BioVendor Group CLIA

Uromodulin

Uromodulin

Clinical topic:
Renal diseases

CE IVD Diagnostic kits are intended for professional use in the laboratory.

Designed for the platform Kleeya®

Introduction

In current clinical practice, we have well-established markers of glomerular filtration, but we still lack a reliable indicator of renal tubular function. This is why interest in uromodulin (UMOD) is growing, as it is increasingly recognized as an effective biomarker for the early detection of tubulointerstitial damage. Tubular injury often precedes glomerular dysfunction; therefore, monitoring UMOD levels is crucial in the early stages of chronic kidney disease.

Chronic kidney disease (CKD)

CKD is a condition characterized by a gradual and irreversible loss of kidney function. The kidneys become less effective at filtering blood, leading to the accumulation of waste products, electrolytes, and excess fluid in the body. The buildup of waste in the blood can cause high blood pressure, anemia due to a reduced number of red blood cells, and also increases the risk of cardiovascular disease.

Early detection and proper treatment can significantly slow the progression of CKD and often prevent it from advancing to the stage where dialysis or transplantation is required.

Main causes of CKD

Diabetes mellitus
damages the small blood vessels in the kidneys

Use of certain medicines or toxic substances
e.g., long-term use of non-steroidal anti-inflammatory drugs (NSAIDs)

High blood pressure
can put long-term strain on the kidneys

Glomerulonephritis
inflammation of the glomeruli

Polycystic kidney disease
a genetic disorder that causes cysts to form in the kidneys

Chronic urinary tract infections or other kidney inflammations

Stages of CKD

The official KDIGO (Kidney Disease: Improving Global Outcomes) classification defines 5 main stages of CKD based on the estimated glomerular filtration rate (eGFR). Stage 3 is usually divided into 3a and 3b, because the difference in prognosis and risk of complications is significant.

Stage 1: eGFR ≥ 90 ml/min/1.73 m²	Kidney function is preserved, but there are signs of damage (e.g., proteinuria, structural changes).
Stage 2: eGFR 60–89 ml/min/1.73 m²	Mildly reduced kidney function with signs of damage. In this stage, the disease is often asymptomatic.
Stage 3a: eGFR 45–59 ml/min/1.73 m²	Mild to moderate loss of kidney function. The risk of complications begins to increase, especially in patients with other chronic diseases.
Stage 3b: eGFR 30–44 ml/min/1.73 m²	Moderate to severe loss of kidney function. Symptoms such as fatigue, high blood pressure, or anemia appear more often. Closer monitoring and treatment are required.
Stage 4: eGFR 15–29 ml/min/1.73 m²	Severe reduction in kidney function. The risk of metabolic complications increases, and it becomes necessary to prepare the patient for kidney replacement therapy (dialysis or transplantation).
Stage 5: eGFR < 15 ml/min/1.73 m²	Kidney failure (end-stage renal disease). Without kidney replacement therapy (dialysis or transplantation), the patient's life is at risk.

Advantages of uromodulin

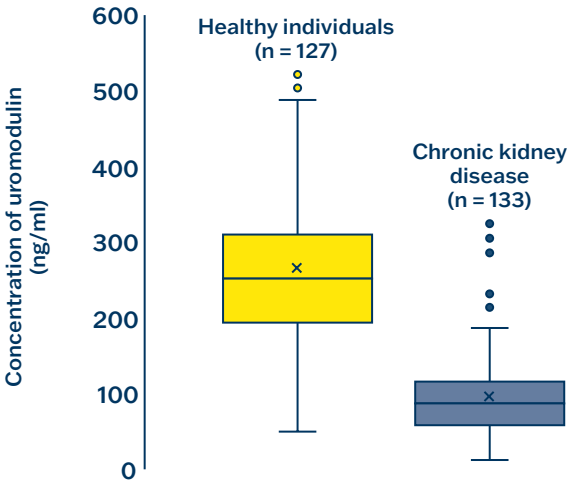
- Uromodulin allows kidney damage to be detected before clinical symptoms appear.
- Unlike most common tests that monitor only glomerular filtration, UMOD can reveal tubulointerstitial damage at an early stage, before eGFR begins to decline.
- Serum UMOD levels closely correlate with estimated eGFR and reliably reflect the stage of chronic kidney disease.
- This allows better risk stratification in the early stages of CKD, for example in patients at stage 1–2, where eGFR is still relatively normal but low UMOD levels already signal early kidney damage.
- It also enables early identification of patients whose creatinine levels are still normal, but whose UMOD levels are reduced, which may be a signal to refer the patient for more detailed nephrological examination.
- Several studies have also shown that individuals with kidney stones consistently have lower UMOD levels.
- A link has also been confirmed between higher UMOD levels and a lower incidence of urinary tract infections, suggesting that UMOD may play a protective role.
- Thanks to its high stability in serum, UMOD is ideal for routine laboratory testing.
- The serum stability of UMOD also simplifies the pre-analytical phase – it can be reliably measured even in samples that were not processed immediately.
- The CLIA Uromodulin test kit provides results in just 20 minutes, with a throughput of up to 120 tests per hour.

