MAYO CLINIC LABORATORIES

Test Definition: OVAWA

Ovarian Mass Risk Monitoring, OvaWatch, Serum

Overview

Useful For
Serial monitoring and risk assessment for ovarian malignancy in women who present with an adnexal mass clinically assessed as indeterminate or benign

Testing Algorithm
For information see Clinical Triage for Adnexal Masses

Highlights
OvaWatch is a non-invasive lab blood test to determine the risk of ovarian cancer in conjunction with clinical assessment for patients with an adnexal mass. OvaWatch utilizes a neural network-based algorithm combining serum biomarkers and clinical covariates (CA-125 II, prealbumin, apolipoprotein A1, beta2-microglobulin, transferrin, follicle-stimulating hormone, human epididymis protein 4, age and menopausal status) to examine malignancy risk with individuals with an adnexal mass.

Method Name
Immunoassay/Multivariate Index Assay/Electrochemiluminescence Immunoassay (ECLIA)

NY State Available
Yes

Specimen

Specimen Type
Serum

Ordering Guidance
OvaWatch is intended for use as a non-invasive test to assess the risk of ovarian cancer for women with adnexal masses evaluated by initial clinical assessment as indeterminate or benign.

Shipping Instructions
1. Specimens sent refrigerated must reach Mayo Clinic Laboratories within 4 days of collection.
2. Specimens sent frozen must be shipped on dry ice.

Specimen Required
Collection Container/Tube: Sarstedt Aliquot Tube, 5 mL (T914)
Preferred: Serum gel
Acceptable: Red top
Submission Container/Tube: Plastic vial
Specimen Volume: 2 mL Serum

Collection Information:

1. Allow the specimen to clot for at least 30 minutes.
2. Within 2 hours of collection, centrifuge the specimen.
3. For serum gel tubes, aliquot serum into a plastic vial or send centrifuged serum gel tube.
4. For red top tubes, aliquot serum into a plastic vial within 10 minutes of centrifugation.

Specimen Minimum Volume

Serum 1.5 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	Reject
Gross icterus	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Refrigerated (preferred)	8 days	
	Frozen	90 days	

Clinical & Interpretive

Clinical Information

OvaWatch employs a combination of age, menopausal status, and serum protein biomarkers with a proprietary algorithm to provide a personalized risk assessment. OvaWatch performance characteristics were established in a study of 2000 women with adnexal mass, in which the ovarian cancer prevalence was 4.9%. OvaWatch specificity was validated at 84% with negative predictive value of 99.4%, whereas its sensitivity was validated at 90% (98.0% for Stage 3 and 4 and 76.9% for Stage 1 and 2 cancers) with positive predictive value of 22.5%.

Reference Values

An interpretive report will be provided

Interpretation

A low-risk score is highly suggestive of a benign mass (less than 5.0% probability of cancer).

An indeterminate score suggests that presence of cancer cannot be ruled out.

Cautions

OvaWatch results should always be interpreted in combination with clinical assessment, personal history, and imaging studies.

Clinical Reference

1. Reilly G, Bullock RG, Greenwood J, et al. Analytical validation of a deep neural network algorithm for the detection of ovarian cancer. JCO Clin Cancer Inform. 2022;6:e2100192. doi:10.1200/CCI.21.00192
2. Dearking AC, Aletti GD, McGree ME, Weaver AL, Sommerfield MK, Cliby WA. How relevant are ACOG and SGO guidelines for referral of adnexal mass?. Obstet Gynecol. 2007;110(4):841-848. doi:10.1097/01.AOG.0000267198.25223.b
3. American College of Obstetricians and Gynecologists' Committee on Practice Bulletins—Gynecology. Practice Bulletin No. 174: Evaluation and Management of Adnexal Masses. Obstet Gynecol. 2016;128(5):e210-e226. doi:10.1097/AOG.0000000000001768
4. Reilly GP, Dunton CJ, Bullock RG, et al. Validation of a deep neural network-based algorithm supporting clinical management of adnexal mass. Front Med (Lausanne). 2023;10:1102437. Published 2023 Jan 23. doi:10.3389/fmed.2023.1102437
5. Roy Choudhury M, Pappas TC, Twiggs LB, Caoili E, Fritsche H, Phan RT. Ovarian cancer surgical consideration is markedly improved by the neural network powered-MIA3G multivariate index assay. Front Med (Lausanne). 2024;11:1374836. Published 2024 May 2. doi:10.3389/fmed.2024.1374836
6. Pappas TC, Roy Choudhury M, Chacko BK, et al. Neural network-derived multivariate index assay demonstrates effective clinical performance in longitudinal monitoring of ovarian cancer risk. Gynecol Oncol. 2024;187:21-29. doi:10.1016/j.ygyno.2024.04.020

Performance

Method Description

OvaWatch is a laboratory developed qualitative serum test that generates a single numerical score by applying a machine learning algorithm to seven immunoassay results combined with patient age and menopausal status. The biomarkers measured are CA-125 II, prealbumin, apolipoprotein A1, beta-2 microglobulin, transferrin, follicle-stimulating hormone (FSH), and human epididymis protein 4 (HE4). All biomarker values are determined using assays on the Roche cobas, an automated analyzer which uses electrochemiluminescence detection. The biomarker assays are conducted according to the manufacturer's directions as detailed in the Instructions for Use for each product.(Reilly G, Bullock RG, Greenwood J, et al. Analytical validation of a deep neural network algorithm for the detection of ovarian cancer. JCO Clin Cancer Inform. 2022;6:e2100192. doi:10.1200/CCI.21.00192)

PDF Report

Referral

Day(s) Performed

Monday, Wednesday, Friday

Report Available

5 days

Specimen Retention Time

1 month

Performing Laboratory Location

Aspira Labs, Inc.

Fees & Codes

Fees

- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact Customer Service.

Test Classification

This test was developed and its performance characteristics were determined by Aspira Laboratory. The test has not been cleared or approved by the FDA, nor is it required to be. The laboratory is regulated under CLIA as qualified to perform high-complexity testing. The results represent individual analyses for the patient and were obtained from this multivariate index assay should always be interpreted in the context of clinical examination, patient medical history, and other findings.

CPT Code Information

0375U

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
OVAWA	OvaWatch, S	Not Provided

Result ID	Test Result Name	Result LOINC® Value
OVAWR	OvaWatch	Not Provided