

Name/DOB: **Test, Test (1/1/1985)**
Patient ID: test
Collected Date: 9/14/2022 1:03 PM
Approval date: 9/14/2022 1:07 PMSex: F
Age: 37Provider: Albertson, Chris , MD
Sample ID: 220914001
Entered by: Ashton Leehans**Auria**

Approved By: Leehans, Ashton

Auria Result Negative or Clinically Significant

Auria Score Interpretation

09/14/22 1:03 PM

Auria[®] is a biological breast cancer screening test to be used in conjunction with the current standard of care. Auria is not a replacement for screening mammogram. It is recommended that a patient with an Auria[®] result of Clinically Significant (>0.1) be clinically correlated with a structural examination of the breast tissue. It is recommended that a patient with an Auria[®] result of Negative (<0.1) should be advised to continue participating in a breast cancer screening program.

Auria[®] test type: 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.

Precautions and limitations: Auria[®] is intended for biological women at birth, ages 30 and over. Assigned result is 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.

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

Auria[®] is a lab developed test (LDT) which 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.