MAYO CLINIC LABORATORIES

Test Definition: ROMA

ROMA Score

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

NY State Available

Yes

Specimen

Specimen Type

Serum

Specimen Required

Patient Preparation: Patients receiving therapy with high biotin doses (ie, >5 mg/day) should not have their specimen collected until at least 8 hours following the last biotin administration.

Collection Container/Tube:

Preferred: Serum gel

Acceptable: Red top

Submission Container/Tube: Plastic vial

Specimen Volume: 1 mL

Forms

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

Reject Due To

Gross hemolysis	Reject
Gross lipemia	OK

Specimen Minimum Volume

0.75 mL

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Frozen (preferred)	84 days	
	Refrigerated		

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, interference due to extremely high titers of antibodies to specific reagents (human antimouse antibody or heterophile antibodies, streptavidin or ruthenium) can occur. The laboratory should be alerted if result does not correlate with the clinical presentation.

Clinical Reference

1. 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;203:228.e1-6

2. 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 human epididymal protein 4 (HE4) assay and the serum Elecsys cancer antigen 125 (CA 125) II assay results are used in the calculation. The instrument used is the Roche cobas.

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 reagent, Roche Diagnostics, Indianapolis, IN., V 1.0, 05/2017)

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 reagent, Roche Diagnostics , Indianapolis, IN., V1.0, 05/2017)

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

PDF Report

No

Specimen Retention Time

3 months

Performing Laboratory Location

Rochester

Fees & Codes

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	In Process

Result ID	Reporting Name	LOINC®
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