

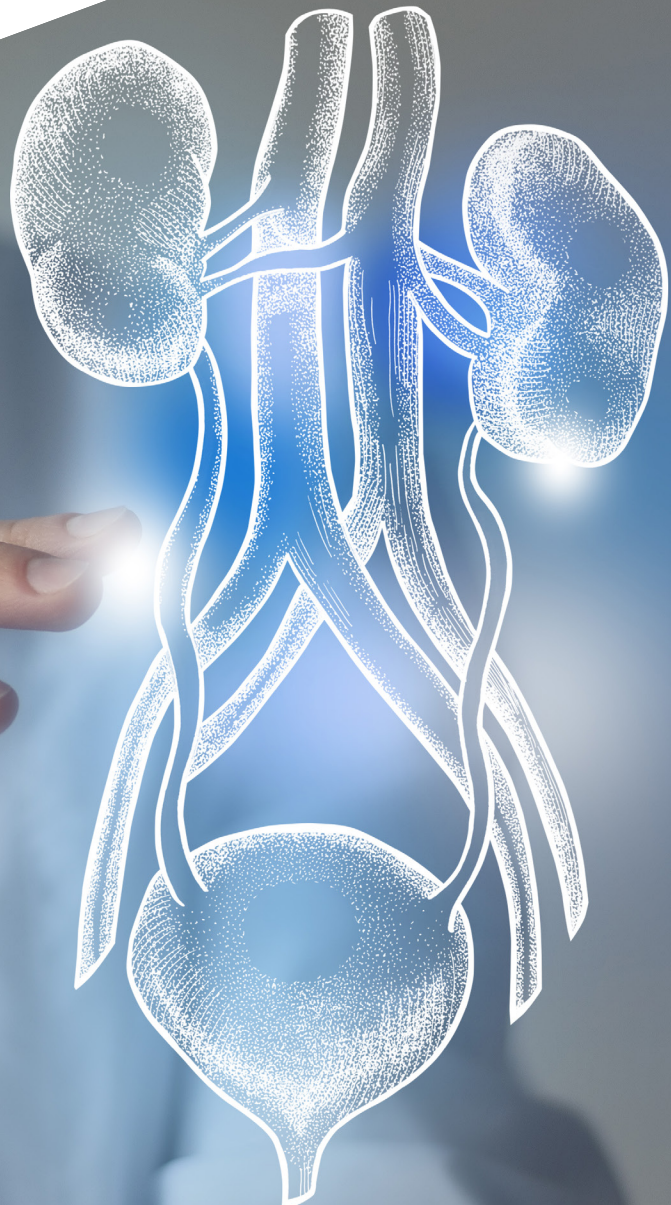


SONIC HEALTHCARE
USA

Information for providers

Chronic Kidney Disease

Sonic Healthcare USA Population Health



Background

30 million+ Americans have chronic kidney disease (CKD). CKD is progressive and the leading cause of end-stage renal disease requiring dialysis. CKD affects multiple organ systems, including cardiovascular, hematologic, and skeletal systems.

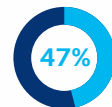
Elevated risk for CKD:

- diabetes
- hypertension
- family history of kidney failure

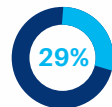


More than **1** in **7**,
that is 15% of US adults, or 37 million people, are estimated to have CKD.*

Causes of kidney failure:



Diabetes



High blood pressure



All other causes combined²

* Source: <https://www.cdc.gov/kidneydisease/publications-resources/ckd-national-facts.html#:~:text=CKD%20is%20Common%20Among%20US%20Adults&text=More%20than%201%20in%207,are%20estimated%20to%20have%20CKD.&text=As%20many%20as%209%20in,not%20know%20they%20have%20CKD>



Underdiagnosis is a major problem: only 15-20% of CKD patients are aware of their diagnosis.

Diagnosis & Management

Kidney Profile

Kidney profile (eGFR + UACR) is essential.

eGFR: Estimated glomerular filtration rate (eGFR): Critical to provide an accurate diagnosis and prognosis for patients with kidney disease.

