

PATIENT INFORMATION	PROVIDER INFORMATION	LAB INFORMATION
Last Name: xxxxxxxxxxxx First Name: xxxxxxxxxxxx MRN: xxxxxxxxxxxx DOB: xx/xx/xxxx Age: xx Ethnicity: xxxxxxxxxxxx Clinical Info: Premenopausal	Ordering Provider: Practice Name Street Address City, State, ZIP Tel: Fax: Copy-to-Physician: Fax:	Accession No: Client No: Collection Date: Received Date: Report Date: 17 August 2022 Comments:

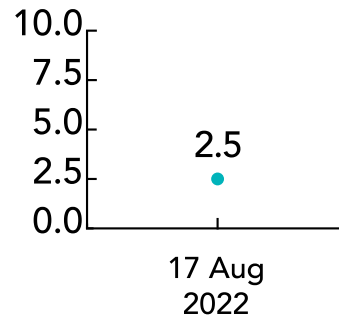
Results:	Score	Status	Reference Range	NPV*	PPV**
OvaWATCH SM	2.5	Low probability of malignancy	Low probability of malignancy <5.0 Indeterminate ≥5.0	99%	N/A

OvaWatchSM Scores

Report date: **17 August 2022**

↓ LOW PROBABILITY OF MALIGNANCY

OvaWatch result indicates a low probability of malignancy for this adnexal mass. Consultation with gynecology and monitoring is recommended. If indicated, follow up imaging and clinical studies.



NR: No Result; TNP: Test Not Performed

OvaWatch result should always be interpreted in combination with clinical assessment, personal history and imaging studies.

OvaWatch employs a combination of AGE, MENOPAUSAL STATUS, and serum PROTEIN BIOMARKERS into an algorithm to provide this personalized risk assessment. CA 125 II and HE4 are components of the OvaWatch Test, and both tests are performed on the Cobas Analyzer manufactured by Roche Diagnostics.

* NPV is the probability of absence of ovarian cancer at this OvaWatch score and at an estimated 5% prevalence of malignancy.

** PPV is the probability of presence of a non-benign or suspicious mass at this OvaWatch score and at an estimated 5% prevalence of malignancy.

OvaWatch performance characteristics were established in a study of 2,000 women with adnexal mass, in which the ovarian cancer prevalence was 4.9%. OvaWatch specificity was validated at 84% with negative predictive value (NPV) of 99.4%, whereas its sensitivity was validated at 90% (98.0% for Stage 3&4 and 76.9% for Stage 1&2 cancers) with positive predictive value (PPV) of 22.5%.¹

Additional Results

Test Name	Result	Status	Reference Range
CA 125 II	80.0 U/mL	Elevated	Premenopausal ≤67.0 U/mL ² Postmenopausal ≤35.0 U/mL ³
HE4	50.0 pmol/L	Normal	Age ≤49 y ≤63.6 pmol/L ⁴ Age >50 y ≤105 pmol/L ⁴

References

1. Reilly G, Bullock R, Greenwood, et al. "Analytical Validation of a Deep Neural Network Algorithm for the Detection of Ovarian Cancer." *JCO Clinical Cancer Informatics* (2022); (6:e2100192).
2. Dearing AC, Aletti GD, McGree ME, Weaver AL, Sommerfield MK, Cliby WA. "How relevant are ACOG and SGO guidelines for referral of adnexal mass?" *Obstet Gynecol* (2007) Oct;110(4):841-8. doi:10.1097/01.AOG.0000267198.25223.bc. PMID:17906018.
3. Practice Bulletin Number 174: Evaluation and Management of Adnexal Masses. *Obstet Gynecol* (2016) 128:5.
4. Instructions For Use; cobas Elecsys HE4, Roche Diagnostics, 2021-07 V 4.0.

Disclaimer

This test was developed and its performance characteristics determined by Aspira Laboratory. It has not been cleared or approved by the FDA, nor is it required to be. The laboratory is regulated under CLIA as qualified to perform high-complexity testing. The results obtained from this multivariate index assay should always be interpreted in the context of clinical examination, patient medical history, and other findings.