PCOCheck™ ELISA

AL-196-i

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INTENDED USE

The PCOCheck ELISA is an enzyme-linked immunosorbent assay (ELISA) for the quantitative measurement of anti-Müllerian hormone (AMH) in human serum, Li-Heparin and K2 EDTA plasma. This assay is not impacted by AMH post translational modifications. It is intended to be used as an aid in the determination of ovarian reserve, and stratification of women with polycystic ovarian morphology (PCOM). This assay is intended for *in vitro* diagnostic use.

SUMMARY AND EXPLANATION

Anti-Müllerian hormone (AMH), a member of the TGFβ superfamily, is secreted as a 140-kDa homodimeric precursor, consisting of two identical 70-kDa monomers[1]. Each monomer consists of two parts: (i) a 25 kDa mature C-terminal region, which becomes bioactive after proteolytic cleavage and binds the AMH receptor II (AMHRII), inducing intracellular Smad-signalling[2], and (ii) a proregion, which is important in AMH synthesis and the extracellular transport. The AMH precursor is cleaved at amino acid (aa) 451 between the two domains. An additional cleavage site at aa 229 in the pro region is known, giving rise to three potential cleavage products[3]. Unlike other members of the TGF-β family, the proregion of the cleaved AMH is critical and enhances the activity of the mature C-terminal when the two cleaved peptides remain associated[2-5]. AMH undergoes proteolytic cleavage to become biologically active and additional proteolytic processing readily takes place[5]. This processing, which may differ between individuals, exposes new antigenic sites which may affect measurements as well as AMH epitopes being masked by protein interaction in the circulation[6]. Biological variability can be minimized by the measurement of AMH using liner epitope antibodies that are not impacted by post-translational modification (i.e. glycosylation or proteolytic processing).

AMH is secreted by the Sertoli cells in males. During embryonic development, AMH is responsible for Müllerian duct regression. AMH continues to be produced by the testes until puberty and then decreases slowly to residual post-puberty values. In females, AMH is produced by the granulosa cells of small growing follicles from the 36th week of gestation onwards until menopause when levels become undetectable. The serum concentration of Anti-Müllerian Hormone (AMH) has gained widespread clinical use as a surrogate marker for ovarian reserve[7-11]. Currently, AMH measurements are used in human fertility counseling[7], to predict age of menopause[8,9], to diagnose polycystic ovarian syndrome (PCOS)[10-12], and to predict response to ovarian stimulation (OS)[13,14]. Other clinical applications of Anti-Müllerian Hormone (AMH) have been published in ovarian aging[15], premature ovarian insufficiency[16] ovarian tumors[17,18] and many more. As AMH levels may have major implications for clinical decision-making during IVF procedures, egg donation, planning delayed childbearing and attaining optimal ovarian stimulation during treatment, PCOM diagnosis, AMH measurements should be reliable and consistent[19].

PRINCIPLE OF THE TEST

The PCOCheck AMH ELISA is a quantitative two-step sandwich type immunoassay that is designed to measure human AMH. In the first step Calibrators, Controls and unknown samples and biotinylated antibody solution are added to antibody coated microtiter wells and incubated. After the first incubation and washing, the wells are incubated with streptavidin horseradish peroxidase conjugate (SHRP) solution. After the second incubation and washing, the wells are incubated with substrate solution (TMB) followed by an acidic stopping solution. In principle, the AMH antibody-biotin conjugate binds to the solid phase antibody-antigen complex which in turn binds to the streptavidin-enzyme conjugate. The antibody-antigen-biotin conjugate-SHRP complex bound to the well is detected by enzyme-substrate reaction. The degree of enzymatic turnover of the substrate is determined by dual wavelength absorbance measurement at 450 nm as primary test filter and 630 nm as reference filter. The absorbance measured is directly proportional to the concentration of AMH in the samples and calibrators.

Representative product for illustrative purposes only. For exact specifications, please refer to package insert included with product.

MATERIALS SUPPLIED

CAL-196A **PCOCheck Calibrator A**

One bottle, 2 mL, labeled PCOCheck Calibrator A, containing 0ng/mL AMH in protein-based buffer and ProClin™ 300. Store unopened at 2 – 8°C until the expiration date.

