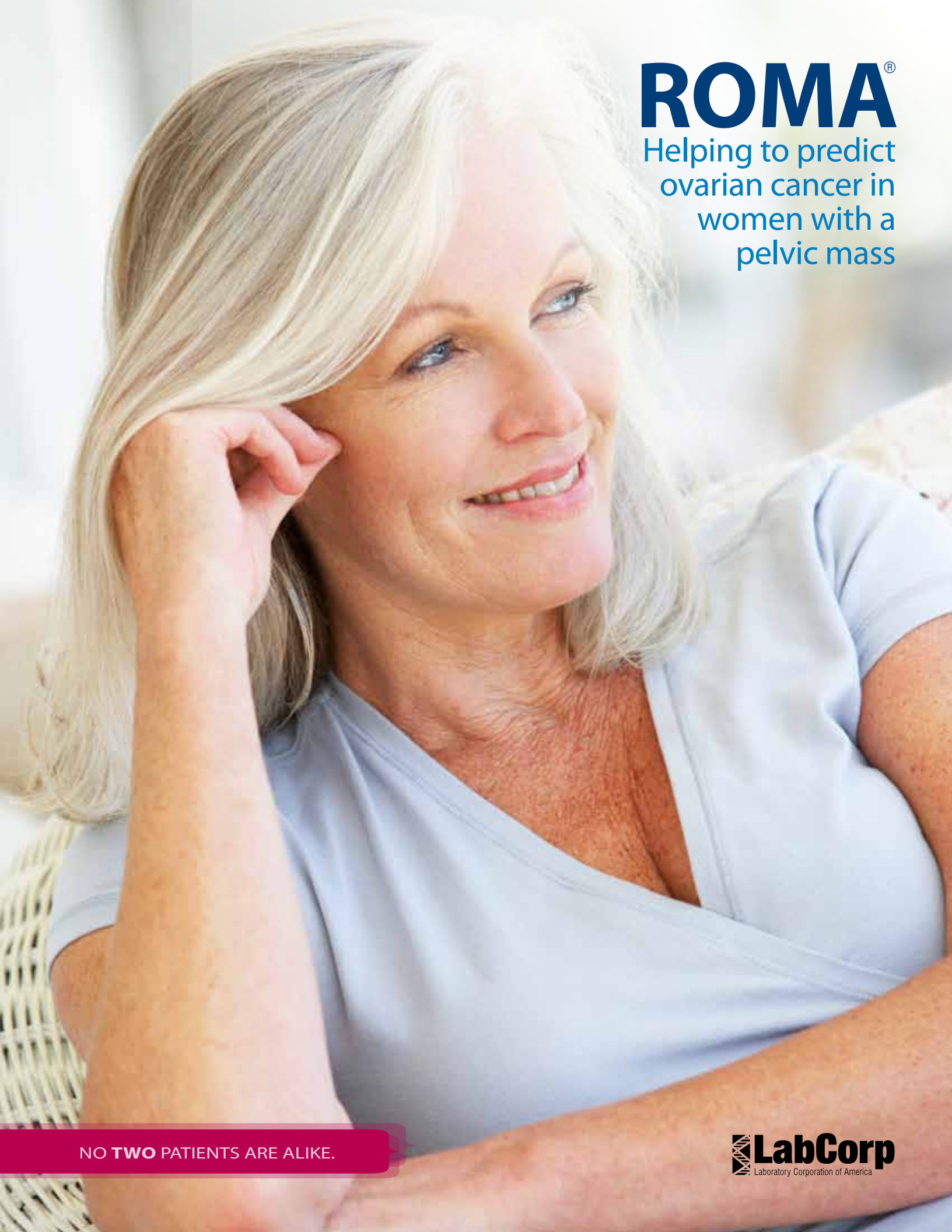

ROMA®
Helping to predict ovarian cancer in women with a pelvic mass
NO TWO PATIENTS ARE ALIKE.
LabCorp
Laboratory Corporation of America

ROMA® - Helping to predict ovarian cancer in women with a pelvic mass

For women who present with a pelvic mass, the Risk of Ovarian Malignancy Algorithm (ROMA) combines CA125 and HE4 with menopausal status for improved risk stratification.

It is estimated that up to 10% of women will have a surgical procedure for a suspected ovarian mass during their lives;[1,2] 80% or more of cases will be diagnosed as benign.[2] Thus, patients who are scheduled to have surgery could benefit from an accurate and specific risk stratification tool to aid in assessing the risk of finding malignancy at surgery.

