

PATIENT AND ORDERING INFORMATION

Name: **SAMPLE, PATIENT**

MRN:

DOB: 06/25/1970

Age: 48

Sex: FEMALE

Collection Date: 09/07/2018 06:06

Received Date: 09/08/2018 13:10

Accession No:

Client No: 1234

Final Report Date: 09/12/2018 08:17

Released By:

Menopausal Status: Unknown

CLIENT INFORMATION

PROVIDER OFFICE

123 MAIN STREET

ANYTOWN, ST 01234

Tel:



Fax:

PHYSICIAN INFORMATION

Ordering Physician:

Copy-to-Physician:

TEST RESULTS

Test Name	Value	Status	Cut-off	
 ¹	5.7	Reflex	Premenopausal: Intermediate Risk: 5.0-7.0	Post-menopausal: Intermediate Risk: 4.4-6.0
 ²	7.4	Elevated Risk	Low Risk: <5.0 Elevated Risk: 5.0	
CA125 II***	42 U/mL		Premenopausal: 0 - 63 U/mL	Post-menopausal: 0 - 35 U/mL

Comments: An Overa value < 5.0 combined with an intermediate risk OVA1 result indicates a lower risk of malignancy. Refer to table. An Overa value ≥ 5.0 combined with an intermediate risk OVA1 result indicates an increased risk of malignancy. Results should be interpreted along with clinical and ultrasound assessment. If you have questions, please contact ASPIRA consult service.

Overa reflex testing reduces the OVA1 falsely elevated rates in both pre and post menopausal women by 38.8% and 46.0% respectively.

Risk of Malignancy (ROM) by Overa Value*

Overa Value	ROM
5	10.1%
6	22.9%
7	44.1%
8	67.6%

*ROM for pre and post menopausal together, with any type of imaging. Manuscript pending publication.

¹In 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

²In a study of 493 subjects with a pelvic mass, Overa's performance data was: Sensitivity - 91.3% and Specificity - 69.1%. Coleman RL, et al. Am J Obstet Gynecol. 2016 J82.ei-82.eii

*** 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%.