CAL-196B-CAL-196F **PCOCheck Calibrator B thru F (Lyophilized)**

Five vials, labeled B-F, containing concentrations of approximately 0.1-24 ng/mL AMH in protein-based buffer and ProClin™ 300. Refer to **calibration card** for exact concentrations. Store unopened at 2 to 8°C until the expiration date. Reconstitute calibrators A-F with 1 mL deionized water. Solubilize, mix well, and use after reconstitution. Aliquot and freeze for multiple use and avoid over two freeze thaw cycles.

Assay Calibration: The recombinant AMH concentrations in calibrators are traceable to purified recombinant AMH preparation that is characterized by mass spectroscopy and optical density at 280 nm. Values assigned by other methodologies may be different. Such differences, if present, may be caused by inter-method bias.

CTR-196-I & CTR-196-II **PCOCheck Controls I & II (Lyophilized)**

Two vials labeled Levels I and II containing low and high AMH concentrations in protein-based buffer and ProClin™ 300. Refer to **calibration card** for exact concentrations. Store unopened at 2 to 8°C until the expiration date. Reconstitute control Levels I and II with 1 mL deionized water. Solubilize, mix well, and use after reconstitution. Aliquot and freeze for multiple use and avoid over two freeze thaws.

PLT-14F **AMH Antibody Coated Microtitration strips**

One strip holder containing 12 strips and 96 microtitration wells with AMH antibody immobilized to the inside wall of each well. Store at 2-8°C until expiration date in the resealable pouch with a desiccant to protect from moisture.

BCR-196 **PCOCheck Biotin Conjugate Ready-To-Use (RTU)**

One bottle, 12 mL, containing biotinylated anti-AMH antibody in protein-based buffer with a non-mercury preservative. Store at 2-8°C until expiration date.

SAR-196 **PCOCheck Streptavidin Enzyme Conjugate-Ready-to-Use (RTU)**

One amber bottle, 12 mL, containing streptavidin-HRP (horseradish peroxidase) in a protein-based buffer and a non-mercury preservative. Store undiluted at 2-8°C until expiration date.

TMB-100 **TMB Chromogen Solution**

One bottle, 12 mL, containing a solution of tetramethylbenzidine (TMB) in buffer with hydrogen peroxide. Store at 2-8°C until expiration date.

STP-100 **Stopping Solution**

One bottle, 12 mL, containing 0.2 M sulfuric acid. Store at 2 to 30°C until expiration date.

WSH-100 **Wash Concentrate A**

One bottle, 60 mL, containing buffered saline with a nonionic detergent. Store at 2-30°C until expiration date. Dilute 25-fold with deionized water prior to use.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Microplate reader capable of absorbance measurement at 450 nm, 405 nm and 630 nm.
2. Microplate orbital shaker.

3. Microplate washer.
4. 96 well dilution plate or culture tubes for dilutions.
5. Semi-automated/manual precision pipette to deliver 10–250 µL.
6. Repeater pipette.
7. Vortex mixer.
8. Deionized water.

WARNINGS AND PRECAUTIONS

For *in vitro* diagnostic use.

The following precautions should be observed:

a) Follow good laboratory practice.
b) Use personal protective equipment. Wear lab coats and disposable gloves when handling immunoassay materials.
c) Handle and dispose of all reagents and material in compliance with applicable regulations.
d) If external package is damaged, inspect the components inside for any other damage. Do not use if the components are damaged.

WARNING: Potential Biohazardous Material

This reagent may contain some human source material (e.g. serum) or materials used in conjunction with human source materials. Handle all reagents and patient samples at a Biosafety Level 2, as recommended for any potentially infectious human material in the Centers for Disease Control/National Institutes of Health manual "Biosafety in Microbiological and Biomedical Laboratories," 6th Edition, 2020.[20]

WARNING: Potential Chemical Hazard

Some reagents in this kit contain ProClin™ 300 and Sodium azide[21] as a preservative. ProClin™ 300 and Sodium Azide in concentrated amounts are irritants to skin and mucous membranes.

For further information regarding hazardous substances in the kit, please refer to the MSDS, either at AnshLabs.com or by request.

