ONCOLOGY

Abbott

IT'S MORE THAN A TEST.
IT'S STRATIFYING THE RISK OF OVARIAN MALIGNANCY.

Improving the patient journey through biomarker utilization in the risk assessment and disease management of epithelial ovarian cancer is crucial.

Ovarian cancer is the third most common gynecological cancer and is **most common in postmenopausal women**[1,2]

The average **five-year survival rate** following diagnosis across all stages is **46%**[3]

~90% of primary ovarian malignancies originate from epithelial cells[4]

It is estimated that ovarian cancer will be attributable to over 19,000 new cancer cases and over 12,000 deaths in the United States in 2024.[5]

Although ovarian adnexal masses are common, **up to 40% are malignant upon surgical evaluation**.[3] Information determining the likelihood of malignancy of pelvic masses is crucial for proper patient referral and management.[6–8]

PATIENT PRESENTING WITH AN ADNEXAL MASS CONFIRMED VIA ROUTINE ASSESSEMENT

CLINICAL ASSESSMENT

- Symptom assessment
- Medical history
- Imaging scan
- Pelvic exam

BIOMARKER ASSESSMENT: CA 125 + HE4 = ROMA*

The combination of HE4 and CA 125 is a more accurate predictor of malignancy than either marker alone.[9–11]

HIGH-RISK PATIENT
Referred to a GYN/ONC for surgical consultation and clinical management†

LOW-RISK PATIENT
Referred to an OB/GYN for further consultation

*Alinity i risk of ovarian malignancy algorithm (ROMA) is intended to aid in assessing whether a premenopausal or postmenopausal woman who presents with an ovarian adnexal mass is at high or low likelihood of finding malignancy on surgery.[11]
†Appropriate referral to a GYN/ONC is associated with improved overall survival rates.[1]

When ovarian cancer is diagnosed at the earliest stage, the average 5-year survival prognosis is 93%.[13] However, **only 20% of cases are detected at an early stage**.[14]

DIAGNOSIS IS OFTEN HINDERED BY:[1,6,15–17]

LACK OF ROUTINE SCREENING

NONSPECIFIC SYMPTOMS — EVEN IN ADVANCED DISEASE

LOW SPECIFICITY OF IMAGING METHODS

TUMOR BIOMARKERS CAN SUPPORT WITH:[1,9,10]

- Risk stratification in patients presenting with adnexal mass
- Tracking treatment response
- The monitoring of disease progression or recurrence

KNOW MORE WITH HE4

Although CA 125 is widely utilized to support the evaluation and management of ovarian cancer, serum levels are often elevated in benign conditions such as endometriosis and normal in up to 50% of patients with stage 1 ovarian cancer.[3]

Incorporating HE4 into your current clinical evaluation pathway provides additional information when pre-surgically assessing an adnexal mass, as well as monitoring disease progression and recurrence.[9]

HE4

- HE4 is less frequently elevated in benign gynecological conditions, such as endometriosis, than CA 125 due to its higher specificity.[3]
- Expressed in 20% of ovarian cancer patients even in the absence of elevated CA 125 levels.[16,17]

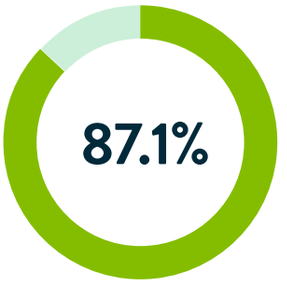
RISK OF OVARIAN MALIGNANCY ALGORITHM (ROMA)

Combining CA 125 and HE4 results with menopausal status into a numerical score can more accurately predict ovarian malignancy in patients with an adnexal mass, prior to surgical intervention.*

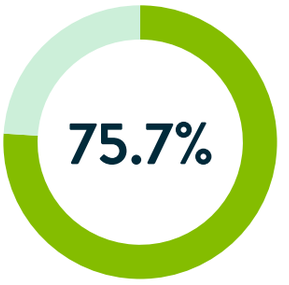
ROMA SCORE TEST ACCURACY[9]

NEGATIVE PREDICTIVE VALUE

SENSITIVITY



SPECIFICITY



*Serial testing for patient CA 125 and HE4 assay values should be used in conjunction with other clinical methods in accordance with standard clinical management guidelines.[9,10] ROMA must be interpreted in conjunction with an independent clinical and radiological assessment.[11]

INTENDED USE AND IMPORTANT SAFETY INFORMATION

Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

ALINITY I ROMA[11]

PRECAUTION: Alinity i 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 Alinity i ROMA carries the risk of unnecessary testing, surgery, and/or delayed diagnosis.

