

Intended Use:

Quantitative determination of ACR (Albumin to Creatinine Ratio) in human urine.

Clinical Significance:

Albuminuria:

Albuminuria is increased excretion of urine albumin and a marker of kidney damage. Normal individuals excrete very small amounts of protein in the urine. Albumin is the most common type of protein in the urine. All patients with CKD should be screened for albuminuria. Persistent increased protein in the urine (two positive tests over 3 or more months) is the principal marker of kidney damage, acting as an early and sensitive marker in many types of kidney disease.

Detection of Albuminuria:

A routine dipstick is not sensitive enough to detect small amounts of urine protein. Therefore, it is recommended that screening in adults with CKD or at risk for CKD be done by testing for albuminuria.

Albumin-to-creatinine ratio (ACR) is the first method of preference to detect elevated protein. The recommended method to evaluate albuminuria is to measure urine ACR in a spot urine sample. ACR is calculated by dividing albumin concentration in milligrams by creatinine concentration in grams.

Although the 24-hour collection has been the "gold standard," alternative methods for detecting protein excretion such as urine albumin-to-creatinine ratio (ACR) correct for variations in urine concentration due to hydration as well as provide more convenience than timed urine collections. The spot specimen correlates well with 24-hour collections in adults.

Albumin-to-creatinine ratio urine test involves measuring the amount of a protein called albumin in the urine (pee). The amount of urine albumin is compared with the quantity of a waste product in the urine called creatinine.

The body normally filters out creatinine in the urine at a steady rate, so comparing the ratio of urine albumin with creatinine in the same urine specimen helps determine if the body is excreting albumin at an increased rate. If this is happening, it may be the result of kidney disease.

In most healthy people, the kidneys prevent albumin and other proteins from entering the urine. However, if kidneys are damaged and start to allow proteins to pass from the blood into the urine, the first type of protein to appear in the urine is albumin. This is because albumin molecules are smaller than most other protein molecules.

The consistent presence of small amounts of albumin in the urine is called Albuminuria and is associated with early-stage kidney disease. Once there are larger amounts of albumin in the urine it is called macroalbuminuria and it could indicate more severe kidney disease

Urine Albumin Reagents:

(R1) Glycine buffer 120 mmol/L, pH 10.0. Preservative.

(R2) Latex Particles coated Rabbit IgG with anti-human albumin, pH 8.0. Preservative

Urine Albumin Liquid Calibrator. Calibrator Concentration is stated on the vial label.

Preparation: All the reagents are ready to use and stable till the expiry date mentioned on the label

Samples:

Spot Urine. Urine should be centrifuged before testing. Use this urine as specimen for the estimation of Urine Albumin and Urine Creatinine

Test Procedure:

To determine ACR (Albumin to Creatinine Ratio) one has to estimate Urine Albumin in mg/dL and Urine Creatinine in gm/dL precisely separately to the perfection.

Test Procedure: Urine Albumin

Urine Albumin R1	400 µl
Urine Albumin Calibrator / Spot Urine Sample	10 µl
Urine Albumin R2	100 µl

Mix well and immediately aspirate in to the analyzer. Read absorbances of Calibrator (C) and Test (T) against distilled water at 546 nm (540-550 nm) as follows:

Initial absorbance A1 -exactly after 5 sec.

Final absorbance A2 -exactly 120 sec after A1

Determine ΔA for Calibrator (C) and Test (T)

Calculations:

Calculate the average change in absorbance per minute (Δ Abs/min).

Activity of Urine Albumin in mg/dL at 546 nm

$$\text{Urine Albumin in mg/dL} = \frac{\Delta \text{ Abs of Test}}{\Delta \text{ Abs of Calibrator}} \times \text{Calibrator Conc (On the Label)}$$

Reaction Type	: Fixed Time / Initial Rate / Two Point Kinetic
Reaction Direction	: Increasing
Sample Volume	: 10 µl
R1	: 400 µl
R2	: 100 µl
Wave Length	: 546 nm (540-550 nm)
Calibrator Conc.	: Concentration on the label
Flow Cell Temp.	: 37°C
Linearity	: 15.0
Zero setting with	: Distilled Water
Units	: mg/dL
Delay	: 5 sec.
Interval	: 120 sec

Urine Creatinine Reagents: Final concentrations as per the below ingredients

R1: Picric acid	-> 1.0 mMol/L
R2: Sodium hydroxide	-> 200 mMol/L
Boric Acid	-> 1.8 mMol/L mMol/L
EDTA	-> 2.0 mMol/L
Activators and stabilizers	

Preparation: All the reagents are ready to use and stable till the expiry date mentioned on the label

Test Procedure: Urine Creatinine

Samples:

Spot Urine. Urine must be centrifuged before testing. Dilute urine 1:10 before the testing (100 µl Urine + 900 µl Distilled Water). **Use the diluted urine as a specimen. Results should be multiplied by 10. Urine dilution is must for Urine Creatinine Estimation.**

System Parameters: Fixed Time (Urine Creatinine)

