BECKMAN COULTER

ACCESS
Immunoassay Systems

Instructions For Use

Access PAPP-A (RUO)
Pregnancy-associated plasma protein A

REF A49209

FOR PROFESSIONAL USE ONLY

FOR RESEARCH USE ONLY

ANNUAL REVIEW

Reviewed by	Date	Reviewed by	Date

PRINCIPLE

INTENDED USE

For Research Use Only (RUO). Not for use in diagnostic procedures. No clinical decision or patient notification may be made based on results using this research assay.

Intended use has not been established

METHODOLOGY

The Access PAPP-A (RUO) assay is a two-site immunoenzymatic (“sandwich”) assay. A sample is added to a reaction vessel and incubated with anti-PAPP-A monoclonal antibody-alkaline phosphatase conjugate. Paramagnetic particles coupled with anti-PAPP-A monoclonal antibody are then added to the reaction mixture.

After incubation in a reaction vessel, materials bound to the solid phase are held in a magnetic field while unbound materials are washed away. Then, the chemiluminescent substrate is added to the vessel and light generated by the reaction is measured with a luminometer. The light production is directly proportional to the concentration of PAPP-A in the sample. The amount of analyte in the sample is determined from a stored, multi-point calibration curve.

SPECIMEN

SPECIMEN COLLECTION AND PREPARATION

1. Serum is the recommended sample.
2. Observe the following recommendations for handling, processing and storing blood samples:[1]
   - Collect all blood samples observing routine precautions for venipuncture.
   - Allow serum samples to clot completely before centrifugation.

- Keep tubes stoppered at all times.
- Physically separate serum from contact with cells as soon as possible.
- Store samples tightly stoppered at room temperature (15 to 30°C) for no longer than eight hours.
- If the assay will not be completed within 8 hours, refrigerate the samples at 2 to 8°C.
- If the assay will not be completed within 24 hours, or for shipment of samples, freeze at -20°C or colder.
- Thaw samples only once.

3. Use the following guidelines when preparing specimens:
   - Ensure residual fibrin and cellular matter have been removed prior to analysis.
   - Follow blood collection tube manufacturer's recommendations for centrifugation.
4. Each laboratory should determine the acceptability of its own blood collection tubes and serum separation products. Variations in these products may exist between manufacturers and, at times, from lot-to-lot.
5. Avoid assaying lipemic/hemolyzed samples.

REAGENTS

PRODUCT INFORMATION

Access PAPP-A (RUO) Reagent Pack

Cat. No. A49209: 100 determinations, 2 packs, 50 tests/pack

- Provided ready to use.
- Store upright and refrigerate at 2 to 10°C.
- Refrigerate at 2 to 10°C for a minimum of two hours before use on the instrument.
- Stable until the expiration date stated on the label when stored at 2 to 10°C.
- Stable at 2 to 10°C for 28 days after initial use.
- Signs of possible deterioration are a broken elastomeric layer on the pack or control values out of range.
- If the reagent pack is damaged (i.e., broken elastomer), discard the pack.
- All antisera are monoclonal unless otherwise indicated.

R1a:	Paramagnetic particles coated with mouse monoclonal anti-PAPP-A, BSA, TRIS buffered matrix, < 0.1% sodium azide, and 0.1% ProClin* 300.
R1b:	Mouse monoclonal anti-PAPP-A, alkaline phosphatase (bovine) conjugate, BSA, Phosphatase buffered matrix, < 0.1% sodium azide, and 0.1% ProClin 300.
R1c:	TRIS buffered matrix, BSA, proteins (murine, bovine, goat), < 0.1% sodium azide, and 0.1% ProClin 300.
R1d:	TRIS buffered matrix, BSA, proteins (murine, bovine, goat), < 0.1% sodium azide, and 0.1% ProClin 300.

*ProClin™ is a trademark of The Dow Chemical Company (“Dow”) or an affiliated company of Dow.

WARNING AND PRECAUTIONS

- **For Research Use Only. Not for use in diagnostic procedures.** No clinical decision or patient notification may be made based on results using this research assay.

- Samples and blood-derived products may be routinely processed with minimum risk using the procedure described. However, handle these products as potentially infectious according to universal precautions and good clinical laboratory practices, regardless of their origin, treatment, or prior certification. Use an appropriate disinfectant for decontamination. Store and dispose of these materials and their containers in accordance with local regulations and guidelines.
- For hazards presented by the product refer to the following sections: REACTIVE INGREDIENTS and GHS HAZARD CLASSIFICATION.