Risk Stratification Through ROMA

ROMA is an FDA-cleared risk stratification tool developed by Fujirebio Diagnostics that combines CA125, HE4, and menopausal status into a numerical score that indicates the risk of malignancy for pelvic masses.[3] ROMA is indicated as an aid in assessing likelihood of malignancy in women in conjunction with clinical evaluation who present with an adnexal mass.[3] In a study of 472 women who presented with an ovarian mass, ROMA correctly stratified 94% of women with epithelial ovarian cancer into a "high-likelihood" group.[4] ROMA also correctly stratified 75% of women with benign disease into a "low-likelihood" group.[4]

ROMA includes 2 recognized markers for ovarian cancer, CA125 and HE4. Cancer antigen 125 (CA125) has been shown to be elevated in most ovarian cancer cells, but has a low specificity for ovarian malignancies.[1,5,6] Human epididymis protein 4 (HE4) is a novel biomarker that is elevated in ovarian cancers, as well as other cancers, and has been shown to have higher specificity than CA125.[5,6] Combining CA125 and HE4 provides a more accurate prediction of malignancy than either test alone.[5,6] **ROMA culminates the benefits of the combined CA125 and HE4 biomarkers with menopausal status to help provide a numeric risk stratification of malignancy for pelvic masses.**[3,4]

Performance of ROMA with Initial Cancer Risk Assessment (ICRA)[3]

	ICRA	ROMA	ICRA + ROMA
Sensitivity	73.3%	82.6%	88.4%
Specificity	84.3%	75.5%	67.2%
PPV	51.6%	43.6%	38.2%
NPV	93.2%	95.0%	96.2%

ROMA provides equal sensitivity to other commercially available risk stratification tools while enhancing the specificity for assessing the risk level of malignancy.[3,4] This can aid in improved patient management within your practice.

ROMA is indicated for women who meet the following criteria: over age 18, ovarian adnexal mass present for which surgery is planned, and not yet referred to an oncologist. "ROMA should not be used without an independent clinical/radiological evaluation and is not intended to be a screening test or to determine whether a patient should proceed to surgery. Incorrect use of ROMA carries the risk of unnecessary testing, surgery, and/or delayed diagnosis."[3]

ROMA provides an easy-to-interpret result that should be considered with other clinical findings.[3]

Risk	Pre-menopausal	Post-menopausal
Low	< 1.31	< 2.77
High	≥ 1.31	≥ 2.77

Clinical Application of ROMA

Woman presents with pelvic mass

Pelvic masses present a diagnostic challenge because they affect a large number of women (up to 10%) but are usually benign.[1,2]

Risk Stratification Through ROMA

ROMA's unique combination of HE4, CA125, and menopausal status provides a presurgical assessment to predict likelihood of malignancy.[3]

Surgery

Those women whose ROMA score indicates a high risk of malignancy would benefit from referral to a gynecologic oncologist. The National Comprehensive Cancer Network® (NCCN) Clinical Practice Guidelines for ovarian cancer indicate that patients whose tumor debulking was performed by a gynecologic oncologist experience a survival advantage.[7]

