Results and Follow-up, Continued



- ▶ What are the next steps following a positive result?
- ▶ What are the CPT codes for the imaging scans mentioned?
- ▶ What does a negative Exact Sciences MCED test result mean?
- ▶ What are the next steps for a negative result?
- ▶ What happens if the follow-up imaging scans come back negative after a positive Exact Sciences MCED test result?

Results and Follow-up



What results does the Exact Sciences MCED test provide?

- The Exact Sciences MCED test generates positive (cancer signal detected) or negative (no cancer signal detected) results.
- In some instances, a QC failure or insufficient clinical material in the sample leads to an invalid test. In the case of an invalid test, you will be required to submit a new order for testing, and specimens will need to be recollected.

Results and Follow-up



How do I receive the Exact Sciences MCED test results during the Falcon Registry study?

- In the Falcon Registry study, results will be sent directly to you via the EMR. A link to a patient-friendly PDF with result information will be available within the EMR result.
- Please refer to the PDF for additional details on follow-up imaging procedures to locate a possible cancer following a positive test result.

Results and Follow-up



What is the expected turnaround time to receive results?

- The expected average turnaround time to receive results is within 3 weeks upon laboratory receipt of patient specimens.

Results and Follow-up



Will I receive results before the patient during the Falcon Registry study?

- In the Falcon Registry study, results will be immediately available to you in the EMR.
- Results may also be available to patients immediately via your health system's EMR/ patient portal and through the Exact Sciences Patient Hub.
- For sites using the Exact Sciences Patient Hub as part of the Falcon Registry:
 - A text or email notification for a result ready will be sent immediately to patients following the availability of a negative result in the Exact Sciences Patient Hub.
 - A text or email notification for a result ready will be sent to patients 7 days following the availability of a positive result in the Exact Sciences Patient Hub, enabling you to discuss results with your patients first.

Results and Follow-up



What does a positive Exact Sciences MCED test result mean?

- A positive Exact Sciences MCED test result means the blood test identified a cancer signal that may indicate the presence of cancer.
- A positive Exact Sciences MCED test result alone does not confirm the presence of any cancer. False positive results can occur.
- Follow-up imaging and further clinical evaluation by a healthcare provider are needed to locate and confirm a diagnosis of cancer or determine that cancer is not present.

Results and Follow-up



What are the next steps following a positive result?

- As part of the Falcon Registry study, patients with a positive result will undergo follow-up imaging scans to confirm the presence of and localize a possible cancer. Results of these scans will inform any additional follow-up steps, including potential transition to oncology care.
- In the absence of a clear suspicion of cancer, based on symptoms, other testing, and/or medical history that points to targeted imaging, CT with IV contrast of the neck (soft tissue), chest, and abdomen/pelvis is recommended.²
- If results of the CT imaging are negative for cancer or any result as “indeterminate,” patients may need follow-up with traditional whole-body, head-to-thigh ¹⁸F-FDG PET-CT scan.
- Additional imaging may be recommended at the discretion of the ordering provider, based on a patient’s clinical presentation.
- The Exact Sciences MCED test is not a replacement for existing recommended cancer screening or diagnostic modalities for cancer. Current recommended screening for cancer should be followed.

Results and Follow-up



What are the CPT codes for the imaging scans mentioned?

- CT with IV Contrast-Soft Tissue Neck: 70491
- CT with IV Contrast-Chest: 71260
- CT with IV Contrast-Abdomen/Pelvis: 74177
- PET-CT, Skull to Thigh with ¹⁸F-FDG: 78815

These codes are provided for informational purposes only. Please select the most appropriate codes based on your clinical assessment of the patient.

Results and Follow-up



What does a negative Exact Sciences MCED test result mean?

- A negative Exact Sciences MCED test result means that the test did not identify a cancer signal. A negative result does not rule out the presence of cancer of any type. False negative results can occur.

Results and Follow-up



What are the next steps for a negative result?

- The Exact Sciences MCED test is not a replacement for existing recommended cancer screening or diagnostic modalities for cancer. Current recommended screening for cancer should be followed.
- As part of the Falcon Registry study, the Exact Sciences MCED test may be offered to patients once annually for up to 3 years (3 tests total).

Results and Follow-up



What happens if the follow-up imaging scans come back negative after a positive Exact Sciences MCED test result?

- If follow-up imaging scans do not identify a potential cancer, it may mean either the Exact Sciences MCED test produced a false positive result or that a cancer is present but was not able to be seen on the imaging scans used.
- The Exact Sciences MCED test is not a replacement for existing recommended cancer screening or diagnostic modalities for cancer. Current recommended screening for cancer should be followed.
- As part of the Falcon Registry, the Exact Sciences MCED test may be offered to patients once annually for up to 3 years (3 tests total).

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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.

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References

1. Exact Sciences Multi-Cancer Early Detection (MCED) Test Clinical Validation Report April 2024
2. Lebech AM, Gaardsting A, Loft A, et al. Whole-body ^{18}F -FDG PET-CT is superior to CT as first-line diagnostic imaging in patients referred with serious nonspecific symptoms or signs of cancer: a randomized prospective study of 200 patients. *J Nucl Med*. 2017;58(7):1058-1064. doi:10.2967/jnumed.116.175380

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