ASPIRA LABS®

Ova1 plus

Patient Info
Last Name: SAMPLE
First Name: PATIENT
MRN: 12345
DOB: 07/01/1974
Age: 46
Gender: FEMALE
Ethnicity: Caucasian

Provider Info
Ordering Provider: PROVIDER
Practice Name: OBGYN OFFICE
Street Address: 123 Main Street
City, State, Zip: ANYTOWN, ST 01234
Tel: 555-555-5555
Fax:
Copy-to-Physician:
Fax:

Laboratory Info
Accession No: A0000789
Client No: 1234A
Collection Date: 06/02/2020
Received Date: 06/03/2020
Final Report Date: 06/04/2020

Clinical Information: ? Ultrasound Results Unknown **Menopausal Status:** ✓ Premenopausal

Test Name	Result	Status	Reference Range
Ova1[1, 2]	**2.5**	**Low Risk**	**Premenopausal** Low Risk < 5.0 Elevated Risk ≥ 5.0

Interpretation:

A **LOW RISK OVA1** results in a Risk of Malignancy of 1%, or 2% when combined with ultrasound results (see below). Results should be interpreted along with clinical and ultrasound assessment. A low risk value has been determined to have a negative predictive value of 98%.

Providing Menopausal status and Ultrasound results helps to narrow down the risk of Malignancy

Risk of Malignancy: 1% (premenopausal, **low risk** ultrasound)
or
Risk of Malignancy: 2% (premenopausal, **high risk** ultrasound)

*Risk of Malignancy is a combination of the OVA1 Result, Menopausal status and Ultrasound results[3]

Test Name	Result	Status	Reference Range
Epithelial Tumor Markers			
CA-125 II[1]	10.0 U/mL	**Normal Range**	**Premenopausal** ≤ 63.0 U/mL

Interpretation: Results in the normal range may suggest low risk for ovarian cancer. Epithelial-Cell Tumors make up an average of 75% of all ovarian cancer tumor types, including serous, mucinous, endometrioid, clear cell, and Brenner tumors.

Notes:

Disclaimer:

Results cannot be interpreted as absolute evidence of the presence or absence of malignant disease and should always be interpretated in combination with clinical assessment.

Methods and Limitations

1. CA 125 II is a component of the OVA1 Test. The CA 125 II assay method used is manufactured by Roche Diagnostics. The diagnostic sensitivity and specificity of the Roche Diagnostics CA 125 II test was calculated by comparing ovarian carcinoma patients at primary diagnosis (FIGO stage I to IV) with patients suffering from benign gynecological diseases. At a cutoff value of 65u/mL, the sensitivity is 79% (at a low specificity of 82%). The optimal clinical value is reached at 150 U/mL sensitivity 69%, specificity 93%).
2. High-risk imaging was defined as any complex ovarian tumor with evidence of solid or papillary components.
3. Low-risk imaging was defined as unilocular or septate cystic ovarian tumor without high-risk findings.

References

1. In a study of 494 subjects with a pelvic mass, the OVA1 performance data was: Sensitivity - 92.4% and Specificity - 53.5%. Bristow RE, et al., Gynecol Oncol. 2013; 128:252-259
2. Bristow RE, et al., Gynecol Oncol. 2013;128:252-259
3. Goodrich ST, et al., Am J Obstet Gynecol. 2014 Jul;211(1):65. e1-65.e11

03480720

www.aspirawh.com
12117 Bee Caves Road Building III, Ste 100
Austin,Texas 78738

aspirasupport@aspirawh.com
P 1-844-ASPiRA1
F 1-866-283-3634

CLIA Lab No: 45D2073394
NYSDOH: 8885
Herbert Fritsche, Ph.D.
Laboratory Director

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