Preclinical study

The following data come from a preclinical study conducted in cooperation with an independent laboratory. The study included two groups of participants: healthy individuals and patients with CKD. Higher UMOD levels were observed in healthy subjects, consistent with preserved kidney function, while significantly lower values were found in CKD patients, indicating impaired function.

Within the two tested groups, the range of UMOD concentrations and their mean within the 95% confidence interval were evaluated as follows:

	Range (ng/ml)	Average (ng/ml)
Healthy individuals	109.9–482.0	265.1
CKD patients	14.4–172.0	86.8

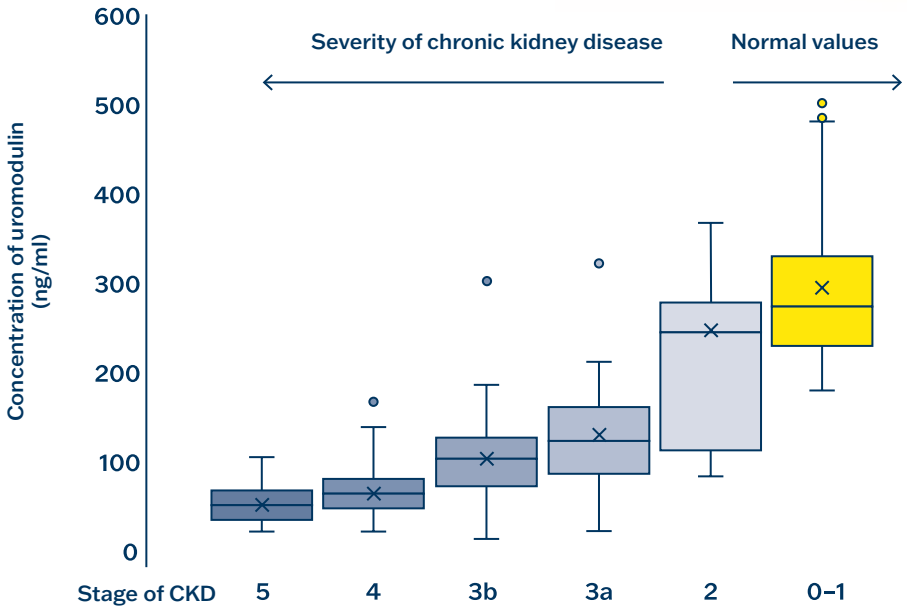


The analysis demonstrated a marked difference between the two groups. Physiological serum UMOD concentrations in the healthy adult population are typically in the range between 200 and 300 ng/ml. A decrease below the defined threshold may indicate reduced kidney function.

According to the ROC curve, the area under the curve (AUC) for distinguishing healthy individuals from CKD patients was nearly 0.9 at the established cut-off point of 168.15 ng/ml.

ROC analysis	
Cut-off	168.15 ng/ml
AUC	0.8934
Specificity	83.46 %
Sensitivity	93.98 %

UMOD levels correlate with the stage of chronic kidney disease.



Stage of CKD	eGFR result	Kidney damage
Stage 0 -1	≥ 90	none to very mild
Stage 2	60–89	mild kidney damage
Stage 3a	45–59	mild to moderate
Stage 3b	30–44	moderate to severe
Stage 4	15–29	severe
Stage 5	< 15	most severe

Clinical application

The chemiluminescent assay kit is intended for the diagnosis of kidney disease by measuring uromodulin in human serum in the general population.

