Minimize the uncertainty in managing adnexal masses by optimizing your risk stratification process
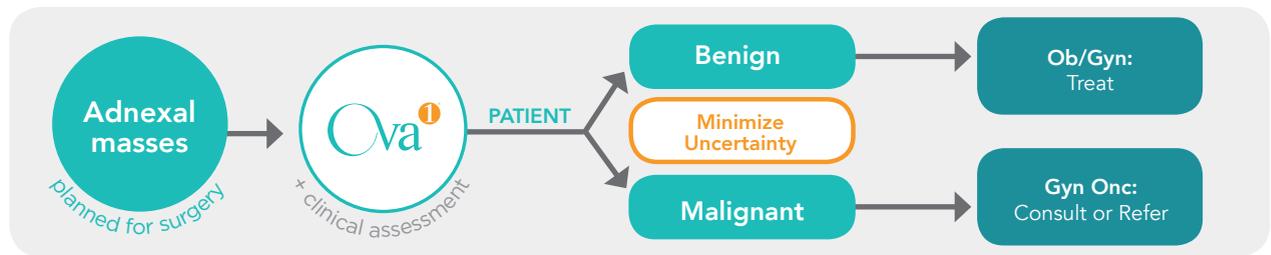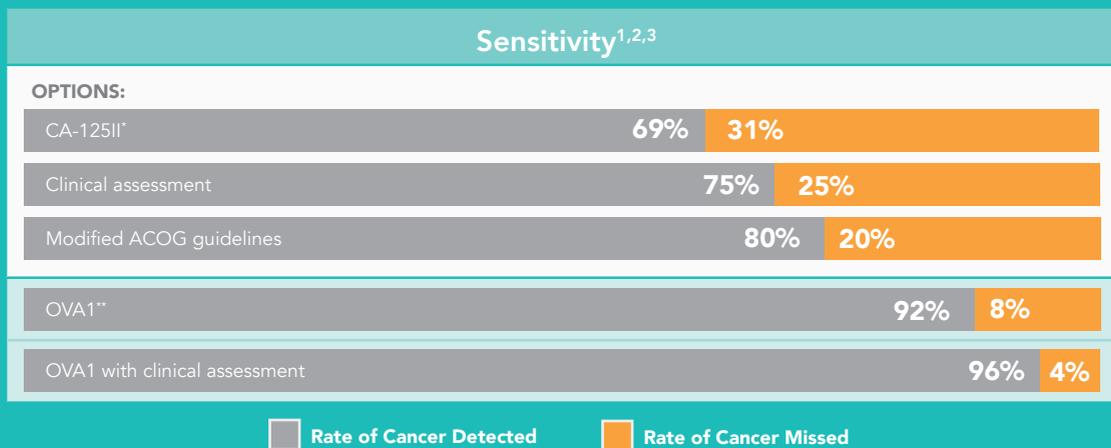
Optimized Pathway

Adnexal masses *planned for surgery* → Ova[1] *+ clinical assessment* → PATIENT

- Benign → **Ob/Gyn:** Treat
- Minimize Uncertainty
- Malignant → **Gyn Onc:** Consult or Refer

Increase Sensitivity for Malignancy in the Care Pathway You Direct

Sensitivity[1,2,3]

OPTIONS:

Option	Rate of Cancer Detected	Rate of Cancer Missed
CA-125II*	69%	31%
Clinical assessment	75%	25%
Modified ACOG guidelines	80%	20%
OVA1**	92%	8%
OVA1 with clinical assessment	96%	4%

◼ Rate of Cancer Detected   ◼ Rate of Cancer Missed

Sensitivity by Stage[1]

	Stage I	Stage II	Early Stage	Pre-menopausal Early Stage	Post-menopausal Early Stage
CA-125II*	64%	71%	66%	46%	75%
OVA1**	89%	100%	91%	91%	92%

Sensitivity Across Subtypes[4]

	EOC	Non-EOC	Borderline/LMP	Metastatic to ovary	Non-ovarian malignancy
OVA1†	99%	92%	86%	100%	90%

