

PCOCheckTM Immunoassay*

An Aid in the Detection of PCO Morphology



* For research use only within the U.S.

Introduction: Discordance in results between AMH and antral follicle counts (AFC) have been observed with several commercial AMH tests. The processing and post translational modification of AMH may differ between individuals with different clinical conditions. This may expose new antigenic sites which affect AMH measurements.

A new test from Ansh Labs, the PCOCheck AMH ELISA, uses a two-sided linear epitope antibody that is specifically designed to avoid antibody binding at mutation sites. Not only does this new assay help address the observed AMH and AFC discrepancies, but when combined with the powerful OVACheck reporting software, this assay provides a next generation tool for clinicians to assess ovarian reserve and polycystic ovarian morphology.

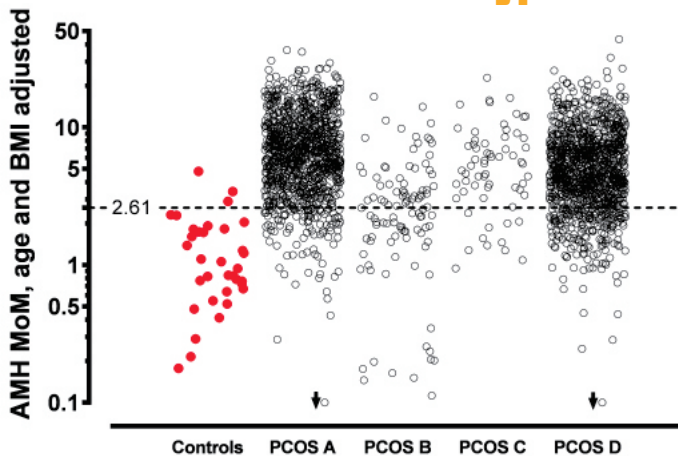
ADVANTAGES OF THIS TEST

- ✓ Uses a two-sided linear epitope antibody with binding epitope away from glycosylation sites.
- ✓ Specially designed to avoid antibody binding to AMH mutation sites.
- ✓ No interference to Biotin or Follistatin.
- ✓ Very precise and clinically accurate results. Highest correlation of any AMH kit to Antral Follicle Count ($R>0.89$).
- ✓ Excellent sample stability. Sample shipment and storage at ambient temperature for 72 hours.
- ✓ Easily automatable on Dynex® platforms or other open ELISA systems.

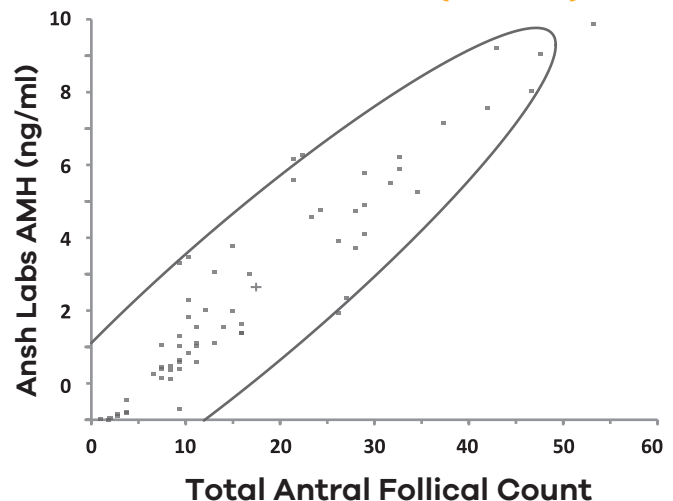
Clinical Case Study: Effect of mutation on Normal and PCOS subjects in their reproductive age, AFC >15

	Pro Mature AMH ELISA (ng/mL)	Mature-Mature AMH ELISA (ng/mL)	PCOCheck AMH ELISA (ng/mL)
Pro + Mature	✓	✓	✓
N-Fragment	✗	✗	✓
C-Fragment	✗	✓	✗
Subject A	0.01	0.056	5.73
Subject B	0.10	0.14	4.99
Subject C	0.11	0.07	6.95
Subject D	0.06	2.61	6.37
Subject E	0.07	3.41	11.11

PCOCheck: PCOS Phenotypes



Antral Follicle Count ($R>0.89$)



OvaCheck™ Software*

Powerful Application for Sample Reporting

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The screenshot displays the OvaCheck Software interface, which is a web-based application for sample reporting. The interface includes a header with the OvaCheck logo and navigation links (HOME, CONTACT US, LOGIN). The main content area shows a sample report for a patient named Jane, with fields for Last Name, First Name, Age, Height, Weight, and BMI. The report also displays the AMH (Anti-Müllerian Hormone) result and the OvaScore. A graph shows the AMH Reference Range and the patient's result. The OvaScore is calculated as 3.3, which corresponds to a PCOS risk score of 4.69. The interface also includes a section for 'Your Relative PCOS Risk Score' and a table for 'OvaScore and PCOS Risk'.