REACTIVE INGREDIENTS

⚠ CAUTION

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

GHS HAZARD CLASSIFICATION

PAPP-A PMP (Compartment R1a)	WARNING	
		
	H317	May cause an allergic skin reaction.
	P280	Wear protective gloves, protective clothing and eye/face protection.
	P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
	P362+P364	Take off contaminated clothing and wash it before use.
		reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) < 0.05%
PAPP-A Conjugate (Compartment R1b)	WARNING	
		
	H317	May cause an allergic skin reaction.
	P280	Wear protective gloves, protective clothing and eye/face protection.
	P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
	P362+P364	Take off contaminated clothing and wash it before use.
		reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) < 0.05%

PAPP-A Blocker (Compartment R1c)	WARNING	
		
	H317	May cause an allergic skin reaction.
	P280	Wear protective gloves, protective clothing and eye/face protection.
	P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
	P362+P364	Take off contaminated clothing and wash it before use.
		reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) < 0.05%
PAPP-A Blocker (Compartment R1d)	WARNING	
		
	H317	May cause an allergic skin reaction.
	P280	Wear protective gloves, protective clothing and eye/face protection.
	P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
	P362+P364	Take off contaminated clothing and wash it before use.
		reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) < 0.05%

SDS	Safety Data Sheet is available at techdocs.beckmancoulter.com

MATERIALS NEEDED BUT NOT SUPPLIED WITH REAGENT KIT

1. Access PAPP-A (RUO) Calibrators
   Provided at zero and approximately 50, 150, 500, 2500 and 5,000 ng/mL.
   Cat. No. A49210
2. Access PAPP-A (RUO) Quality Control (QC) or other commercially available control material.
   Provided at approximately 300, 1000 and 3,000 ng/mL.
   Cat. No. A49211
3. Access Substrate
   Cat. No. 81906
4. Access Wash Buffer II, Cat. No. A16792
   UniCel DxI Wash Buffer II, Cat. No. A16793
   UniCel DxI Access Immunoassay Systems Wash Buffer II, Cat. No A79784
   (Diluent pack for use with the UniCel DxI system onboard dilution feature.)

EQUIPMENT AND MATERIALS

R1	Access PAPP-A (RUO) Reagent Packs

CALIBRATION

CALIBRATION INFORMATION

An active calibration curve is required for all tests. For the Access PAPP-A (RUO) assay, calibration is required every 28 days. Refer to the appropriate system manuals and/or Help system for information on calibration theory, configuring calibrators, calibrator test request entry, and reviewing calibration data.

QUALITY CONTROL

Quality control materials simulate the characteristics of samples and are essential for monitoring the system performance of immunochemical assays. Because samples can be processed at any time in a “random access” format rather than a “batch” format, quality control materials should be included in each 24-hour time period.[2] Include Access PAPP-A (RUO) QC or other commercially available quality control materials that cover at least two levels of analyte. More frequent use of controls or the use of additional controls is left to the discretion of the user based on good laboratory practices or laboratory accreditation requirements and applicable laws.

Follow manufacturer’s instructions for reconstitution and storage. Each laboratory should establish mean values and acceptable ranges to assure proper performance. Quality control results that do not fall within acceptable ranges may indicate invalid test results. Examine all test results generated since obtaining the last acceptable quality control test point for this analyte. Refer to the appropriate system manuals and/or Help system for information about reviewing quality control results.

TESTING PROCEDURE(S)

PROCEDURAL COMMENTS

1. Refer to the appropriate system manuals and/or Help system for a specific description of installation, start-up, principles of operation, system performance characteristics, operating instructions, calibration procedures, operational limitations and precautions, hazards, maintenance, and troubleshooting.
2. Mix contents of new (unpunctured) reagent packs by gently inverting pack several times before loading on the instrument. Do not invert open (punctured) packs.
3. Use fifty (50) µL of sample for each determination in addition to the sample container and system dead volumes. Use one hundred fifty five (155) µL of sample in addition to the sample container and system dead volumes for each determination run with the DxI system onboard dilution feature. Refer to the appropriate system manuals and/or Help system for the minimum sample volume required.
4. The system default unit of measure for sample results is ng/mL.

PROCEDURE

Refer to the appropriate system manuals and/or Help system for information on managing samples, configuring tests, requesting tests, and reviewing test results.

RESULTS INTERPRETATION

Test results are determined automatically by the system software. The amount of analyte in the sample is determined from the measured light production by means of the stored calibration curve. Test results can be reviewed using the

appropriate screen. Refer to the appropriate system manuals and/or Help system for complete instructions on reviewing sample results.

PROCEDURAL NOTES

LIMITATIONS

If a sample contains more than the stated value of the highest Access PAPP-A (RUO) Calibrator (S5), the test sample can be diluted one volume of sample with 1 or 9 volumes of Access Wash Buffer II. Refer to the appropriate system manuals and/or Help system for instructions on entering a sample dilution in a test request. They system reports the results adjusted for the dilution.

The DxI system onboard dilution feature automates the dilution process, using one volume of sample with one volume of UniCel DxI Access Immunoassay Systems Wash Buffer II. The system reports the results adjusted for the dilution.

ADDITIONAL INFORMATION

SYMBOLS KEY

Glossary of Symbols is available at techdocs.beckmancoulter.com (document number C02724)

REFERENCES

1. Approved Guideline - Procedures for the Handling and Processing of Blood Specimens for Common Laboratory Tests, GP44-A4. 2010. Clinical and Laboratory Standards Institute.

2. Cembrowski GS, Carey RN. Laboratory quality management: QC ⇌ QA. ASCP Press, Chicago, IL, 1989.

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