ASPIRA LABS

Ova1 plus

Patient Info

Last Name: XXTEST
First Name: [redacted]
MRN: XXTEST
DOB: [redacted]
Age: [redacted]
Gender: FEMALE
Ethnicity: NOT GIVEN

Provider Info

Provider First: [redacted]
Provider Last: [redacted]
Practice Name: [redacted]
Street Address: [redacted]
City, State, Zip: [redacted]
Fax:
CC Physician:
Fax:

Laboratory Info

Accession No: [redacted]
Client No: [redacted]
Collection Date: [redacted]
Received Date: [redacted]
Final Report Date: [redacted]

Clinical Information: ? Ultrasound Results Not Provided

Menopausal Status: ✓ Premenopausal

Test Name	Result	Status	Reference Range
Ova1 [1]	3.3	Low Risk	**Premenopausal** Low Risk < 5.0 Elevated Risk ≥ 5.0

Interpretation

A **LOW RISK** OVA1 predicts a **Risk of Malignancy of 0.6% or 2.8%** 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: 0.6% (Premenopausal, Low Risk Ultrasound)
or
Risk of Malignancy: 2.8% (Premenopausal, High Risk Ultrasound)

**Risk of Malignancy is a combination of the Ova1 Result, Menopausal Status, and Ultrasound Results.* [2]

Epithelial Tumor Markers

CA-125 II	6.1 U/mL	**Normal**	**Premenopausal** 0.0 - 63.0 U/mL

*CA-125 results cannot be interpreted as absolute evidence of the presence or absence of malignant disease.

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:

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

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Fax:
CC Physician:
Fax:

Laboratory Info

Accession No: [redacted]
Client No: TESTSLDSI
Collection Date: [redacted]
Received Date: [redacted]
Final Report Date: [redacted]

Disclaimer

Results cannot be interpreted as absolute evidence of the presence or absence of malignant disease and should always be interpreted in combination with clinical assessment. Values obtained with different assay methods or kits cannot be used interchangeably.

Ova1Plus® is a reflex process which performs Ova1® and Overa®, both FDA-cleared tests for women with adnexal masses. Before making any treatment decisions, all women should discuss the results with their healthcare provider, who can recommend follow up testing or procedures when appropriate. This test was developed and its performance characteristics determined by Aspira Labs®, a wholly owned subsidiary of Aspira Women's Health. Ova1Plus®, an offering from Aspira Women's Health Inc., is a reflex process which performs Ova1® and then performs Overa® if the Ova1® result is in the intermediate range.

Aspira Labs®, a wholly owned subsidiary of Aspira Women's Health, in Austin, Texas, USA, which is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high complexity clinical testing.

Ova1Plus® is performed by Aspira Labs®, a wholly owned subsidiary of Aspira Women's Health, 12177 Bee Caves Road Building III, Ste 100. Austin, Texas 78738. CAP: 9021192; CLIA: 45D2073394; AU ID: 1742426; State CA Laboratory Certificate Lab ID#: CDS00800490; State NY Laboratory Permit: PFI 8885; Laboratory Director: Herbert Fritsche, Ph.D.

Methods And Limitations

- 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%).
- High-risk imaging was defined as any complex ovarian tumor with evidence of solid or papillary components.
- 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. Goodrich ST, et al., Am J Obstet Gynecol. 2014 Jul;211(1):65. e1-65.e11