Introduction to Auria®

For Health Care Providers

Indications for Use

Auria® is a biological breast cancer screening test intended to be used in conjunction with standard of care testing. Auria® is not a replacement for a screening mammogram.

Warnings and Precautions

Auria® is intended as a short-term breast health assessment for women ages 30 and over. Assigned classifications are associated with the indication that protein levels detected by the Auria® test may be associated with the development of an abnormality in the breast tissue. Auria® is not a diagnostic test for breast cancer.

Breast Health screening guideline recommendations vary for persons under the age of 40 and over the age of 70. The decision to screen persons in these categories should be made on an individual basis in consultation with a healthcare provider. Auria® test results should be interpreted with caution as the rate of false positives increases with age.

Auria® may produce a false positive or false negative result. An Auria Score® below 0.1 does not guarantee the absence of an abnormality in the breast tissue or breast cancer. Patients with an Auria Score® below 0.1 should be advised to continue participating in breast health standard care testing for their age group. An Auria Score® above 0.1 does not guarantee the presence of an abnormality in the breast tissue or breast cancer. Patients with an Auria Score® above 0.1 should be referred for breast imaging.

Auria® Overview

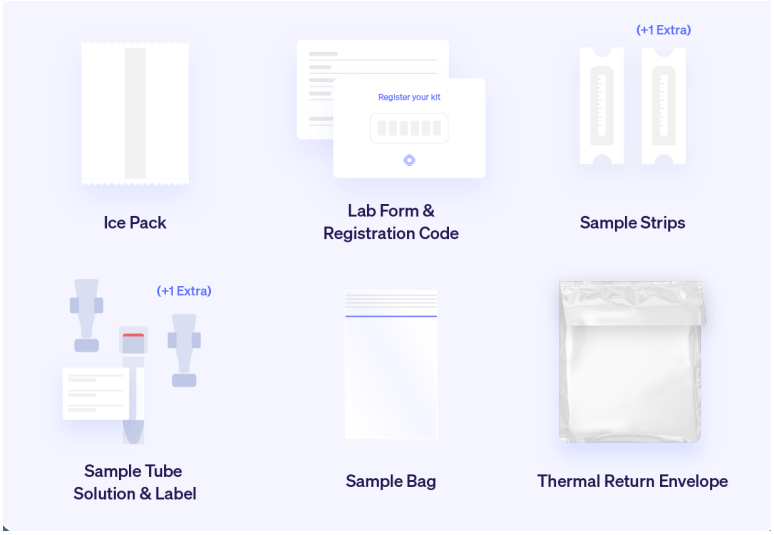
Auria® uses composite algorithmic analysis of tear protein biomarkers. Quantitative values of individual biomarkers are not reportable and are not associated with individual biomarker result reference ranges. Auria® is 92% sensitive for the detection of breast abnormalities and 54% specific.

Auria® is designed to analyze two protein biomarkers present in tears which could be present due to the early inflammatory process in tumor formation. These markers are also elevated in association with benign masses. Similar to a screening mammogram, Auria® should not be used to differentiate between malignant and benign masses.

Auria® is a lab-developed test (LDT) that has been validated in Namida Lab's Clinical Laboratory Improvement Amendments (CLIA) certified, high-complexity, clinical laboratory lab under the supervision of our Medical Director. An LDT is a test that is designed, developed, and performed within a single laboratory, regulated by the Centers for Medicare & Medicaid Services (CMS), through the Clinical Laboratory Improvement Amendments (CLIA). Currently, the FDA exercises enforcement discretion over LDTs. Certification of the laboratory is required under CLIA to ensure the validity and quality of the test.

Patient Samples for Auria®

Patients follow the detailed instruction guide and/or instructions for use video provided in the Auria® collection kit. The following components are included in the collection kit. Samples are sent to Namida Lab's certified high-complexity CLIA lab for testing.



Instructions for Sample Collection

Wash your hands

Before beginning the collection process, wash your hands thoroughly with soap and water for 20 seconds.

Prepare your test

Unscrew the lid of the sample tube and place on a flat surface.

Open & remove the sample strip from packaging.

Fold the sample strip

Hold the sample strip with the printed side facing you and the rounded tip up.

Fold the tip away from you at the first black line to create a lip.

Set the timer

Set the timer for 5 minutes.

Place the strip

Gently place the folded portion of the strip on the inside of your lower eyelid.

Close your eye. Start the timer.

Wait 5 minutes

Leave the strip in place for a total of five minutes. Adjust the placement of the strip if needed.

*If the strip falls out before the five minutes is up, no problem! That's what the extra supplies are for. You'll need to wait 30 minutes before repeating the collection.

Remove the strip

Holding the end of the strip, open your eye and gently lift the strip out of your eyelid.

Don't be concerned with the amount of fluid on the strip.

Drop in tube

Drop and release the sample strip into the open sample tube, ensuring that the folded tip that was in your eyelid enters the tube first.

Apply sample solution

Open the sample solution by twisting to remove the cap.

Squeeze all of the liquid into the open sample tube.

Close the tube

Tighten the lid onto the sample tube, ensuring it is seated properly and sealed securely.

Ordering Auria®

Auria® is available for customers to order through the online ordering portal at auria.care. For any questions about Auria® or specific questions on how to order, please contact customer service at:

support@auria.care
833-MY-AURIA (833-692-8742)

Interpretation of Auria® results

A low test result means that the score produced from the Auria® algorithm did not indicate a clinically relevant level of activity. A test in this category can result in a false negative. Patients with a Low Auria score should be advised to continue participating in a breast cancer screening program. A test results in the medium category indicates elevated clinically relevant activity in the breast tissue and should be followed with a mammogram within 6 months. A test result in the High category indicates elevated clinically relevant activity in the breast tissue and should be followed with a mammogram within 3 months.

Consultation

Included with every Auria® purchase is the opportunity to discuss results with a Breast Health Specialists. Our Breast Health Specialists are RN's with extensive experience in breast health and helping patients navigate the breast health continuum of care. The goal of every consultation is to educate Auria customers on breast cancer screening.

References

Tears as the Next Diagnostic Biofluid:
A Comparative Study between Ocular Fluid and Blood
https://www.mdpi.com/2076-3417/12/6/2884

Using Tears as a Non-invasive Source for Early Detection of Breast Cancer
https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0267676#sec001

Development and validation of a short-term breast health measure as a supplement to screening mammography
https://biomarkerres.biomedcentral.com/articles/10.1186/s40364-022-00420-1