SAMPLE COLLECTION AND PREPARATION

a) Serum, Lithium heparin plasma and K_2EDTA plasma is the recommended sample type.
b) Sample handling, processing, and storage requirements depend on the brand of blood collection tube that you use. Please reference the manufacturer's instructions for guidance. Each laboratory should determine the acceptability of its own blood collection tubes and serum separation products.
c) Within two hours after centrifugation, transfer at least 500 µL of cell free sample to a storage tube, vortex and tightly stopper the tube immediately.
d) Samples may be stored at 4°C if assayed within 24 hours; otherwise samples must be stored at -20°C or -80 to avoid loss of bioactivity and contamination.
e) Avoid assaying lipemic, hemolyzed or icteric samples.
f) Avoid repeated freezing and thawing of samples. Thaw samples no more than 3 times.
g) For shipping, place specimens in leak proof containers in biohazard specimen bags with appropriate specimen identification and test requisition information in the outside pocket of the biohazard specimen bag. Follow DOT and IATA requirements when shipping specimens.[22]

PROCEDURAL NOTES

1. A thorough understanding of this package insert is necessary for successful use of the PCOCheck ELISA assay. It is the user's responsibility to validate the assay for their purpose. Accurate results will only be obtained by using precise laboratory techniques and following the package insert.
2. A calibration curve must be included with each assay.
3. Bring all kit reagents to room temperature before use. Thoroughly mix the reagents before use by gentle inversion. Do not mix various lots of any kit component and do not use any component beyond the expiration date.
4. Use a clean disposable pipette tip for each reagent, calibrator, control or sample. Avoid microbial contamination of reagents, contamination of the substrate solutions with the HRP conjugates. The enzyme used as the label is inactivated by oxygen, and is highly sensitive to microbial contamination, sodium azide, hypochlorous acid and aromatic chlorohydrocarbons often found in laboratory water supplies. Use deionized water.
5. Incomplete washing will adversely affect the outcome and assay precision. Care should be taken to add TMB into the wells to minimize potential assay drift due to variation in the TMB incubation time. Avoid exposure of the reagents to excessive heat or direct sunlight.

PREPARATION OF REAGENTS

1. **PCOCheck Calibrators B-F and PCOCheck Controls I & II**: Tap and reconstitute PCOCheck Calibrator B-F and PCOCheck Controls I & II each with 1 mL deionized water. Solubilize, mix well, and use after reconstitution.
2. **Wash Solution:** Dilute wash concentrate 25-fold with deionized water. The wash solution is stable for one month at room temperature when stored in a tightly sealed bottle.
3. **Microtitration Wells:** Select the number of coated wells required for the assay. The remaining unused wells should be placed in the resealable pouch with a desiccant. The pouch must be resealed to protect from moisture.

ASSAY PROCEDURE

Allow all specimens and reagents to reach room temperature and mix thoroughly by gentle inversion before use. Calibrators, controls, and unknowns should be assayed in duplicate.

Note: *Specimens producing absorbance readings above the measurable range can be diluted with Calibrator A prior to testing. The read out (pg/mL) for diluted specimens must be corrected for the dilution factor.*

1. Label the microtitration strips to be used.
2. Pipette **20 µL** of the Calibrators, Controls and Unknowns to the appropriate wells.
3. Add **100 µL** of PCOCheck Biotin Conjugate Ready-To-Use (RTU) to each well using repeater pipette.
4. Incubate the plate, shaking at a fast speed **(600-800 rpm)** on an orbital microplate shaker, for **60 minutes** at room temperature (23±2°C).
5. Aspirate and wash each strip **5 times** with Wash Solution using an automatic microplate washer.
6. Add **100 µL** of PCOCheck Streptavidin Enzyme Conjugate Ready-To-Use (RTU) to each well using a repeater pipette.
7. Incubate the plate, shaking at a fast speed **(600-800 rpm)** on an orbital microplate shaker, for **15 minutes** at room temperature (23±2°C).
8. Aspirate and wash each strip **5 times** with Wash Solution using an automatic microplate washer.
9. Add **100 µL** of the TMB chromogen solution to each well using a repeater pipette to each well. Avoid exposure to direct sunlight.
10. Incubate the wells, shaking at 600-800 rpm on an orbital microplate shaker, for **5-12 min** at room temperature (23±2°C). NOTE: *Visually monitor the color development to optimize the incubation time.*
11. Add 100 µL of the Stopping solution to each well using a precision pipette. Read the absorbance of the solution in the wells within 20 minutes, using a microplate reader set to 450 nm.
    NOTE: *Zero calibration should be programmed as "Blank" while reading the optical density. If instrument has a wavelength correction, set the instrument to dual wavelength measurement at 450nm with background wavelength correction at 630nm.*