Monitoring

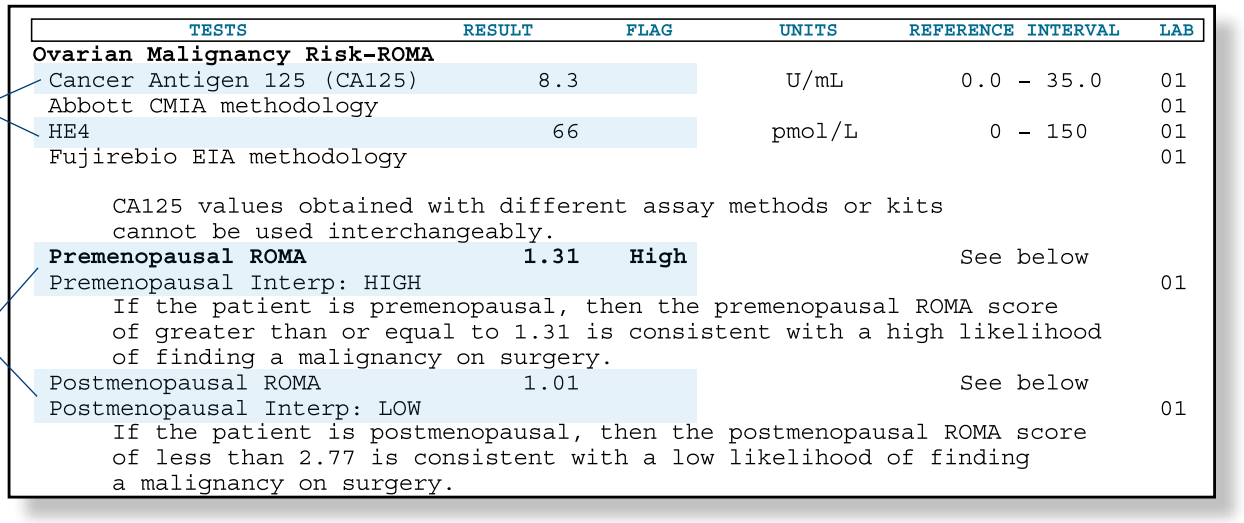
- CA125 + HE4
- HE4
- CA125

For postsurgical monitoring, LabCorp offers the ovarian cancer monitor profile, which includes results for both CA125 and HE4. CA125 and HE4 can also be ordered individually.

LabCorp's ROMA Result Report

Individual results for both CA125 and HE4 are provided.

Considered together with menopausal status, a ROMA risk assessment is generated.



TESTS	RESULT	FLAG	UNITS	REFERENCE INTERVAL	LAB
Ovarian Malignancy Risk-ROMA					
Cancer Antigen 125 (CA125)	8.3		U/mL	0.0 - 35.0	01
Abbott CMIA methodology					01
HE4	66		pmol/L	0 - 150	01
Fujirebio EIA methodology					01
CA125 values obtained with different assay methods or kits cannot be used interchangeably.					
Premenopausal ROMA	**1.31**	**High**		See below	
Premenopausal Interp: HIGH					01
If the patient is premenopausal, then the premenopausal ROMA score of greater than or equal to 1.31 is consistent with a high likelihood of finding a malignancy on surgery.					
Postmenopausal ROMA	1.01			See below	
Postmenopausal Interp: LOW					01
If the patient is postmenopausal, then the postmenopausal ROMA score of less than 2.77 is consistent with a low likelihood of finding a malignancy on surgery.					

Ovarian Malignancy Risk-ROMA

Test Number 140045
Specimen 1 ml serum in a red-top or gel-barrier tube. If a red-top tube is used, transfer separated serum to a plastic transport tube.

For postsurgical monitoring, LabCorp offers the ovarian cancer monitor profile, which includes results for both CA125 and HE4. CA125 and HE4 can also be ordered individually.

Ovarian Cancer Monitor

Test Number 081610
Test Includes HE4; CA125
Volume 1 mL serum in a red-top tube or gel-barrier tube. If red-top tube is used, transfer separated serum to a plastic transport tube.

Cancer Antigen (CA) 125, Serum

Test Number 002303
Specimen 0.8 mL serum in a red-top or gel-barrier tube. If a red-top tube is used, transfer separated serum to a plastic transport tube.
Methodology Electrochemiluminescence immunoassay (ECLIA)
For serial monitoring, use test number 480061.

Human Epididymis Protein 4

Test Number 081700
Specimen 0.5 mL serum in a red-top or gel-barrier tube. If red-top tube is used, transfer separated serum to a plastic transport tube.
Methodology Enzyme-linked immunosorbent assay (ELISA)
For serial monitoring use, test number 481700.

Note: The CA125 component of ROMA is performed using a different methodology than LabCorp's standalone CA125 assay (002303) or the ovarian cancer monitor assay (test 081610). Results from different methodologies cannot be used interchangeably.

References

1. Curtin JP. Management of the adnexal mass. *Gynecol Onc*. 1994;55:S42-46.
2. Ovarian cancer: screening, treatment, and followup. NIH Consensus Statement. 1994 Apr 5-7;12(3):1-29.
3. ROMA [Instructions for use]. Göteborg, Sweden: Fujirebio Diagnostics AB; 2011. Prod No 404-10US.
4. Moore RG, Miller MC, Disilvestro P, et al. Evaluation of the diagnostic accuracy of the risk of ovarian malignancy algorithm in women with a pelvic mass. *Obstet Gynecol.* 2011;118:280-288.
5. Escudero JM, Auge JM, Filella X, Torne A, Pahisa J, Molina R. Comparison of serum human epididymis protein 4 with cancer antigen 125 as a tumor marker in patients with malignant and nonmalignant diseases. *Clin Chem.* 2011;57(11):1534-1544.
6. Moore RG, Brown AK, Miller MC. The use of multiple novel tumor biomarkers for the detection of ovarian carcinoma in patients with a pelvic mass. *Gynecol Onc.* 2008;108:402-408.
7. *NCCN Clinical Practice Guidelines in Oncology™ Ovarian Cancer V.2.2012.* Fort Washington, Pa: National Comprehensive Cancer Network®; 2011.

LabCorp
Laboratory Corporation of America