- **eGFR-Creatinine:** mainstay for diagnosis and monitoring of CKD.
- **eGFR-Cystatin C (with or without Creatinine):** improved performance, useful for confirming CKD in borderline cases.

UACR: Urine albumin creatinine ratio (UACR)

“For nephrologists, estimated GFR is a critical workhorse, a starting point for much of what we do. Diagnosis, prognostication, treatment options, and the use of medications all hinge on eGFR.”

Harold Feldman (Editor-in-Chief AJKD) & Josephine Briggs (Editor-in-Chief JASN) in Race and the Estimation of GFR: Getting It Right. JASN June 2021, 32 (6) 1269-1270

				Persistent Albuminuria Categories Description and Range		
				A1	A2	A3
Guide to Frequency of Monitoring (number of times per year) by GFR and Albuminuria Category				Normal to mildly increased <30 mg/g <3 mg/mmol	Moderately increased 30-300 mg/g 3-30 mg/mmol	Severely increased >300 mg/g >30 mg/mmol
GFR categories (ml/min/1.73 m ²) Description and Range	G1	Normal or high	≥90	1 if CKD	1	2
	G2	Mildly decreased	60-99	1 if CKD	1	2
	G3a	Mildly to moderately decreased	45-59	1	2	3
	G3b	Moderately to severely decreased	30-44	2	3	3
	G4	Severely decreased	15-29	3	3	4+
	G5	Kidney failure	<15	4+	4+	4+

GFR and albuminuria grid to reflect the risk of progression by intensity of coloring (green, yellow, orange, red, deep red). The numbers in the boxes are a guide to the frequency of monitoring (number of times per year).

Sonic Healthcare USA is committed to improving kidney health



Superior eGFR Analysis

- Enhanced creatinine enzymatic methodology
- Elimination of race-based eGFR
- Confirmatory testing with cystatin C*

* In accordance with NKF, Sonic laboratories provide an interpretive note on all eGFR's of 45-59 ml/min/BSA to inform providers to consider adding an order for eGFR creatinine-cystatin method and equation for newly diagnosed Grade 3a CKD.

Clinical Decision Support (CDS) & Advanced Reporting

Superior eGFR Analysis

Enhanced creatinine enzymatic methodology

Creatinine is the primary component of the 2021 CKD-EPI eGFRcr equations. Therefore, the quality of the assay is essential to establish the correct diagnosis and classification of chronic kidney disease.


Creatinine may be measured by the Jaffe method or the enzymatic method.

Jaffe Method:

- Used by the vast majority of US laboratories
- Interference - Falsely elevated creatinine may occur due to:
 - Low protein
 - Increased glucose
 - Ketone bodies
 - and others
- Potential eGFR calculation errors

Enzymatic Method:

- More specific to creatinine, less prone to interference compared with Jaffe method
- Superior precision and accuracy, particularly at medical decision points for CKD



As part of our commitment to kidney health, Sonic Healthcare USA is currently the only major medical laboratory service provider which broadly uses enzymatic methodology for superior creatinine measurement and eGFR evaluation. The NKF-ASN Task Force recommends use of enzymatic assays to “limit serum creatinine variability and increase eGFR accuracy”.



Changes in Estimated Glomerular Filtration Rate (eGFR) Calculation: Removal of Race-Based Adjustment

The National Kidney Foundation and American Society of Nephrology (NKF-ASN) Task Force was established in July 2020 to consider inequity in diagnosis, management and outcomes of chronic kidney disease in Black patients, including recognition and management of kidney-disease risk factors, comorbidities, and progression to kidney failure.

