AnshLabs

PAPP-A2 ELISA

AL-109

RUO

INTENDED USE

The PAPP-A2 enzyme linked immunosorbent assay (ELISA) kit provides materials for the quantitative measurement of PAPP-A2 in human serum and other biological fluids.

SUMMARY AND EXPLANATION

Pregnancy associated plasma protein-A2 (PAPP-A2) is a metalloproteinase protein identified as a homolog of PAPP-A in the metzincin superfamily of pappalysins.[1-8] PAPP-A2 is a noncovalently linked dimer of two 220-kDa subunits[4]. PAPP-A2 cleaves insulin-like growth factor-binding protein 5 (IGFBP5) and Insulin like growth factor binding protein 3[4]. PAPP-A2 is function as a local regulator of insulin-like growth factor (IGF) bioavailability[1-8]. PAPP-A2 is expressed in a wide range of tissues and abundantly present in the placental syncytiotrophoblast and the pregnant uterus[3]. The insulin-like growth factors are important in human embryo implantation and placentation[1-8]. Numerous studies have identified the associations between the placental levels of PAPP-A2 and preeclampsia[1-8]. It is being suggested that either altered levels PAPP-A2 cause abnormal placental development, or the production of these proteins is altered to compensate for abnormal placentation[1-8].

PRINCIPLE OF THE TEST

The PAPP-A2 ELISA is a quantitative three-step sandwich type immunoassay. In the first step Calibrators, Controls and unknown samples are added to anti-PAPP-A2 antibody coated micro titer wells and incubated. After first incubation and washing step, the wells are incubated with biotin labelled antibody conjugate. After a second incubation and washing step, the wells are incubated with streptavidin horseradish peroxidase conjugate (SHRP) solution. After the third incubation and washing step, the wells are incubated with substrate solution (TMB). After TMB incubation, an acidic stopping solution is added. In principle, the 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 PAPP-A2 in the samples and calibrators.

MATERIALS SUPPLIED

CAL-109A PAPP-A2 Calibrator A/Sample Diluent

One bottle, 10 mL, labeled PAPP-A2 Cal A/Sample Diluent, containing 0 ng/mL PAPP-A2 in a protein-based buffer with a non-mercury preservative. Store unopened at 2-8°C until the expiration date.

CAL-109B -CAL-109F PAPP-A2 Calibrators B thru F (Lyophilized)

Five vials, labeled B-F containing concentrations of approximately 0.09 – 9.4 ng/mL PAPP-A2 in protein-based buffer with non-mercury preservative. Refer to **calibration card** for exact concentrations. Store unopened at 2 to 8°C until the expiration date. Reconstitute calibrators B-F with **1.0 mL** deionized water. Solubilize for **10 minutes**, mix well and use after reconstitution. Discard after 5 days, if stored at 2 to 8°C. For longer storage after reconstitution, aliquot and freeze at -20°C or colder for up to one year.

CTR-109-I and CTR-109-II PAPP-A2 Controls I & II (Lyophilized)

Two vials, labeled Levels I and II containing low and high PAPP-A2 in protein based buffer with non-mercury preservative. Refer to **calibration card** for exact control ranges. Store unopened at 2 to 8°C until the expiration date. Reconstitute control Levels I and II with **1.0 mL** deionized water. Solubilize for **10 minutes**, mix well and use after reconstitution. Discard after 5 days, if stored at 2 to 8°C. For longer storage after reconstitution, aliquot and freeze at -20°C or colder for up to one year.

PLT-109 Anti-PAPP-A2 Antibody Coated Microtitration Strips

One strip holder, containing 96 microtitration wells with PAPP-A2 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.

ASB-109 PAPP-A2 Assay Buffer

One bottle, 8 mL, containing a protein-based (BSA)-buffer with a non-mercury preservative. Store at 2-8°C until expiration date.