Non-Epithelial Ovarian Cancer: sex cord-stromal, germ cell, other

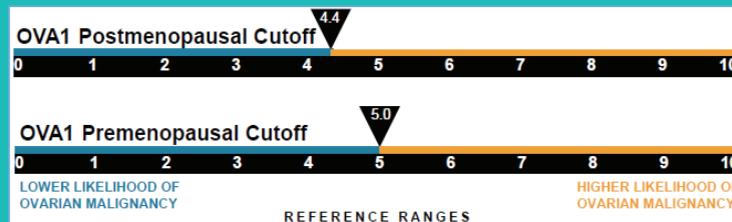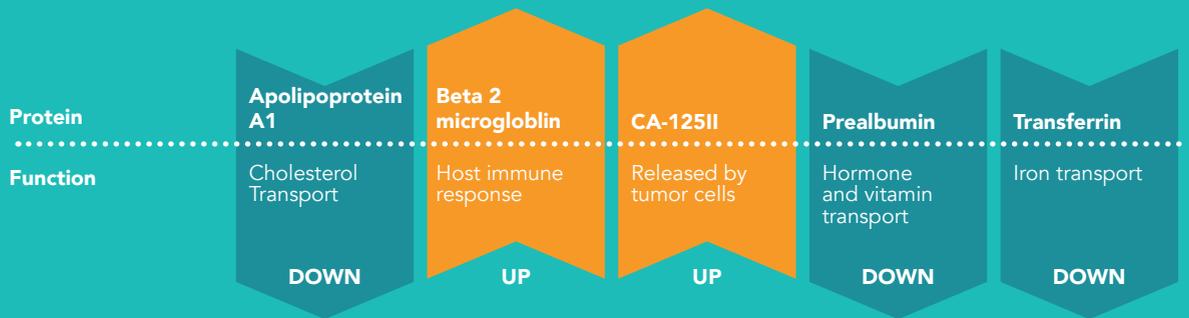## Confidence in Managing Patients with Negative Results

Negative Predictive Value[1]:

98%
Bristow et al., 2013
n = 494
Confidence Intervals: 95.2–99.2

Ova¹ by ASPiRA LABS®
YOUR HEALTH. OUR PASSION.

- An FDA-cleared blood test that assesses malignancy risk in adnexal masses planned for surgery

- The OvaCalc® algorithm generates a single risk score based on menopausal status, CA-125, and four host response biomarkers

- In the validation study by Bristow et al.,[1] OVA1® with clinical assessment demonstrated:
  - Q Sensitivity: 96%
  - Q Negative Predictive Value: 98%
  - Q Specificity: 51%
  - Q Positive Predictive Value: 31%

Protein	Apolipoprotein A1	Beta 2 microgloblin	CA-125II	Prealbumin	Transferrin
Function	Cholesterol Transport	Host immune response	Released by tumor cells	Hormone and vitamin transport	Iron transport
	DOWN	UP	UP	DOWN	DOWN

OVA1 Postmenopausal Cutoff ▼ 4.4
0 1 2 3 4 5 6 7 8 9 10

OVA1 Premenopausal Cutoff ▼ 5.0
0 1 2 3 4 5 6 7 8 9 10

LOWER LIKELIHOOD OF OVARIAN MALIGNANCY | HIGHER LIKELIHOOD OF OVARIAN MALIGNANCY
REFERENCE RANGES

Patient 1: 41 y/o P3013

Visit type: Pelvic pain

Finding: Right sided pelvic mass; U/S showed 5.5 x 8.4 X 9.1cm mass

"Moderate right ovarian enlargement. Cyst measuring 3.3 x 3.9 cm in size. There is a small amount of tissue along the posteromedial margin of this cyst over an area measuring 5mm in diameter."

Assessment results:
OVA1 score = 9.4 (elevated risk)

Management:
- Ob/Gyn referred patient to Gyn Onc
- Ovarian cancer identified and optimally staged and debulked

Outcome
Patient was optimally managed by a specialist, reducing risk of reoperation for initial staging and debulking

Patient 2: 34 y/o P0000

Visit type: Annual Exam

Finding: Right sided pelvic mass; U/S showed 11.49cm X 6.47cm mass

"Large complex right adnexal mass likely of ovarian origin. Irregular borders and echogenic wall. There is also questionable mural nodularity." - Malignancy indeterminate

Assessment results:
OVA1 score = 3.7 (low risk)

Management:
- Ob/Gyn performed laparoscopic surgery
- Benign mucinous cystadenoma identified

Outcome
Patient had minimally invasive surgery and did not have needless anxiety, inconvenience, and cost

*Actual cases

OVA1 has been FDA-cleared for use in women meeting the following criteria:

- Are over 18 years of age
- Have an ovarian adnexal mass
- Have surgery planned
- Have not yet been referred to a gynecologic oncologist
- Have not had cancer in the past five years
- Have a rheumatoid factor concentration <250 IU/mL

OVA1 is a qualitative serum test that combines the results of 5 immunoassays into a single numerical result. It is indicated for women who meet the following criteria: over age 18, ovarian adnexal mass present for which surgery is planned, and not yet referred to an oncologist. OVA1 is an aid to further assess the likelihood that malignancy is present when the physician's independent clinical and radiological evaluation does not indicate malignancy.

PRECAUTION: OVA1 should not be used without an independent clinical/radiological evaluation and is not intended to be a screening test or to determine whether a patient should proceed to surgery. Incorrect use of OVA1 carries the risk of unnecessary surgery, and/or delayed diagnosis.