Reaction Type	: Fixed Time / Initial Rate / Two Point Kinetic
Reaction Direction	: Increasing
Sample Volume	: 25 µl
Reagent Volume	: R1 500 µl + R2 500 µl
Wave Length	: 505 nm (500-520 nm)
Calibrator Conc.	: Concentration on the label
Flow Cell Temp.	: 37°C
Linearity	: 75.0
Zero setting with	: Distilled Water
Units	: mg/dl
Delay	: 20 sec.
Measuring	: 120 sec



**Pariksha
Biotech**
A game changer in IVD

Chronic Kidney Disease (CKD) Estimation Kit

High-Q ACR

Albumin : Creatinine Ratio



Procedure Fixed Time:
Test Procedure:

	(C)	(T)
Urine Creatinine R1	500 µl	500 µl
Urine Creatinine Calibrator	25 µl	----
Diluted(1:10) Spot Urine Sample	----	25 µl
Urine Creatinine R2	500 µl	500 µl

Mix well and immediately aspirate in to the Analyzer. Read absorbance of Calibrator (C) and Test (T) against distilled water at 505 nm (500- 520 nm) as follows:

Initial absorbance A0 -exactly after 20 sec (Delay)
Final absorbance A1 -exactly 120 sec.(Measuring)

Determine Δ A for Calibrator© and Test (T)

Calculations:
Urine Creatinine (mg/dL) = $\frac{\Delta AT}{\Delta AC} \times \text{Calibrator Concentration} \times 10$ (Dilution Factor)

Urine Creatinine (gm/dL) = $\frac{\text{Urine Creatinine (mg/dL)}}{1000}$

Calculations:

ACR = $\frac{\text{Urine Albumin in mg/dL}}{\text{Urine Creatinine in gm/dL}}$

Units for ACR is mg/g:

- 1) Calculate Urine Albumin Concentration in spot urine by High-Q ACR Kit in mg/dL
- 2) Calculate Urine Creatinine Concentration in spot urine by High-Q ACR Kit in gm/dL
- 3) Divide Creatinine mg/dL by 1000 to get Creatinine g/dL

ACR Reference Range:
Albuminuria categories in CKD (Chronic Kidney Disease):

Category	ACR (mg/g)	Terms
A1	<30	Normal
A2	30-300	Moderately increased
A3	>300	Severely increased

Relative to young adult level: ACR between 30 - 300 mg/g for >3 months indicate CKD (Patient's condition can be reversed if the proper treatment is given)

Nephrotic Syndrome: ACR >2220 mg/g (CKD may be serious and treatment may be difficult). Clinician should evaluate the seriousness of the disease and suggest accordingly.

Estimation of ACR:

Example:

Estimated Urine Albumin in Urine of a patient : 1.82 mg/dL

Estimated Creatinine in Urine of the same patient : 0.0153 gm/dL

ACR for this sample:

ACR (mg/g) = $\frac{1.82 \text{ mg/dL (Urine Albumin)}}{0.0153 \text{ gm/dL (Urine Creatinine)}}$

ACR For this sample: 118.95 mg/g

This sample results falls in the A2 Category and indicates Moderately increased ACR.

Notes:

- 1) Uncontrolled Diabetes(High Blood Glucose) can lead to kidney damage and this condition can be detected by this important Kidney Function Test ACR.
- 2) If ACR is detected in the range of 30-300 mg/g the condition can be reversed to normal through proper treatment.
- 3) The normal ratio of Albumin to Creatinine is seen to be around less than 30 mg/g of creatinine. In men, the level is seen to be less than or equal to 17 mg/g of creatinine whereas in women, the level is around 25 mg/g of creatinine.
- 4) If the ratio of albumin to creatinine is more than 300 mg/g of creatinine, the condition is known as Albuminuria, which means, there is a large amount of albumin in the urine. This means that there is a kidney disease which is severely affecting the normal functioning of kidneys and if not treated in time, could lead to kidney failure.
- 5) If the ratio of albumin to creatinine is more than 300 mg/g of creatinine, the condition is known as Albuminuria, which means, there is a large amount of albumin in the urine. This means that there is a kidney disease which is severely affecting the normal functioning of kidneys and if not treated in time, could lead to kidney failure.

Ordering information:

Ref./Cat. No. Pack Size Presentation
P-ACR - 100 100 Tests (Urine Albumin Reagents and Urine Creatinine Reagents sufficient to perform 100 ACR Tests.)

Product Features

- **ACR (Albumin to Creatinine Ratio) Estimation in mg/g for Chronic Kidney Disease(CKD)**
- **Specially formulated Reagents for Urine Albumin Estimation in mg/dL and Reagents for Urine Creatinine Estimation in gm/dL are provided in the kit.**
- **No interference from Reducing substances of urine in Creatinine Estimation.**
- **Precise and accurate estimation of Urine Albumin and Urine Creatinine there by accurate ACR Estimation.**

Symbols used with IVD devices

	Date of manufacture		Manufactured by
	In vitro diagnostic medical device		Keep away from sunlight
	Do not freeze		This way up
	Use-by date		Do not use if package is damaged
	Keep dry		Batch Code
	Consult instructions for use		Reagent
	Consult electronic instructions for use		Calibrator Material
	Catalogue number		
	Caution		

eIFU Indicator



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