ASPIRA LABS®

Ova1 plus

Patient Info
Last Name: SAMPLE
First Name: PATIENT
MRN: 12345
DOB: 12/01/1973
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
Overa[4]	4.0	Low Risk	Low Risk < 5.0 Elevated Risk ≥ 5.0
Ova1[1,2]	5.0	Reflex	**Premenopausal** Reflex Range 5.0-7.0

Interpretation:

A **LOW RISK OVA1** results in a Risk of Malignancy of 1.5% or 2.0% 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: 1.5% (premenopausal, **low risk** ultrasound)
or
Risk of Malignancy: 2.0% (premenopausal, **high risk** ultrasound)

*Risk of Malignancy is a combination of the OVERA Result, Menopausal status and Ultrasound results[5]

Test Name	Result	Status	Reference Range
Epithelial Tumor Markers			
CA-125 II	10.0 U/mL	**Normal Range**	**Premenopausal** ≤ 63.0 U/mL
HE4	23.0 pmol/L	**Normal Range**	**Premenopausal** ≤ 63.6 pmol/L
Epithelial Tumor Markers (Mucinous type)			
CA19-9	15.0 U/mL	**Normal Range**	≤ 35.0 U/mL
CEA	3.0 ng/mL	**Normal Range**	Non Smokers < 5.0 ng/mL Smokers < 6.5 ng/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.

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Germ Cell Tumor Markers

AFP	15.2 ng/mL	**Elevated**	≤ 8.3 ng/mL
BETA HCG	2.0 mIU/mL	**Normal Range**	**Premenopausal** (non-pregnant) ≤ 5.3 mIU/mL
LDH	140.0 IU/L	**Normal Range**	135.0 – 214.0 IU/L

Interpretation: The AFP value is elevated, elevated AFP results may suggest increased risk for germ-cell ovarian cancer, such as Endodermal sinus tumors. Clinical Correlation is advised. Germ-Cell tumors are suspected in women < 35 years of age but may occur at any age. Germ Cell-tumors make up an average of 15% of all ovarian cancer tumor types.

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.

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.
4. HE4 was performed using Roche Diagnostics Electrochemiluminescence Immunoassay (ECLIA).
5. CEA was performed on the Roche cobas 6000 using the ECLIA method.
5. CA19-9 was performed on the Roche cobas 6000 using the ECLIA method. Patients known to be genotypically negative for Lewis blood group antigens will be unable to produce the CA19-9 antigen even in the presence of malignant tissue. Phenotyping for the presence of the Lewis blood group antigen may be insufficient to detect true Lewis antigen negative individuals. Even patients who are genotype positive for the Lewis antien may produce varying levels of CA19-9 as the result of gene dosage effect.
6. AFP was performed on the Roche cobas 6000 using the ECLIA method.
7. LDH: In very rare cases, gammopathy, in particular type IgM (Waldenström's macroglobulinemia), may cause unreliable LDH results.

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
4. In a study of 493 subjects with a pelvic mass, Overa's performance date was: Sensitivity - 91.3% and Specificity - 69.1%. Coleman RL, et al. Am J Obstet Gynecol. 2016 J82.ei-82.eii
5. Fredericks T et al. Combining A Second-Generation Multivariate Index Assay with Ovarian Imaging Improves the Preoperative Assessment of An Adnexal Mass. Journal of Surgical Oncology 2019. DOI: 10.31487/j.JSO.2019.03.04

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