CND-109 PAPP-A2 Biotin Conjugate Diluent

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

BCC-109 PAPP-A2 Biotin Conjugate Concentrate

One vial, 0.4 mL containing a solution of anti-PAPP-A2 antibody biotin concentrate in a protein-based buffer with a non-mercury preservative. Dilute prior to use in PAPP-A2 Conjugate diluent. Store at 2-8°C until expiration date.
NOTE: *The dilution of this reagent should be made 15-30 minutes prior to use in the assay.*

SAR-109 PAPP-A2 Streptavidin-Enzyme Conjugate—Ready-to-Use (RTU)

One 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 SUPPLIED

1. Microtitration plate reader capable of absorbance measurement at 450 nm, 405 nm and 630 nm.
2. Microtitration orbital plate shaker.
3. Microtitration plate washer.
4. Semi-automated/manual precision pipette to deliver 10–250 µL.
5. Vortex mixer.
6. Deionized water.
7. Disposable 12 x 75 mm culture tubes.
8. Tight fitting 12 x 75 mm tube racks.

9. PECheck™ PAPP-A2 ELISA, Catalog Number AL-1015 is designed to measure neat pregnancy serum samples.

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.

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," 5th Edition, 2007[9].

WARNING: Potential Chemical Hazard

Some reagents in this kit contain Pro-Clean 400 and Sodium azide[10] as a preservative. Pro-Clean 400 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 is the recommended sample type.

b) Use the following recommendations for handling, processing, and storing blood samples.[11]

- Allow samples to clot for two hours at room temperature or overnight at 4°C and follow blood collection tube manufacturer's recommendations for centrifugation. Keep tubes stoppered always. Within two hours after centrifugation, transfer at least 500 µL of cell free sample to a storage tube. Tightly stopper the tube immediately.
- Samples if used within 24 hours may be stored at 4°C, otherwise, samples must be stored at -20°C or -80°C to avoid loss of bioactivity and contamination.
- Remove residual fibrin and cellular matter prior to analysis.

c) Avoid assaying lipemic, hemolyzed or icteric samples.

d) Each laboratory should determine the acceptability of its own blood collection tubes and serum separation products.

e) Avoid repeated freezing and thawing of samples. Thaw samples no more than 3 times.

PROCEDURAL NOTES

1. A thorough understanding of this package insert is necessary for successful use of the PAPP-A2 ELISA assay. It is the responsibility of the customer to validate the assay for their use. 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 different 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 enzyme 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. **PAPP-A2 Calibrators B-F and Controls I & II**: Tap and reconstitute PAPP-A2 Calibrators B-F and Controls I & II each with 1 mL deionized water. Solubilize for 10 minutes, 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. **PAPP-A2 Antibody-Biotin Conjugate Solution:** The PAPP-A2 Antibody-Biotin Conjugate Concentrate should be diluted at a ratio of 1-part conjugate to 50 parts of PAPP-A2 Conjugate Diluent, according to the number of wells used. If an entire plate is to be used pipet exactly 220 µL of the Concentrate in to 11 mL of the PAPP-A2 Conjugate Diluent.
4. **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.

SAMPLE PREPARATION

Note: All pregnancy serum should be diluted in Sample dilution buffer. Normal males and non-pregnant females should be run undiluted.

Prepare Sample Dilution buffer as per the procedure detailed in the Preparation of Reagents section. Dilution of pregnancy serum specimens should be performed on the same day of testing.

For First Trimester serum samples:

1. Serum specimens should be diluted 1:20 folds in Sample dilution buffer.
2. For each unknown serum sample, label one 12 X 75 culture tubes.
3. Add 190 µL of the Sample dilution buffer to each tube.
4. Add 10 µL of the serum specimens to the pre-labeled tube and vortex well.
5. The sample is now ready for analysis.

For Second trimester and till-term samples (14 wks. or higher):

1. Serum specimens should be diluted 1:80 folds in sample dilution buffer.
2. For each unknown serum sample, label one 12 X 75 culture tubes.
3. Add 790 µL of the sample dilution buffer to each tube.
4. Add 10 µL of the serum specimens to the pre-labeled tube and vortex well.
5. The sample is now ready for analysis.

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: All samples reading higher than the highest calibrator should be re-assayed by diluting two-four folds in Calibrator A/sample diluent prior to assay.

Do not dilute Calibrators or Controls.

1. Mark the microtitration strips to be used.
2. Pipette **50 µL** of the **Calibrator, Controls and Unknowns (neat for non-pregnancy and diluted for pregnancy serum specimens)** to the appropriate wells.

