MAYO CLINIC LABORATORIES

# Test Definition: ROMA

ROMA Score (Ovarian Malignancy Risk Algorithm), Serum

## Overview

### Useful For

Risk assessment for finding an ovarian malignancy during surgery in women who present with an adnexal mass

The test is **not intended** as a screening or stand-alone diagnostic assay for ovarian cancer.

### Profile Information

| Test Id | Reporting Name | Available Separately | Always Performed |
|---|---|---|---|
| HE4R | HE4,S | Yes, (Order HE4) | Yes |
| CA125 | Cancer Ag 125 (CA 125), S | Yes, (Order CA25) | Yes |
| ROMA1 | Risk Score, if premenopausal | No | Yes |
| ROMA2 | Risk Score, if postmenopausal | No | Yes |

### Method Name

Electrochemiluminescence Immunoassay (ECLIA)

### NY State Available

No

## Specimen

### Specimen Type

Serum

### Specimen Required

**Patient Preparation:** For 12 hours before specimen collection, patient **should not** take multivitamins or dietary supplements (eg, hair, skin, and nail supplements) containing biotin (vitamin B7).
**Supplies:** Sarstedt Aliquot Tube, 5 mL (T914)
**Collection Container/Tube:**
**Preferred:** Serum gel
**Acceptable:** Red top
**Submission Container/Tube:** Plastic vial
**Specimen Volume:** 1 mL Serum
**Collection Instructions:** Centrifuge and aliquot serum into a plastic vial.

## Forms

If not ordering electronically, complete, print, and send an Oncology Test Request (T729) with the specimen.

## Specimen Minimum Volume

Serum: 0.75 mL

## Reject Due To

| | |
|---|---|
| Gross hemolysis | Reject |
| Gross lipemia | OK |

## Specimen Stability Information

| Specimen Type | Temperature | Time | Special Container |
|---|---|---|---|
| Serum | Frozen (preferred) | 84 days | |
| | Refrigerated | 48 hours | |

## Clinical & Interpretive

### Clinical Information

Women with ovarian cancer symptoms and adnexal masses present primarily to gynecologists, primary care physicians, or general surgeons. Triage guidelines from the American College of Obstetricians and Gynecologists and the Society of Gynecologic Oncologists recommend referral of women with a pelvic mass at high risk for ovarian cancer to gynecologic oncologists. Specialized treatment improves patient outcomes resulting in fewer complications and better survival rates when compared to patients treated by surgeons less familiar with the management of ovarian cancer.

The risk of ovarian malignancy algorithm (ROMA) incorporates cancer antigen 125 (CA125), human epididymal protein 4 (HE4), and menopausal status to assign women that present with an adnexal mass into a high-risk or low-risk group for finding an ovarian malignancy. ROMA is indicated for women who meet the following criteria: older than age 18, presenting with an adnexal mass for which surgery is planned, and who have not yet been referred to an oncologist. ROMA must be interpreted in conjunction with clinical and radiological assessment.

### Reference Values

Males: Not applicable

Females:
HUMAN EPIDIDYMIS PROTEIN 4< or =140 pmol/L

CANCER ANTIGEN 125 <46 U/mL

ROMA SCORE
Premenopausal: <1.14 (low risk)

Postmenopausal: <2.99 (low risk)

### Interpretation

In premenopausal women, a risk of ovarian malignancy algorithm (ROMA) value of 1.14 or greater indicates a high risk of finding epithelial ovarian cancer, whereas a ROMA value less than 1.14 indicates a low risk of finding epithelial ovarian cancer at surgery.

In postmenopausal women, a ROMA value of 2.99 or greater indicates a high risk of finding epithelial ovarian cancer, whereas a ROMA value less than 2.99 indicates a low risk of finding epithelial ovarian cancer at surgery.

The use of these cut-points provides a 75% specificity and sensitivity of 84% in patients with stage I-IV epithelial ovarian cancer.

### Cautions

The risk of ovarian malignancy algorithm (ROMA) test should not be used without an independent clinical/radiological evaluation and is not intended to determine whether a patient should proceed to surgery. A low-likelihood ROMA result in the setting of a positive initial cancer risk assessment should not preclude an oncology referral.