Test characteristics

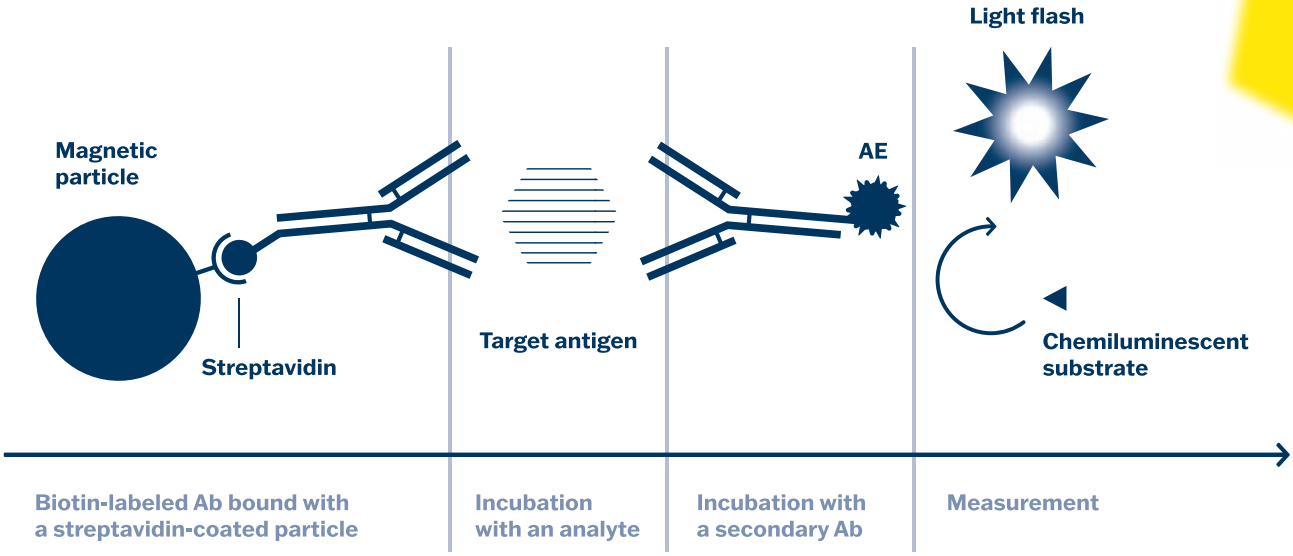
	Uromodulin
Sample	serum
Measuring range	15 – 800 ng/ml
Assay time	20 min

Uromodulin

- UMOD, also known as Tamm-Horsfall protein, is kidney-specific and is synthesized exclusively by the epithelial cells lining the renal tubules.
- UMOD is released into both urine and the bloodstream. Serum levels reflect kidney function more accurately, showing a closer correlation with eGFR than urinary UMOD.
- UMOD can be used as a marker to identify individuals with a genetic predisposition to CKD.
- Ongoing research continues to expand the potential applications of UMOD in other clinical areas. Its predictive value for cardiovascular diseases and related risks is becoming increasingly evident.

How does CLIA method work?

CLIA- Chemiluminescent Immunoassay is a highly advanced method known for its complete automation, rapidity, specificity, and sensitivity. It leverages magnetic particles to separate antigens in immunocomplexes and utilizes flash chemiluminescence for precise detection. The magnetic particle suspension enables automation, reduces reaction times significantly, and enhances specificity. Flash chemiluminescence using acridinium ester produces a strong light signal even at extremely low antigen concentrations, measured in relative light units (RLU). CLIA kits are specifically designed for seamless operation on the KleeYa® automated platform.



The scheme illustrates a sandwich-type reaction.

CLIA kits

Diagnostic CLIA kits are intended for the diagnosis of kidney disease by measuring uromodulin in human serum in the general population on the KleeYa® analyzer. Results are reported in ng/ml.

Control set CLIA

Control sets CLIA are designed to ensure the accuracy and reliability of results obtained from analyses using CLIA kits.

Ease of use

- Fully automated method
- Kits include all necessary reagents, incl. calibrators
- Control materials are available as independent sets

Advantages

- High diagnostic sensitivity and specificity
- Low sample (10 µl) and reagent consumption
- Short test time
- Full traceability of reagent consumption and number of tests available using RFID tags
- LIS connectivity available
- Superior customer service

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Ordering information

CLIA kits

Diagnostic CLIA kits are intended for the diagnosis of kidney disease by measuring uromodulin in human serum in the general population on the KleeYa® analyzer.

Kit	Catalogue number	Number of tests
CLIA Uromodulin	CL-UMOD050	50

Control sets

Control sets CLIA are designed to ensure the accuracy and reliability of results obtained from analyses using CLIA kits.

Kit	Catalogue number	Number of tests
Control set CLIA Uromodulin	CL-UMODCON	2 x 20

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