Malignancy Risk Assessment, Pelvic Mass, OVA1 Plus

Patient: [redacted]
DOB: [redacted] Age: [redacted] Gender: [redacted]
Patient Identifiers: [redacted]
Visit Number (FIN): [redacted]

Client: [redacted]
Physician: [redacted]

ARUP Test Code: 3002309

Collection Date: 08/10/2020
Received in lab: 08/13/2020
Completion Date: 08/14/2020

Test Information

Test performed at: ASPiRA Labs, 12117 Bee Caves Road Building III, Suite 100, Austin, TX 78738,www.aspiralab.com

Patient Report

Patient's report from ASPiRA Labs continues on following page(s).

ARUP LABORATORIES | 800-522-2787 | aruplab.com
500 Chipeta Way, Salt Lake City, UT 84108-1221
Tracy I. George, MD, Chief Medical Officer

Chart continues on following page(s)

ASPiRA LABS
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Ova1

Pelvic Mass Risk Assessment

PATIENT AND ORDERING INFORMATION

Name:	[redacted]	**Accession No:**	[redacted]
MRN:	[redacted]	**Client No:**	
DOB:	[redacted] **Age:** [redacted] **Sex:** [redacted]	**Final Report Date:**	08/14/2020 15:35
Date Specimen Collected:	08/10/2020 13:26	**Released By:**	EKS
Date Specimen Received:	08/14/2020 11:15	**Menopausal Status:**	Unknown

CLIENT INFORMATION

ARUP LABS
500 S CHIPETA WAY
SALT LAKE CITY, UT 84108
Tel: 801-583-2787
Fax: 801-584-5132

PHYSICIAN INFORMATION

Ordering Physician: UNKNOWN

Copy-to-Physician:

Fax:

OVA1 TEST RESULT

Test Name	Value	Status	Cut-Off
OVA1	3.7	Low Risk	Premenopausal Low Risk < 5.0; Elevated Risk ≥ 5.0 Postmenopausal Low Risk < 4.4; Elevated Risk ≥ 4.4

In a study of 269 subjects with a pelvic mass, in which 72 subjects were found to have ovarian cancer, the Ova1 performance data was: Sensitivity=87.5% and Specificity=50.8%

CA 125 II*	**6 U/mL**	**Premenopausal 0 - 63 U/mL** **Postmenopausal 0 - 35 U/mL**	**Notes:**

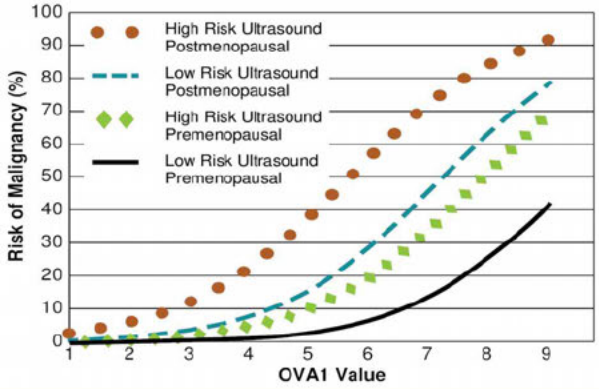
The results cannot be interpreted as absolute evidence of the presence or absence of malignant disease.

In studies, OVA1 demonstrated a negative predictive value of up to 98%. NPV is the percent of patients with a negative test result who had a benign mass.[1]

*CA 125 II is a component of the OVA1 Test. The CA 125 II assay method used is manufactured by Roche Diagnostics. Values obtained with different assay methods or kits cannot be used interchangeably. 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 65 U/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%).

Combining the OVA1 score with ultrasound results can help further define Risk of Malignancy (ROM)

Predicted Risk of Malignancy of OVA1 Score and Ultrasound by Menopausal Status and Ultrasound Risk[2]



If you have any questions, please call Client Services to speak with our lab director at 1-844-ASPiRA1

OVA1 value ROM when combined with imaging results

OVA1 Value	**3.7**
Pre menopausal Low Risk Ultrasound	**3%**
Pre menopausal Elevated Risk Ultrasound	**4%**
Post menopausal Low Risk Ultrasound	**7%**
Post menopausal Elevated Risk Ultrasound	**20%**

High-risk imaging was defined as any complex ovarian tumor with evidence of solid or papillary components.[2]
Low-risk imaging was defined as unilocular or septate cystic ovarian tumor without high-risk findings.[2]

References:

[1]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

ASPiRA LABS
12117 Bee Caves Road Building III, Suite 100
Austin, Texas 78738
P 1-844-ASPiRA1
F 1-866-283-3634
www.aspiralab.com
aspirasupport@vermillion.com
Herbert Fritsche, Ph.D.
Laboratory Director
CLIA Lab No: 45D2073394