

# Kidney Profile

**Test Code:** 39165

**Specimen Requirements:**

**Preferred:** 1 mL room-temperature serum (SST red-top tube) **and** 10 mL room-temperature random urine (yellow-top, blue fill line, preservative tube)

**Minimum:** 0.5 mL serum **and** 2 mL urine

**CPT Codes\*:** 82043, 82565, 82570

## CLINICAL USE

- Detect chronic kidney disease (CKD) in adults
- Monitor CKD therapy and/or progression in adults

## CLINICAL BACKGROUND

About 37 million people in the United States are estimated to have CKD, but the majority (about 90%) are unaware that they are affected.<sup>1</sup> High-risk populations (% untested) include individuals with hypertension (94%), diabetes (61%), or both (60%).<sup>2</sup> In addition, individuals who are obese, are of older age ( $\geq 65$  years), had previous kidney damage, or have a family history of CKD are also at higher risk of having CKD.<sup>1</sup> Overall, CKD awareness is suboptimal and has not improved over the last 2 decades.<sup>3</sup>

Identifying and treating CKD at earlier stages may prevent or delay adverse outcomes. Using the Kidney Failure Risk equation (KidneyFailureRisk.com), patients categorized as having high risk for end-stage renal disease are  $>10$  times as likely as low-risk patients to have kidney failure within 5 years, yet about half remain unaware of their CKD.<sup>3</sup> Knowledge of the presence of CKD may guide lifestyle changes that mitigate risk factors that are common to kidney- and cardiac-related disease.<sup>3</sup> The risk of cardiovascular events and death increases with the increasing CKD severity.<sup>2</sup> Thus, monitoring and managing patients with CKD is also important for decreasing morbidity and mortality.<sup>4</sup>

CKD is defined based on the presence of an estimated glomerular filtration rate (eGFR)  $<60$  mL/min/1.73 m<sup>2</sup> for

$>3$  months, evidence of kidney damage for  $>3$  months, or both.<sup>5</sup> Evidence of kidney damage is assessed by detecting albuminuria, which involves measuring a urine albumin-creatinine ratio  $\geq 30$  mg/g ( $\mu\text{g}/\text{mg}$ ).<sup>5</sup> Albuminuria is one of the first signs of renal disease which, if left untreated, may progress to overt renal failure.<sup>5,6</sup> A study based on data from the 2013 to 2016 National Health and Nutrition Examination Survey (NHANES) showed that only 8% of people with an eGFR  $<60$  mL/min/1.73 m<sup>2</sup> knew they had CKD.<sup>7</sup> For those with the same eGFR and albuminuria, only 28% were aware they had CKD.<sup>7</sup>

Albuminuria is independently associated with an increased risk of cardiovascular events and an increased mortality.<sup>6</sup> In patients with diabetes, early detection of albuminuria, followed by improvement of glucose control and treatment with angiotensin-converting enzyme inhibitors or angiotensin receptor blockers, may slow or prevent progression to end stage renal disease.<sup>6</sup>

Quest Diagnostics offers the Kidney Profile (test code 39165) to assist in CKD staging based on eGFR and urine albumin-creatinine ratio. The National Kidney Foundation recommends using the test results to identify CKD in at-risk patients (listed below) and to monitor disease progression.<sup>2</sup> eGFR and albumin-creatinine ratio are also important independent risk predictors of major adverse cardiovascular events (myocardial infarction or stroke).<sup>8</sup>

## INDIVIDUALS SUITABLE FOR TESTING

- Adults aged 18 years and older who are at risk of or who have CKD, including individuals with diabetes, cardiovascular disease, hypertension, previous kidney damage, systemic disease with potential kidney involvement (eg, systemic lupus erythematosus), or a family history of CKD, as well as individuals who are moderately obese or  $\geq 65$  years old

Creatinine-based eGFR may be affected by unstable creatinine levels caused by diet, increased muscle bulk or wasting. Cystatin C with eGFR (test code 94588) may be the preferred test under these conditions.

## METHOD

- eGFR: calculated according to the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation using<sup>9</sup>
    - Serum creatinine: colorimetric, kinetic, alkaline picrate assay traceable to an isotope- dilution mass spectrometry reference method
    - The patient's age (18 years and older), sex, and race (African American vs non-African American)
  - Urine albumin: immunoturbidimetric assay
    - Analytical sensitivity: 2 mg/L
    - Analytical specificity: immunoreactive albumin
  - Urine creatinine: colorimetric, modified Jaffe, kinetic assay
- Panel components Creatinine (test code 375), Albumin, Random Urine with Creatinine (test code 6517, which includes albumin

and creatinine, random urine [test code 8459]) may be ordered separately.

## REFERENCE RANGES

- eGFR:  $\geq 60$  mL/min/1.73m<sup>2</sup>
- Albumin-creatinine ratio  $< 30$   $\mu\text{g}/\text{mg}$  creatinine

## INTERPRETIVE INFORMATION

The **Figure** demonstrates the use of eGFR and urine albumin-creatinine ratio for predicting CKD prognosis and for managing patients with CKD.

Exercise within 24 hours of collection, infection, fever, congestive heart failure, marked hyperglycemia, marked hypertension, pyuria, and hematuria may cause elevated urinary albumin levels. Results should be interpreted in conjunction with other laboratory and clinical findings.

**Figure.** Frequency of Monitoring Chronic Kidney Disease Based on Risk of Disease Progression Assessed Using eGFR and Urine Albumin-Creatinine Ratio (Kidney Profile, test code 39165)

			Albuminuria categories and ACR ranges (mg/g creatinine)		
			Normal to mildly increased	Moderately increased	Severely increased
			$< 30$	30-300	$> 300$
CKD stage and eGFR range (mL/min/1.73 m <sup>2</sup> )	1 and 2	$\geq 60$	1	1	2,R
	3A	45-59	1,C	2	3,R
	3B	30-44	2	3	3,R
	4	15-29	3,R	3,R	$\geq 4,R$
	5	$< 15$	$\geq 4,R$	$\geq 4,R$	$\geq 4,R$

- Low risk: monitor yearly if evidence of kidney damage (eg, indicated by imaging or biopsy). The NKDEP recommends that actual values above 60 mL/min/1.73m<sup>2</sup> be reported only as  $> 60$  due to variability near the upper limit of the reference range.<sup>10</sup>
- Moderately high risk: monitor yearly
- High risk: monitor 2 times yearly
- Very high risk: monitor 3 times yearly
- Very high risk: monitor  $\geq 4$  times yearly

ACR, albumin-creatinine ratio; C, confirm using eGFR based on (1) cystatin C (test code 94588) or (2) creatinine plus cystatin C; CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate; NKDEP, National Kidney Disease Education Program; R, refer to specialist  
 This figure was adapted from references 5 (with permission) and 10, is provided for informational purposes only as a guide for using laboratory tests, and is not intended as medical advice. A physician's test selection and interpretation, diagnosis, and patient management decisions should be based on his/her education, clinical expertise, and assessment of the patient.

## References

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