RESULTS

1. Calculate the mean optical density (OD) for each calibrator, control, or unknown specimen.
2. Plot the log of the mean OD readings for each of the Calibrators along the y-axis versus log of the AMH concentrations in ng/mL along the x-axis.
3. Determine the PCOCheck AMH concentrations of the Controls and Unknown specimens from the calibration curve by matching their mean OD readings with the corresponding AMH concentrations.

LIMITATIONS

1. PCOCheck results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings when being interpreted for diagnostic purposes.
2. If there is evidence of microbial contamination or excessive turbidity in a reagent, discard the vial.
3. As for any assay employing antibodies, the possibility exists for interference

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by heterophile antibodies in the samples.[23] Interference from heterophile antibodies has not been evaluated for this assay.

QUALITY CONTROL

- Each laboratory should establish mean values and acceptable ranges to ensure proper performance.
- Kit controls or other commercial controls should fall within established confidence limits.
- The confidence limits for kit controls are printed on the **Calibration card**.
- A full calibration curve, low- and high-level controls, should be included in each assay.
- TMB should be colorless. Development of any color may indicate reagent contamination or instability.

REPRESENTATIVE CALIBRATION CURVE DATA

Well Number	Well Contents Calibrators	Mean Absorbance	Conc (ng/mL)	Conc (pMol/L)
A1, A2	A	0.016 (Blank)	0	0
B1, B2	B	0.021	0.135	0.96
C1, C2	C	0.093	0.62	4.4
D1, D2	D	0.39	2.8	20.0
E1, E2	E	1.20	9.2	65.7
F1, F2	F	2.77	24	171.4

CAUTION: *The above data must not be employed in lieu of data obtained by the user in the laboratory*

PERFORMANCE CHARACTERISTICS

The performance characteristic results are reported in ng/mL and can be converted to pMol/L using the conversion factor below:

1 ng/mL = 7.14 pMol/L

Analytical Sensitivity: The analytical sensitivity in the assay as calculated by the interpolation of mean plus two standard deviation of 16 replicates of calibrator A (0 ng/mL) and calibrator B (0.14 ng/mL) is 0.029 ng/mL.

Imprecision:

Reproducibility of the PCOCheck assay was determined in a study using two serum pools and two kit controls. The study included a total of 40 assay runs, samples run in replicates of two (n=80). Representative data were calculated using simple precision and are presented in the following table.

SUMMARY:		Within run		Between run		Total	
Sample	Mean	SD	CV	SD	CV	SD	CV
Control I	6.0	0.1	2.3%	0.0	0.8%	0.1	2.5%
Control II	10.8	0.3	2.3%	0.1	1.2%	0.3	2.6%
Serum Pool-1	1.5	0.0	2.5%	0.0	2.0%	0.0	3.2%
Serum Pool-2	3.3	0.1	2.0%	0.0	1.3%	0.1	2.4%

Linearity:

Multiple dilutions of the two serum samples and recombinant AMH antigen were prepared in Calibrator A matrix and assayed. The % recovery on individual samples are represented in the following table.

Sample ID	Dilution Factor	Expected Conc. (ng/mL)	Observed Conc. (ng/mL)	%Recovery
1	Neat	30.000	Neat	NA
	2	15.000	14.764	98%
	4	7.500	7.184	96%
	8	3.750	3.618	96%
	16	1.875	1.798	96%
2	Neat	19.343	Neat	NA
	2	9.672	9.982	103%
	4	4.836	4.926	102%
	8	2.418	2.511	104%
	16	1.209	1.226	101%
3	Neat	10.584	Neat	NA
	2	5.292	5.504	104%
	4	2.646	2.668	101%
	8	1.323	1.383	105%
	16	0.662	0.666	101%

Recovery:

Known amounts of AMH were added to three serum samples containing different levels of endogenous AMH. The concentration of AMH was determined before and after the addition of exogenous AMH and the percent recovery was calculated.