3. Add **50 µL** of the **PAPP-A2 Assay Buffer** to each well using a repeater pipette.
4. Incubate the wells, shaking at a fast speed **(600-800 rpm)** on an orbital microplate shaker, for **1 hour** at room temperature (23 ± 2°C).
5. With 30-40 minutes remaining of incubation time, prepare the PAPP-A2 Antibody-Biotin Conjugate Solution by diluting the PAPP-A2 Biotin Conjugate Concentrate in PAPP-A2 Conjugate Diluent as described under the Preparation of the Reagents section of this insert.
6. Aspirate and wash each well **5 times** with Wash Solution **(350 µL /per well)** using an automatic microplate washer.
7. Add **100 µL** of the **Antibody-Biotin Conjugate solution** to each well using a repeater pipette.
8. Incubate the wells, shaking at a fast speed **(600-800 rpm)** on an orbital microplate shaker, for **1 hour** at room temperature (23 ± 2°C).
9. Aspirate and wash each well 5 times with the Wash Solution **(350 µL/per well)** using an automatic microplate washer.
10. Add **100 µL** of the **Streptavidin-Enzyme Conjugate-RTU** to each well using a repeater pipette.
11. Incubate the wells, shaking at a fast speed **(600-800 rpm)** on an orbital microplate shaker, for **30 minutes** at room temperature (23 ± 2°C).
12. Aspirate and wash each well **5 times** with the Wash Solution **(350 µL /per well)** using an automatic microplate washer.
13. Add **100 µL** of the **TMB chromogen solution** to each well using a repeater pipette. Avoid exposure to direct sunlight.
14. Incubate the wells, shaking at **600–800 rpm** on an orbital microplate shaker, for **10-12 min** at room temperature (23 ± 2°C).
    NOTE: *Visually monitor the color development to optimize the incubation time.*
15. Add **100 µL** of the **Stopping solution** to each well using a repeater pipette. Read the absorbance of the solution in the wells within 20 minutes, using a microplate reader set to **450 nm**.
    NOTE*: Zero calibrator should be programmed as "**Blank**" while reading the optical density. If instrument has a wavelength correction, set the instrument to dual wavelength measurement at **450 nm** with background wavelength correction at **630 nm**.*
    Note: Observed sample concentration should be corrected for its dilution factor if applicable.

RESULTS

NOTE: *The results in this package insert were calculated by plotting the **log optical density (OD) data on the y-axis and log PAPP-A2 concentration on X-axis** using a cubic regression curve-fit. Alternatively, log vs. log quadratic regression curve-fit can be used. Other data reduction methods may give slightly different results.*

1. Optimum results can be obtained at incubation temperature of **23 ± 2°C**.
2. Calculate the mean absorbance for each calibrator, Control, or Unknown. Plot the log of the mean absorbance readings for each of the Calibrators along the y-axis versus log of the PAPP-A2 concentrations in ng/mL along the x-axis, using a cubic regression curve-fit.
3. Determine the PAPP-A2 concentrations of the Controls and unknowns from the calibration curve by matching their mean absorbance readings with the corresponding PAPP-A2 concentrations.
4. Multiply the results with the dilution factor.
5. Any sample reading higher than the highest Calibrator should be appropriately diluted further with the Calibrator A/sample diluent and re-assayed. Multiply the concentration by a dilution factor.
6. Any sample reading lower than the analytical sensitivity should be reported as such.

LIMITATIONS

The reagents supplied in this kit are optimized to measure PAPP-A2 levels in human serum. If there is evidence of microbial contamination or excessive turbidity in a reagent, discard the vial. For assays employing antibodies, the possibility exists for interference by heterophile antibodies in the samples[12].

QUALITY CONTROL

a) Each laboratory should establish mean values and acceptable ranges to assure proper performance.
b) PAPP-A2 ELISA controls or other commercial controls should fall within established confidence limits.
c) The confidence limits for PAPP-A2 ELISA controls are printed on the control vial labels.
d) A full calibration curve, low and high-level controls, should be included in each assay.
e) The TMB chromogen solution should be colorless. Development of a blue color may indicate reagent contamination or instability.