Key Findings:

- Significantly higher prevalence of hypertension and decline in measured GFR at an earlier age for Black vs. non-Black patients
- Lower rates of nephrology referral, dialysis options and transplantation for Black patients
- As a part of the NKF-ASN TF, the CKD Epidemiology Collaboration conducted a major analysis and validated a new single equation for eGFR. The new equation balanced performance equally between Black and non-Black study participants
- With input from more than 90 experts in the field and public members, the Task Force recommended:
 - Immediate implementation of the new 2021 CKD-EPIcr_R calculation for eGFR based on creatinine, to replace separately reported race-based eGFRs.
 - National efforts to facilitate routine and timely use of cystatin C, to confirm eGFR in adults who are at risk for or have CKD. Cystatin C can be used alone or paired with simultaneous creatinine measures for the most accurate eGFR (eGFRcr-cys_R)

In response to recommendations from the NKF-ASN Task Force on estimated glomerular filtration rate (eGFR), effective 05/04/2022, Sonic Healthcare USA adopted the single **CKD-EPI Refit** equation to replace the separately reported **eGFR - Black** and **eGFR - non-Black** calculations for all serum creatinine measures.

Superior eGFR Analysis (continued)

Cystatin C

For most clinical circumstances, estimating GFR from serum creatinine (eGFR-cr) is appropriate for staging and tracking the progression of chronic kidney disease (CKD). However, the influence of factors including age, muscle mass, diet, and tubular secretion on creatinine may render eGFR-cr misleading in some populations.

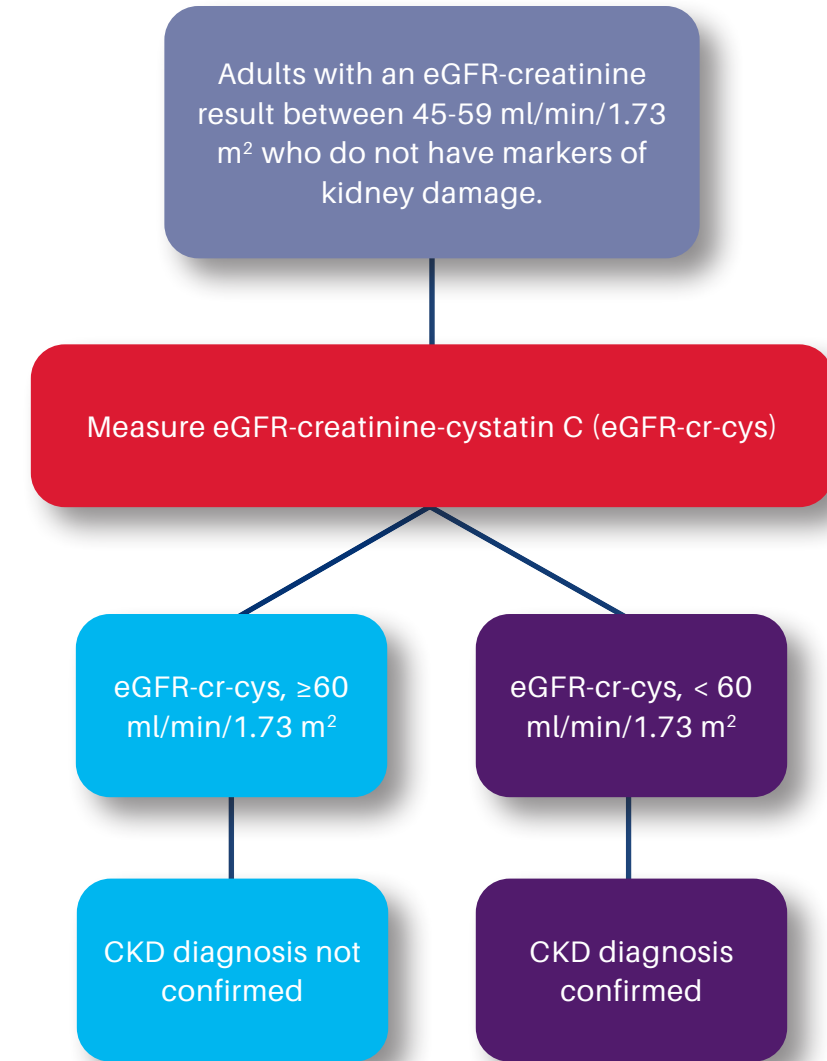
- Low molecular weight cysteine protease inhibitor produced at a constant rate by nucleated cells
- Elimination from circulation is performed almost entirely by glomerular filtration in the kidneys, making cystatin C serum concentration inversely correlated with glomerular filtration rate (GFR)
- Compared with creatinine, cystatin C is more specific and more closely associated with clinical outcomes in CKD