Sample ID	Endogenous Conc. (ng/mL)	Expected Conc. (ng/mL)	Observed Conc. (ng/mL)	%Recovery
1	0.6400	1.090	1.130	104%
		1.540	1.574	102%
		1.990	1.960	98%
2	0.8030	1.245	1.196	96%
		1.687	1.658	98%
		2.129	2.195	103%

Analytical Specificity:

This monoclonal antibody used in the assay detects human AMH and does not detect rat, mouse, canine, bovine, equine, ovine and porcine.

Cross-Reactant	Concentration	% Cross-reactivity
Human Mature AMH	50 ng/mL	ND
Pro-Mature AMH	30 ng/ml	100%
Activin A	50 ng/mL	ND
Activin B	50 ng/mL	ND
Activin AB	50 ng/mL	ND
Myostatin	50 ng/mL	ND
Follistatin 288	50 ng/mL	ND
FSTL-3	50 ng/mL	ND
Inhibin A	100 ng/mL	ND
Inhibin B	15 ng/mL	ND
FSH	50 ng/mL	ND
LH	500 mIU/mL	ND

Interference:

When potential interferents (Hemoglobin, biotin, intralipids, and bilirubin) were added at least at two times their physiological concentration to control sample, AMH concentration were within ± 10% of the control as represented in the following table.

Interferent	Interferent Dose	Sample AMH (ng/mL)	Dosed Sample AMH (ng/mL)	AMH Difference (ng/mL)	% Difference to Reference
Hemoglobin	1 mg/mL	2.30	2.20	-0.10	-1.6
	0.5 mg/mL	2.40	2.30	-0.10	-2.7
	0.1 mg/mL	2.40	2.40	0.00	3.6
Hemoglobin	1 mg/mL	7.00	7.20	0.20	3.9
	0.5 mg/mL	7.80	7.70	-0.10	-0.6
	0.1 mg/mL	8.00	8.10	0.10	0.7
Biotin	1200 ng/mL	2.10	2.20	0.10	0.7
	600 ng/mL	2.30	2.40	0.10	4.9
	200 ng/mL	2.50	2.50	0.00	-1.7
Biotin	1200 ng/mL	7.30	7.20	-0.10	-0.2
	600 ng/mL	7.60	7.50	-0.10	-1.0
	200 ng/mL	7.60	8.10	0.50	6.8
Intralipids	20 mg/mL	2.30	2.50	0.20	8.2
	5 mg/mL	2.50	2.60	0.10	4.1
Intralipids	20 mg/mL	7.00	7.60	0.60	8.9

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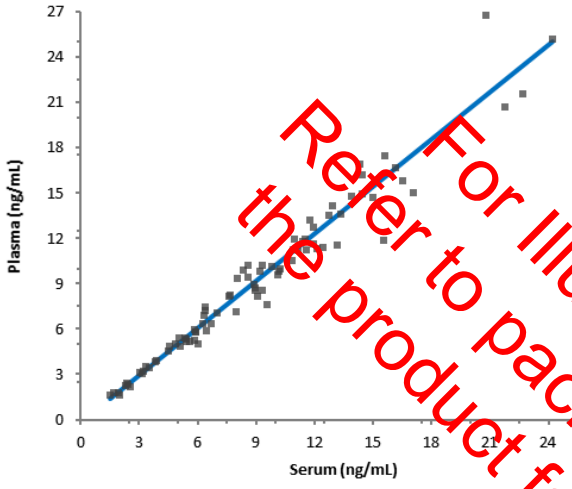
	10 mg/mL	7.90	8.30	0.40	4.6
	5 mg/mL	8.10	8.20	0.10	0.9
Bilirubin	0.66 mg/mL	1.40	1.40	0.00	-1.6
	0.2 mg/mL	2.30	2.20	-0.10	-1.3
Bilirubin	0.66 mg/mL	4.70	4.70	0.00	0.9
	0.2 mg/mL	7.10	7.20	0.10	1.4

Sample Type:

Eighty-Six matched Serum and EDTA plasma specimens were compared in PCOCheck ELISA assay.