OvaCheck™ Test Results

Patient: Last Name: Jane, First Name: Abnorma, Age (years): 29, Patient ID: 21-Jun-1991, Height: 5ft 2 inch, Weight (kg): 72, BMI (kg/m²): 29.03

AMH Result: 10.00 ng/mL

AMH Reference Range:

Age (years)	Inter Quartile Range AMH (ng/mL)
<18	2.18 to 9.30
18-25	2.09 to 8.20
26-30	1.43 to 6.14
31-35	0.87 to 3.71
36-40	0.30 to 2.03
41-45	0.30 to 1.00

For Patients over 40 years of age, we highly recommend testing using the MenoCheck™ immunoassay. Refer to www.anshlabs.com for the instructions for use!

Your OvaScore is: 3.3

OvaScore Interpretation

OvaScore	OvaScore Interpretation
≥2.2	High OvaScore: A high OvaScore may suggest the presence of ovarian dysfunction such as Polycystic Ovary Syndrome. Refer to the risk calculations below for more information based on OvaScore values (see PCOS Risk and OvaScore). It may also indicate the potential risk for excessive response to ovarian stimulation. Consult your doctor for further evaluation.
≥1.7 to <2.2	Borderline high OvaScore: A borderline high OvaScore may suggest a greater than usual number of ovarian follicles (high ovarian reserve). It may also indicate the potential risk for increased response to ovarian stimulation. Consult your doctor for further evaluation.
≥0.6 to <1.7	Normal OvaScore: A normal OvaScore suggests an expected number of ovarian follicles (normal ovarian reserve) in women of comparable age and other relevant factors.
≥0.2 to <0.6	Borderline low OvaScore: A borderline low OvaScore may suggest fewer than usual number of ovarian follicles (low ovarian reserve). It may also indicate reduced fertility and the potential risk for decreased response to ovarian stimulation. Consult your doctor for further evaluation.
<0.2	Low OvaScore: A low OvaScore may be associated with diminished ovarian reserve. For women 45 years of age (and younger), this OvaScore may indicate an earlier menopausal transition or a potential risk for Primary Ovarian Insufficiency (POI). Consult your doctor for further evaluation.

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Your Relative PCOS Risk Score is: 4.69

Polycystic Ovary Syndrome
Polycystic Ovary Syndrome (PCOS) is one of the most common endocrine and metabolic disorders among women of reproductive age. The symptoms may include irregular menstrual cycles, unwanted hair growth on face and back, acne, weight gain, difficulty getting pregnant, and more.

OvaScore and PCOS Risk
The figure below shows the OvaScore on the bottom axis and its correspondence with the relative change in PCOS risk score on the top axis.

Relative change in PCOS Risk Score

Decreased Risk Increased Risk

OvaScore

Relative PCOS Risk Score	Interpretation
<0.05	Very Low PCOS Risk
≥0.05 to <0.38	Low PCOS Risk
≥0.38 to <0.84	Moderately Low PCOS Risk
≥0.84 to <1.40	Average Risk
≥1.40 to <3.30	Moderately High PCOS Risk
≥3.30 to <6.60	High PCOS Risk
≥6.6	Very High PCOS Risk

Examples:

- Decreased Risk: A reproductive age woman has an OvaScore of 1.5. On the graphic, this corresponds to a PCOS risk score of 0.25. This is a four-fold reduction in risk with respect to a woman with an OvaScore of 2.2 and an average relative PCOS risk score of 1.0.
- Increased Risk: A reproductive age woman has an OvaScore of 3.2. On the graphic, this corresponds to a PCOS risk score of 4.0. This is a four-fold increase in risk with respect to a woman with an OvaScore of 2.2 and an average relative PCOS risk score of 1.0.

A clinical diagnosis should NOT be made solely based on OvaCheck™ results. The diagnosis should be made by a qualified physician after reviewing all relevant clinical and laboratory findings.

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Features and Benefits:

- ✓ Web-based, no software to install
- ✓ Easily generate sample reports in pdf format for printing or attaching to patient records
- ✓ Import data from LIS exports and bulk generate pdf reports
- ✓ Importation function pre-screens data for proper formatting, helps prevent corrupt records
- ✓ Customizable header space for facility logo and contact details

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