INTENDED USE: Alinity i Risk of Ovarian Malignancy Algorithm (ROMA) is a qualitative serum test that combines the results of Alinity i HE4, Alinity i CA 125 II, and menopausal status into a numerical score.

Alinity i ROMA is intended to aid in assessing whether a premenopausal or postmenopausal woman who presents with an ovarian adnexal mass is at high or low likelihood of finding malignancy on surgery.

Alinity i 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. Alinity i ROMA must be interpreted in conjunction with an independent clinical and radiological assessment.

This test is not intended as a screening or standalone diagnostic test.

ALINITY I CA 125 II ASSAY[10]

WARNING: The concentration of CA 125 in a given specimen, determined with assays from different manufacturers, can vary due to differences in assay methods and reagent specificity. The results reported by the laboratory to the physician must include the identity of the CA 125 assay used. Values obtained with different assay methods cannot be used interchangeably. If, in the course of monitoring a patient, the assay method used for determining CA 125 levels serially is changed, additional sequential testing should be carried out. Before changing assays, the laboratory MUST confirm baseline values for patients being serially monitored.

United States Federal Law restricts this device to sale and distribution by or on the order of a physician, or to a clinical laboratory; and use is restricted to by or on the order of a physician.

INTENDED USE: The Alinity i CA 125 II assay is a chemiluminescent microparticle immunoassay (CMIA) used for the quantitative determination of OC 125 defined antigen in human serum and plasma on the Alinity i analyzer.

The Alinity i CA 125 II assay is to be used as an aid in monitoring response to therapy for patients with epithelial ovarian cancer. Serial testing for patient CA 125 II assay values should be used in conjunction with other clinical methods used for monitoring ovarian cancer.

ALINITY I HE4 ASSAY[9]

WARNING: HE4 assay values obtained with different assay methods cannot be used interchangeably due to differences in assay methods and reagent specificity. The results reported by the laboratory to the physician must include the identity of the HE4 assay used. If, in the course of monitoring a patient, the assay method used for determining serial HE4 levels is changed, additional sequential testing should be carried out. Prior to changing assays, the laboratory MUST confirm baseline values for patients being serially monitored. **The Alinity i HE4 assay should not be used as a cancer screening test.**

INTENDED USE: The Alinity i HE4 assay is a chemiluminescent microparticle immunoassay (CMIA) used for the quantitative determination of HE4 antigen in human serum on the Alinity i analyzer.

The Alinity i HE4 assay is to be used as an aid in monitoring recurrence or progressive disease in patients with epithelial ovarian cancer. Serial testing for patient HE4 assay values should be used in conjunction with other clinical methods used for monitoring ovarian cancer.

CAUTION: The Alinity i CA 125 II assay and Alinity i HE4 assay require the handling of human specimens. It is recommended that all human sourced materials be considered potentially infectious and handled in accordance with the OSHA Standard on Bloodborne Pathogens. Biosafety Level 2 or other appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents. The Alinity i CA 125 II assay contains sodium azide. Contact with acids liberates very toxic gas. Dispose of contents/container in accordance with local regulations.United States Federal Law restricts this device to sale and distribution by or on the order of a physician, or to a clinical laboratory; and use is restricted to by or on the order of a physician.

EARLY AND APPROPRIATE REFERRAL TO GYNECOLOGICAL ONCOLOGISTS HAS THE POTENTIAL TO IMPROVE PATIENT CARE, DISEASE MANAGEMENT AND SURVIVAL RATES IN PATIENTS WITH EPITHELIAL OVARIAN CANCER.

Discover how the utilization of biomarkers can help physicians to further stratify the risk of ovarian malignancy in patients who present with an adnexal mass.

LEARN MORE

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CORELABORATORY.ABBOTT

For *in vitro* diagnostic use.

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