MAYO CLINIC LABORATORIES

Test Definition: OVAPA

Ovarian Malignancy Risk Assessment, Ova1Plus, Serum

Overview

Useful For
Risk assessment for ovarian malignancy in women who present with an adnexal mass and are indicated for surgical management

Testing Algorithm
Ova1Plus is comprised of two separate tests, Ova1 and Overa. The Ova1 test is always performed. The Overa test is performed reflexively only when an intermediate risk is determined from Ova1.

For more information see Clinical Triage for Adnexal Masses

Highlights
Ova1Plus is a non-invasive blood test that combines two US Food and Drug Administration-cleared tests (Ova1 [high sensitivity] and Overa [high specificity]) for women with adnexal masses planned for surgery.

Ova1 is a multivariate index assay combining results from five tests: CA-125 II, prealbumin, apolipoprotein A1, beta2-microglobulin, and transferrin into a single-valued index between 0 and 10; a higher value corresponds to a higher risk of malignancy.

Overa is a second-generation multivariate index assay that seeks to improve the specificity of the Ova1 by looking at three markers (CA-125 II, transferrin, and apolipoprotein A1) and two new biomarkers (follicle-stimulating hormone and human epididymis protein 4).

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

NY State Available
Yes

Specimen

Specimen Type
Serum

Ordering Guidance
This test is intended for individuals with a detected pelvic mass and supportive evidence suggests surgical management.

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:
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

Ova1Plus is a non-invasive blood test that combines two US Food and Drug Administration-cleared tests (Ova1 [high sensitivity] and Overa [high specificity]) for women with adnexal masses planned for surgery. Results in the normal range may suggest a low risk for ovarian cancer. Epithelial cell tumors make up an average of 75% of all ovarian cancer tumor types, including serous, mucinous, endometrioid, clear cell, and Brenner tumors.

Reference Values

An interpretive report will be provided.

Interpretation

Low risk Ova1 results indicate a low risk of malignancy. A low-risk value has been determined to have a negative

predictive value of 98%.

Elevated risk Overa results predict a risk of malignancy when combined with ultrasound results. Results should be interpreted along with clinical and ultrasound assessment.

High-risk imaging was defined as any complex ovarian tumor with evidence of solid or papillary components.

Low risk imaging was defined as unilocular or septate cystic ovarian tumor without high-risk findings.

Cautions

Results cannot be interpreted as absolute evidence of the presence or absence of malignant disease and should always be interpreted in combination with clinical assessment.

Clinical Reference

1. Bristow RE, Smith A, Zhang Z, et al. Ovarian malignancy risk stratification of the adnexal mass using a multivariate index assay. Gynecol Oncol. 2013;128(2):252-259
2. Goodrich ST, Bristow RE, Santoso JT, et al. The effect of ovarian imaging on the clinical interpretation of a multivariate index assay. Am J Obstet Gynecol. 2014;211(1):65.e1-65.e11

Performance

Method Description

Ova1Plus is a reflex process that incorporates both Ova1 and Overa; in cases of an intermediate Ova1 result, the Overa reflex is performed to increase specificity. Both Ova1 and Overa are qualitative serum tests that generate a single numerical score by applying an algorithm to five immunoassay results. For Ova1, the biomarkers measured are CA-125 II, prealbumin, apolipoprotein A-1, beta-2 microglobulin, and transferrin. For Overa, the biomarkers are follicle-stimulating hormone (FSH), human epididymis protein 4 (HE4), apolipoprotein A-1, transferrin, and CA-125 II. 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.

PDF Report

Referral

Day(s) Performed

Monday, Wednesday, Friday

Report Available

5 days

Specimen Retention Time

1 month

Test Definition: OVAPA

Ovarian Malignancy Risk Assessment, Ova1Plus, Serum

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 determined by Aspira Labs, a wholly owned subsidiary of Aspira Women's Health. The laboratory is regulated under CLIA as qualified to perform high-complexity testing. Before making any treatment decisions, all women should discuss the results with their healthcare provider, who can recommend follow up testing or procedures when appropriate. Ova1 Plus is a reflex process which performs Ova1 and Overa, both independently FDA-cleared tests for women with adnexal masses.

CPT Code Information

81503
0003U

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
OVAPA	Ova1Plus, S	Not Provided

Result ID	Test Result Name	Result LOINC® Value
OVA1P	Ova1Plus	Not Provided