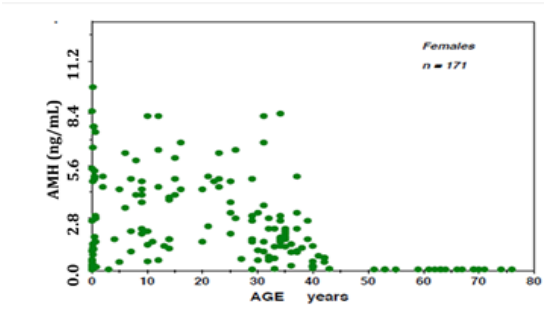
Passing-Bablok Analysis of the results yielded the following Regression:

EDTA Plasma=1.04 (Serum) – 0.163 (r=0.98).



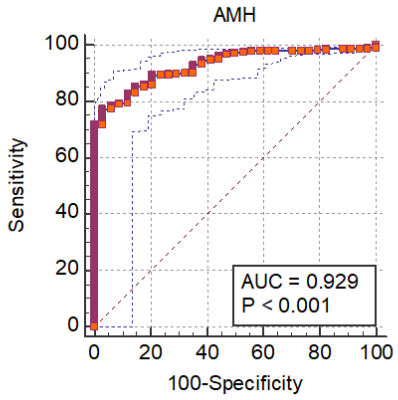
Expected Value:

The expected ranges for AMH were calculated in serum samples using well characterized 171 females in the ages of 0.1-80 years are plotted below.



Gender	Age	n	5th-95th Percentile AMH (ng/mL)
Females	0 – 1 yr	37	0.1 – 8.5
	2 yrs – 6 yrs	8	0.04 – 6.3
	7 yrs – 15 yrs	30	0.5 – 8.3
	16 yrs – 31 yrs	33	0.3 – 6.6
	32 yrs – 43 yrs	45	0.15 – 4.5
	51 yrs – 80 yrs	18	<0.03

Method Comparison: ROC analysis was performed using well characterized controls (n=34) and 2445 PCOS subjects with phenotypes A, B, C, D. AUC for PCOS Was 0.93, with a p value of <0.001 as shown below.



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This assay is intended for *in-vitro diagnostic* use only. **Not for sale in U.S.A.**

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FOR EXPORT ONLY

Symbols used with Ansh Labs Assays

Symbol	English	Deutsch	Français	Español	Italiano
	European Conformity	CE-Konfirmitäts-kennzeichnung	Conformité aux normes européennes	Conformidad europea	Conformità europea
	Caution	Vorsicht	mise en garde	precaución	attenzione
	Consult instructions for use	Gebrauchsanweisung beachten	Consulter les instructions d'utilisation	Consulte las instrucciones de uso	Consultare le istruzioni per l'uso
	In vitro diagnostic device	In-vitro-Diagnostikum	Usage Diagnostic in vitro	Para uso Diagnóstico in vitro	Per uso Diagnostica in vitro
	Catalogue number	Katalog-Nr.	Numéro de catalogue	Número de catálogo	Numero di Catalogo
	Lot No. / Batch code	Chargen-Nr.	Numéro de lot	Número de lote	Numero di lotto
	Storage Temperature	Lagerungstemperatur	Température de conservation	Temperatura de conservación	Temperatura di conservazione
	Expiration Date	Mindesthaltbarkeits-datum	Date limite d'utilisation	Fecha de caducidad	Data di scadenza
	Date of Manufacture	Herstellungsdatum	date de fabrication	fecha de manufactura	Data di produzione
	Legal Manufacturer	Hersteller	Fabricant	Fabricante	Fabbricante
Content	Content	Inhalt	Conditionnement	Contenido	Contenuto
Volume/No.	Volume / No.	Volumen/Anzahl	Volume/Quantité	Volumen/Número	Volume/Quantità
	96-well plate	Platte mit 96 Vertiefungen	Plaque à 96 puits	placa de 96 pocillos	piastra a 96 pozzetti

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