ROMA has not been validated for the following groups: women previously treated for malignancy, women currently being treated with chemotherapy, pregnant women, or women younger than age 18.

Serum markers are not specific for malignancy and values may vary by method. Values obtained with different assay methods cannot be used interchangeably.

In rare cases, some individuals can develop antibodies to mouse or other animal antibodies (often referred to as human anti-mouse antibodies [HAMA] or heterophile antibodies), which may cause interference in some immunoassays. The presence of antibodies to streptavidin or ruthenium can rarely occur and may also interfere in this assay. Caution should be used in interpretation of results, and the laboratory should be alerted if the result does not correlate with the clinical presentation.

### Clinical Reference

1. Dochez V, Caillon H, Vaucel E, Dimet J, Winer N, Ducarme G. Biomarkers and algorithms for diagnosis of ovarian cancer: CA125, HE4, RMI and ROMA, a review. J Ovarian Res. 2019;12(1):28. doi:10.1186/s13048-019-0503-7
2. Moore RG, Jabre-Raughley M, Brown AK, et al. Comparison of a novel multiple marker assay vs the Risk of Malignancy Index for the prediction of epithelial ovarian cancer in patients with a pelvic mass. Am J Obstet Gynecol. 2010;203(3):228.e1-6
3. Karlsen MA, Sandhu N, Hogdall C, et al. Evaluation of HE4, CA125, risk of ovarian malignancy algorithm (ROMA) and risk of malignancy index (RMI) as diagnostic tools of epithelial ovarian cancer in patients with a pelvic mass. Gynecol Oncol. 2012;127(2):379-383

## Performance

### Method Description

Serum Elecsys HE4 (human epididymal protein 4) assay and CA 125 II (cancer antigen 125) assay results are used in the calculation.

The Roche Elecsys HE4 assay is a sandwich electrochemiluminescence immunoassay that employs a biotinylated monoclonal HE4-specific antibody and a monoclonal HE4-specific antibody labeled with ruthenium complex. HE4 in the specimen reacts with both the biotinylated monoclonal HE4-specific antibody (mouse) and the monoclonal HE4-specific antibody (mouse) labeled with a ruthenium, forming a sandwich complex. Streptavidin-coated microparticles are added and the mixture is aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode. Unbound substances are then removed with ProCell. Application of voltage to the electrode induces the chemiluminescent emission, which is then measured against a calibration curve to determine the amount of HE4 in the patient specimen. (Package insert: Elecsys HE4. Roche Diagnostics; V 3.0, 06/2024)

The Roche Elecsys CA 125 II assay is a sandwich electrochemiluminescence immunoassay that employs biotinylated monoclonal CA125-specific antibody (mouse) and a monoclonal CA 125-specific antibody (mouse) labeled with ruthenium. CA125 in the specimen reacts with both antibodies to form a sandwich complex. Streptavidin-coated microparticles are added and the antibody sandwich complex binds to the microparticles through interaction of biotin and streptavidin. This mixture is aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode, and unbound substances are removed with ProCell. Application of voltage to the electrode induces the chemiluminescent emission, which is then measured against a calibration curve to determine the amount of CA125 in the patient specimen.(Package insert: Elecsys CA 125 II. Roche Diagnostics; V 2.0 07/2024)

Both HE4 and CA125 results are reported, along with a calculated Ovarian Malignancy Risk Score for both premenopausal and postmenopausal women.

### PDF Report
No

### Day(s) Performed
Monday through Saturday

### Report Available
1 to 3 days

### Specimen Retention Time
14 days

### Performing Laboratory Location
Mayo Clinic Jacksonville Clinical Lab

## 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 has been cleared, approved, or is exempt by the US Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

## CPT Code Information

86305-HE4, S
86304-Cancer Ag 125 (CA 125), S

## LOINC® Information

| Test ID | Test Order Name | Order LOINC® Value |
|---|---|---|
| ROMA | ROMA Score | 104551-7 |

| Result ID | Test Result Name | Result LOINC® Value |
|---|---|---|
| HE4R | HE4,S | 55180-4 |
| CA125 | Cancer Ag 125 (CA 125), S | 83082-8 |
| ROMA1 | Risk Score, if premenopausal | 69569-2 |
| ROMA2 | Risk Score, if postmenopausal | 69570-0 |