

HOTLINE: Effective May 20, 2019

2012618 Risk of Ovarian Malignancy Algorithm ROMA

Methodology: Quantitative Electrochemiluminescent Immunoassay (ECLIA)

Performed: Sun-Sat

Reported: Within 24 hours

Specimen Required: Collect: Serum Separator Tube (SST). Also acceptable: Green (Sodium or Lithium Heparin), Lavender (EDTA), or Pink (K2EDTA).

Specimen Preparation: Allow specimen to clot completely at room temperature. Transfer 1.5 mL serum or plasma to an ARUP

Standard Transport Tube. (Min: 1 mL) Storage/Transport Temperature: Frozen.

<u>Unacceptable Conditions:</u> Hemolyzed specimens.

Stability (collection to initiation of testing): Ambient: 5 hours; Refrigerated: 48 hours; Frozen: 4 months

Interpretive Data: The Risk of Ovarian Malignancy Algorithm (ROMA) combines the results of HE4, CA125, and menopausal status into a numerical score. If the patient is premenopausal, then a ROMA score of less than 1.14 is consistent with a low likelihood of finding a malignancy on surgery. If the patient is postmenopausal, then a ROMA score of less than 2.99 is consistent with a low likelihood of finding a malignancy on surgery.

ROMA is intended as an aid in assessing whether a premenopausal or postmenopausal woman who presenting with an ovarian adnexal mass is at high or low likelihood of having malignancy on surgery. ROMA is indicated for women who meet the following criteria: over age 18; ovarian adnexal mass present for which surgery is planned, and who has not yet referred to an oncologist. ROMA must be interpreted in conjunction with an independent clinical and radiological assessment. ROMA is not intended as a screening or stand-alone or tumor-monitoring assay. Tumor monitoring using HE4 and/or CA125 should be ordered separately.

Testing for HE4 and CA125 was performed using Roche Cobas e602 electrochemiluminescent methods. Analyte results obtained with different test methods or kits cannot be used interchangeably.

HOTLINE NOTE: There is a numeric map change associated with this test.

Change the numeric map for component 2012621, ROMA Cancer Antigen 125 from XXXXX to XXXXXXX.

Change the numeric map for component 2012622, ROMA Human Epididymis Protein 4 from XXXXX to XXXXXXX.

There is also a unit of measure change associated with this test.

Change the unit of measure for component 2012622, ROMA Human Epididymis Protein 4 from pM to pmol/L.