REPRESENTATIVE CALIBRATION CURVE DATA

Well Number	Well Contents Calibrators	Mean Absorbance	Conc.(ng/mL)
A1, A2	A	0.039 (**Blank**)	0
B1, B2	B	0.029	0.09
C1, C2	C	0.088	0.27
D1, D2	D	0.35	1.15
E1, E2	E	1.18	3.9
F1, F2	F	2.62	9.4

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

ANALYTICAL CHARACTERISTICS

All analytical characteristics are stated ng/mL.

Limit of Detection (LoD):

The lowest amount of PAPP-A2 in a sample that can be detected with a 95% probability (n=24) is 0.071 ng/mL. The value was determined by processing a complete six-point calibration curve, controls and six serum samples in the range of 0.091 to 3.085 ng/mL following CLSI EP17 guidelines. Three assay runs per day were performed over four days with all samples run in duplicate per run.

Limit of Quantitation (LoQ):

The estimated minimum PAPP-A2 dose achieved at 20% total imprecision is 0.08 ng/mL. The value was determined by processing a complete six-point calibration curve, controls and eight samples in the range of 0.091-3.08 ng/mL over twelve runs and four days in duplicates (n=24) following CLSI EP17 guidelines.

Imprecision:

Reproducibility of the PAPP-A2 ELISA assay was determined in a study using four serum pools. The study included a total of 12 assays, four replicates of each per assay (n=48). Representative data were calculated based on NCCLS EP5-A guidelines and are presented in the following table.

Sample	Mean conc.	Within run		Between run		Total	
	(ng/mL)	SD	%CV	SD	%CV	SD	%CV
Pool-1	1.029	0.044	4.25%	0.020	1.94%	0.048	4.67%
Pool-2	1.813	0.059	3.28%	0.046	2.53%	0.075	4.14%
Pool-3	2.651	0.111	4.18%	0.050	1.89%	0.122	4.59%
Pool-4	3.128	0.115	3.68%	0.076	2.42%	0.138	4.41%

Linearity:

Based on NCCLS EP-6-P multiple dilutions of the four serum samples containing various PAPP-A2 levels were diluted with Calibrator A/sample

diluent. The % recovery on individual samples is represented in the following table.

Sample	Dilution Factor	Expected Conc. (ng/mL)	Observed Conc. (ng/mL)	% Recovery
1	1:10	8.134	N/A	N/A
	1:20	4.067	4.239	104
	1:40	2.034	2.126	105
	1:80	1.017	1.070	105
2	1:10	7.541	N/A	N/A
	1:20	3.771	3.808	101
	1:40	1.885	1.996	106
	1:80	0.943	1.025	109
3	1:10	6.636	N/A	N/A
	1:20	3.318	3.599	108
	1:40	1.659	1.751	106
	1:80	0.830	0.882	106
4	1:10	5.245	N/A	N/A
	1:20	2.623	2.693	103
	1:40	1.311	1.372	105
	1:80	0.656	0.824	126

Recovery:

Known amounts of PAPP-A2 were added to four serum samples containing different levels of endogenous PAPP-A2. The concentration of PAPP-A2 was determined before and after the addition of exogenous PAPP-A2 and the percent recovery was calculated.

Sample	Endogenous Conc.(ng/mL)	Expected Conc. (ng/mL)	Observed Conc. (ng/mL)	% Recovery
1	0.297	0.788	0.675	86
		1.179	0.978	83
2	0.302	0.793	0.699	88
		1.184	1.058	89
3	0.329	0.819	0.698	85
		1.208	1.009	84
4	0.53	1.009	0.934	93
		1.39	1.167	84

Analytical Specificity:

The antibody pair used in the PAPP-A2 ELISA measures PAPP-A2 and does not detect other similar molecules. The assay does not detect dimeric PAPP-A, STC-2, PAPP-A proMBP, PAPP-A-STC-2 complex and MMP-9.

Interference:

When potential interferents (hemoglobin, triglycerides, biotin, and bilirubin) were added at least at two times their physiological concentration to control sample, PAPP-A2 concentration were within ± 15% of the control as represented in the following table. This study was based on NCCLS EP7-P to serum matrix added.

