OvaWATCH®

PATIENT INFORMATION

Last Name: OVAWATCHREPORT
First Name: NEW
MRN:
DOB:01/01/1992
Age: 31
Ethnicity: CAUCASIAN
Clinical Info: Premenopausal

PROVIDER INFORMATION

Ordering Provider: TEST PHYSICIAN
Practice Name: TEST CLIENT
Street Address: TEST ADDRESS

City, State, Zip: TEST ADDRESS
Tel: TEST PHONE
Fax:
Copy-to-Physician:
Fax:

LAB INFORMATION

Accession No: AZ002686
Client No: TEST
Collection Date: 08/08/2023
Received Date: 08/08/2023
Report Date: 08/08/2023
Comments:

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

OvaWatch® 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.

Collection Date:	30-Jul-22	8-Nov-22	8-Aug-23
OvaWatch Score:	2.6	2.4	2.1

The scores shown were determined at the time points indicated.
No conclusion can be drawn from the score changes from point to point.

NR: No Result; TNP: Test Not Performed

OvaWatch is intended for use in as a non-invasive test to assess the risk of ovarian cancer for women with adnexal masses, evaluated by initial clinical assessment as indeterminate or benign. A low risk score is highly suggestive of a benign mass (less that 5.0% probability of cancer), while an indeterminate score suggests that the presence of cancer cannot be ruled out.

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 a proprietary algorithm to provide this personalized risk assessment. CA 125 II and HE4 are components of the OvaWatch Test, all 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	4.27 U/mL	Normal	**Premenopausal** ≤67.0 U/mL[2]	**Postmenopausal** ≤35.0 U/mL[3]
HE4	42.3 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. Dearking 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.
5. Reilly, G. P., Dunton, C. J., Bullock, R. G., Ure, D. R., Fritsche, H., Ghosh, S., ... & Phan, R. T. (2023). Validation of a deep neural network-based algorithm supporting clinical management of adnexal mass. Frontiers in Medicine, 10,1102437.
6. Choudhury et al., 2024, "Ovarian Cancer Surgical Consideration is Markedly Improved by the Neural Network Powered- MIA3G Multivariate Index Assay" Front. Med.Sec. Obstetrics and Gynecology Volume 11 - 2024 | doi: 10.3389/fmed.2024.1374836
7. Pappas T, Choudhury M, Chacko B, Twiggs L, Fritsche H, Elias K, Phan R, "Neural Network-derived Multivariate Index Assay Demonstrates Effective Clinical Performance in Longitudinal Monitoring of Ovarian Cancer Risk". Accepted for publication.

Disclaimer

This test was developed and its performance characteristics were determined by Aspira Laboratory. The test 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 represent individual analyses for the patient and were obtained from this multivariate index assay should always be interpreted in the context of clinical examination, patient medical history, and other findings.

ASPIRA LABS®

12117 Bee Caves Road Building III, Suite 100, Austin, Texas 78738
Phone (844) 277-4721 | Fax (866) 283-3634
www.aspirawh.com | aspirasupport@aspirawh.com

Laboratory Director
Herbert Fritsche, Ph.D.
CLIA # 45D2073394 CAP # 9021192