Based on these findings, the National Kidney Foundation and American Society of Nephrology (NKF-ASN) Task Force recommended national efforts to facilitate routine and timely use of cystatin C, to confirm eGFR in adults who are at risk for or have CKD.

As part of our ongoing commitment to improving the diagnosis of kidney disease, Sonic Healthcare USA offers eGFR by creatinine and cystatin C (eGFR-cr-cys):

- The cystatin C assay is a particle enhanced immunoturbidimetric assay which is FDA-cleared for in vitro quantitative determination of cystatin C in human serum
- In accordance with the NKF-ASN Task Force guidelines, Sonic Healthcare USA has adopted the 2021 eGFR-creatinine-cystatin C equation, and it is appropriate for adult (age ≥ 18 years) patients only

According to Kidney Disease Improving Global Outcomes (KDIGO) practice guidelines, confirmation by eGFR-creatinine-cystatin C is warranted in specific circumstances when decisions depend on more accurate knowledge of GFR.



Other instances when eGFR-creatinine-cystatin C may be clinically indicated include:

- Determining eligibility for kidney donation
- Adjusting dosage of toxic drugs that are excreted by the kidneys

Advanced Reporting & Clinical Decision Support

Diagnosis and management of CKD is highly variable. Underdiagnosis of CKD remains a significant challenge, where reports suggest only 15-20% of patients are aware of their diagnosis. Early identification and management of CKD and exacerbating comorbid conditions are critical to improve prognosis and healthcare outcomes.

Sonic Healthcare USA Advanced Reporting & Clinical Decisions Support for Chronic Kidney Disease is an automated supplement, which leverages pattern-based recognition and evidence-based guidelines to inform clinical management by providing:

- Comprehensive Kidney Profile
- Follow-up considerations based on internationally recognized KDIGO guidelines
- Diagnosis Support
- eGFR and UACR trends to improve identification for patients at risk for disease progression
- Educational links for practice guidelines and comprehensive kidney care

Per KDIGO 2020: CKD is defined as abnormalities of kidney structure or function, present for >3 months, with implications for health. CKD is classified based on Cause, GFR category (G1-G5), and Albuminuria category (A1-A3), abbreviated as CGA. The CKD CDS report provides clinical decision support based on published guidelines and/or expert opinion from leading authorities on kidney health, including KDIGO, and others. The report is for informational purposes only, and it was generated based on data provided by a clinician and/or testing performed by a Sonic Healthcare USA clinical laboratory. The report does not include data related to testing performed for the patient by other laboratories or other healthcare providers. Clinicians must take into account underlying comorbid conditions and disease states, and they are ultimately responsible for determining appropriate diagnostic, treatment, management, and testing decisions for their patients. CKD Clinical Decision Support is a supplemental report. Test names and data are identical to that given in the core laboratory information system (LIS). Reference intervals in this report may be expressed differently for purposes of assessment and management of CKD. eGFR >=90 is considered normal; eGFR between 60-89 is mildly decreased. The core LIS may contain additional testing not given in this supplement.

