ASPIRA LABS®

Ova1 plus®

Patient Info

Last Name: **SAMPLE**
First Name: **CASE ONE**
MRN:
DOB: **01/01/1963**
Age: 59
Gender: FEMALE
Ethnicity: CAUCASIAN

Provider Info

Provider First: HERBERT
Provider Last: FRITSCHE PHD
Practice Name: ASPIRA LABS
Street Address: 12117 BEE CAVES RD,BLDG 3 STE 100
City, State, Zip: AUSTIN, TX 78738
Fax:
CC Physician:
Fax:

Laboratory Info

Accession No: **A0091163**
Client No: TEST
Collection Date: 06/20/2022 UNK
Received Date: 06/21/2022 13:27
Final Report Date: 06/21/2022 14:59

Clinical Information: ? Ultrasound Results Not Provided

Menopausal Status: ✓ Postmenopausal

Test Name	Result	Status	Reference Range
Overa® [3]	**6.7**	**Elevated Risk**	**Low Risk < 5.0** **Elevated Risk ≥ 5.0**

Interpretation

An **ELEVATED RISK** OVERA predicts a **Risk of Malignancy of 20.8% or 49.5%** when combined with ultrasound results (see below). Results should be interpreted along with clinical and ultrasound assessment.

Ova1® [1]	5.0	Reflex to Overa	**Postmenopausal** Reflex Range 4.4 - 6.0

Providing menopausal status and ultrasound results helps to narrow down the risk of malignancy.

Risk of Malignancy: 20.8% (Postmenopausal, Low Risk Ultrasound)
or
Risk of Malignancy: 49.5% (Postmenopausal, High Risk Ultrasound)

**Risk of Malignancy is a combination of the OVERA Result, Menopausal Status, and Ultrasound Results.* [4]

Epithelial Tumor Markers

CA-125 II	26.2 U/mL	**Normal**	**Postmenopausal** 0.0 - 35.0 U/mL

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

HE4	80.0 pmol/L	**Normal**	**Ages ≥ 50 y** ≤ 105.2 pmol/L

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 interpreted in combination with clinical assessment. Values obtained with different assay methods or kits cannot be used interchangeably. 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.
- HE4 was performed using Roche Diagnostics Electrochemiluminescence Immunoassay (ECLIA).

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