Interferents	Analyte Conc.	Non-spiked Sample Value (ng/mL)	Spiked Sample Value (ng/mL)	% Difference
Hemoglobin	1.35 mg/mL	0.221	0.229	3.62
		0.271	0.292	7.75
Triglycerides	11 mg/mL	0.221	0.213	-3.62
		0.358	0.343	-4.19
Biotin	1200 ng/mL	0.313	0.291	-7.2
		0.128	0.133	4.3
Bilirubin	0.6 mg/mL	0.214	0.225	5.14
		0.271	0.286	5.53

Expected Value:

These samples were analyzed using PAPP-A2 ELISA kit on site. The expected ranges for PAPP-A2 were calculated using 90-95% non-parametric estimation using Analyse-It® for Microsoft Excel.

Sample	Median Conc. (ng/ml)	2.5–97.5th Percentile Conc. (ng/ml)
Random First Trimester Pregnancy (N=50)	30.76	1.3-97.1
Random Second Trimester Pregnancy (N=65)	42.14	16.19-119.7
Random Third Trimester Pregnancy (N=36)	73.85	51.2-117.8

Note: *The values above are for reference only. It is recommended that each research organization should determine the reference values for their own study population.*

The expected ranges for PAPP-A2 in pediatric male samples in the age range of 3.0 – 18.0 years were calculated using 95% non-parametric estimation. A total of 389 samples in Pubic Hair Tanner stages 1 - 5 were evaluated using Analyse-It® for Microsoft Excel as seen in table 2 below.

Pubic Hair Tanner Stage	No of specimens (n)	Median Conc. (ng/mL)	PAPP-A2 (ng/mL) 95% CI
1	217	0.26	0.1 - 0.69
2	49	0.22	0.11 - 0.37
3	31	0.23	0.1 - 0.58
4	48	0.19	0.08 - 0.35
5	44	0.14	0.06 - 0.49

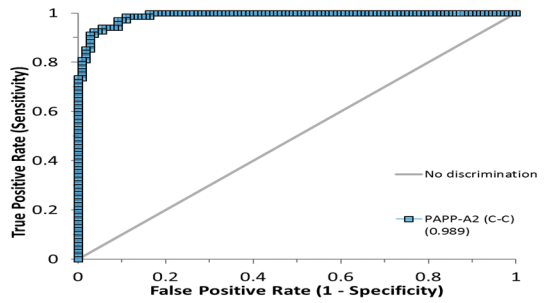
The expected ranges for PAPP-A2 in pediatric female samples in the age range of 2.4 – 18.0 years were calculated using 95% non-parametric estimation. A total of 423 samples in Breast Tanner stages 0 - 5 were evaluated using Analyse-It® for Microsoft Excel as seen in table 3 below.

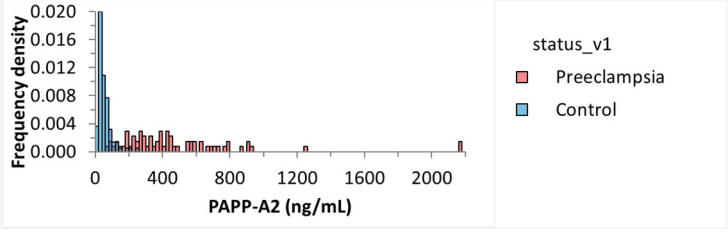
Breast Tanner Stage	No of specimens (n)	Median Conc. (ng/mL)	PAPP-A2 (ng/mL) 95% CI
0	14	0.32	0.1 - 0.71
1	174	0.28	0.12 - 0.81
2	60	0.25	0.11 - 0.83
3	57	0.14	0.09 - 0.42
4	49	0.17	0.07 - 0.31

NOTE: It is recommended that each laboratory should determine the reference range(s) for its own patient population. The results of this assay should be used in conjunction with other relevant and applicable clinical information.

Method Comparison:

A total of 178 pregnancy (18-34 wks.) serum samples from 110 controls and 68 preeclampsia subjects were analyzed. The ROC analysis showed an area under the curve of 0.99 and the frequency distributions of the two groups with respect to PAPP-A2 concentrations are shown in the figure below.





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