Advanced Reporting & Clinical Decision Support

Chronic Kidney Disease Clinical Decision Support By iMorpheus				
Specimen Information		Patient Information		Ordering Physician
Accession #	T0087675	ZTEST, MICKEY		ATLAS TEST ACCT-IMAGE REPORTS
Date Collected:	11/03/2021 07:00	Date Of Birth:	04/06/1964	Client Information ATLAS TEST ACCT-IMAGE REPORTS 9200 WALL STREET AUSTIN, 78754 TX (512) 873-5034
Date Received:		Age:	57 Years	
Date Reported:	11/03/2021	Gender:	Male	
Client Record:	-	Telephone:		
EMPI:	T44521-1101211			

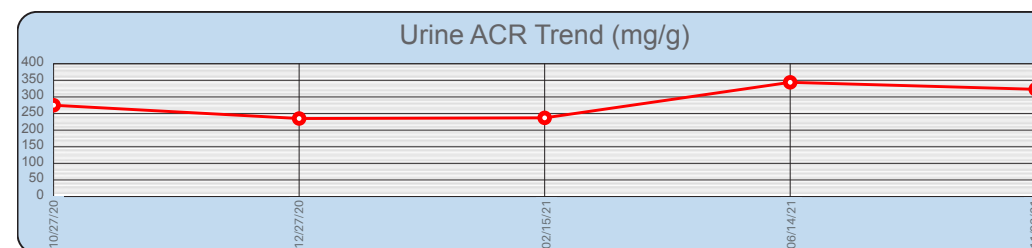
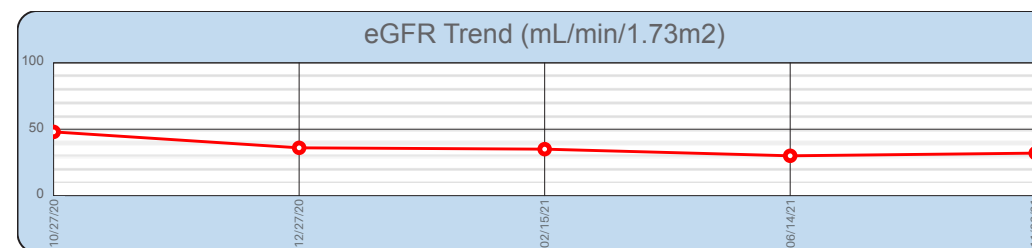
Kidney Profile				
Test Name	Value	Unit	Ref Range	Interpretation #
eGFR(CKD-EPI)	34	mL/min/1.73m2	>=90	G3b
Urine ACR	323	mg/g	<30	A3

KDIGO Follow Up Considerations (G3b,A3)			
Test Name	Code	Frequency per Year (Min)	
Metabolic panel (e.g., CMP, BMP)	142	3	
Urine ACR	4895	3	
Phosphate	2227	1	
Parathyroid Hormone	2814	0 - 1	
Vitamin D, 25(OH)	4958	To Be Determined by baseline	
Lipid Profile	200	To Be Determined by baseline	
Complete Blood Count	1000	See note*	
Ferritin	2090	See note**	
Iron Status	2118	See note**	

***Anemia Evaluation**
 -For CKD patients without anemia, measure hemoglobin concentration when clinically indicated and:
 At least annually in patients with CKD 3
 At least twice per year in patients with CKD 4-5 non-dialysis
 At least every 3 months in patients with CKD 5 dialysis
 -For CKD patients with anemia not being treated with an erythropoietin stimulating agent (ESA), measure hemoglobin concentration when clinically indicated and:
 At least every 3 months in patients with CKD 3-5 non-dialysis and CKD 5 peritoneal dialysis

****Iron Status Evaluation**
 -Evaluate iron status (iron saturation and ferritin) at least every 3 months during ESA therapy, including the decision to start or continue iron therapy -Test iron status more frequently when initiating or increasing ESA dose, when there is blood loss, when monitoring response after a course of IV iron, and in other circumstances where iron stores may become depleted

Diagnosis Support		
CKD ICD-10 on File	Description	Interpretation #
No Diagnosis On File		Possible Under-DX



Comprehensive Kidney Profile with interpretation

Follow-up Considerations based on internationally-recognized KDIGO guidelines

Diagnosis Support

eGFR and UACR trends to improve identification for patients at risk for disease progression

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