

Overview

Useful For

Cystatin C:

An index of glomerular filtration rate, especially in patients where serum creatinine may be misleading (eg, very obese, elderly, or malnourished patients)

Assessing renal function in patients suspected of having kidney disease

Monitoring treatment response in patients with kidney disease

Estimated Glomerular Filtration Rate (eGFR):

An index of GFR, especially in patients where serum creatinine may be misleading (eg, very obese, elderly, or malnourished patients); for such patients, use of CKD-EPI cystatin C equation is recommended to estimate GFR

Assessing renal function in patients suspected of having kidney disease

Monitoring treatment response in patients with kidney disease

Method Name

Immunoturbidimetric

NY State Available

Yes

Specimen

Specimen Type

Serum

Specimen Required

Container/Tube:

Preferred: Red top

Acceptable: Serum gel

Specimen Volume: 1 mL

Forms

If not ordering electronically, complete, print, and send 1 of the following forms with the specimen:

-[Cardiovascular Test Request Form](#) (T724)

-[Renal Diagnostics Test Request](#) (T830)

Specimen Minimum Volume

0.5 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	OK

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Refrigerated (preferred)	7 days	
	Ambient	7 days	
	Frozen	7 days	

Clinical and Interpretive
Clinical Information

Cystatin C:

Cystatin C is a low molecular weight (13,250 kD) cysteine proteinase inhibitor that is produced by all nucleated cells and found in body fluids, including serum. Since it is formed at a constant rate and freely filtered by the kidneys, its serum concentration is inversely correlated with the glomerular filtration rate (GFR); that is, high values indicate low GFRs while lower values indicate higher GFRs, similar to creatinine.

The renal handling of cystatin C differs from creatinine. While both are freely filtered by glomeruli, once it is filtered, cystatin C, unlike creatinine, is reabsorbed and metabolized by proximal renal tubules. Thus, under normal conditions, cystatin C does not enter the final excreted urine to any significant degree.

The serum concentration of cystatin C remains unchanged with infections, inflammatory or neoplastic states, and is not affected by body mass, diet, or drugs. Thus, cystatin C may be a more reliable marker of renal function (GFR) than creatinine.

Estimated Glomerular Filtration Rate (GFR):

GFR can be estimated (eGFR) from serum cystatin C utilizing an equation which includes the age and gender of the patient. The CKD-EPI cystatin C equation was developed by Inker et al:(1) and demonstrated good correlation with measured iothalamate clearance in patients with all common causes of kidney disease, including kidney transplant recipients. Cystatin C eGFR may have advantages over creatinine eGFR in certain patient groups in whom muscle mass is abnormally high or low (for example quadriplegics, very elderly, or malnourished individuals). Blood levels of cystatin C also equilibrate more quickly than creatinine, and therefore, serum cystatin C may be more accurate than serum creatinine when kidney function is rapidly changing (for example amongst hospitalized individuals).

Reference Values

CYSTATIN C

Males:

0 days-22 years: no reference values established

23-29 years: 0.60-1.03 mg/L

30-39 years: 0.64-1.12 mg/L

40-49 years: 0.68-1.22 mg/L

50-59 years: 0.72-1.32 mg/L

60-69 years: 0.77-1.42 mg/L

70-79 years: 0.82-1.52 mg/L

>79 years: no reference values established

Females:

0 days-22 years: no reference values established

23-29 years: 0.57-0.90 mg/L

30-39 years: 0.59-0.98 mg/L

40-49 years: 0.62-1.07 mg/L

50-59 years: 0.64-1.17 mg/L

60-69 years: 0.66-1.26 mg/L

70-80 years: 0.68-1.36 mg/L

81-86 years: 0.70-1.45 mg/L

>86 years: no reference values established

eGFR

>60 mL/min/BSA

eGFR will not be calculated for patients under 18 years.

Interpretation

Cystatin C:

Cystatin C inversely correlates with the glomerular filtration rate (GFR), that is elevated levels of cystatin C indicate decreased GFR. Cystatin C may provide more accurate assessment of GFR for very obese, elderly, or malnourished patients than creatinine. Cystatin C equation does not require patient ethnic data, and can be used for those patients with this information unavailable.

Due to immaturity of renal function, cystatin C levels are higher in neonates <3 months of age.(2)

Estimated Glomerular Filtration Rate (eGFR):

Chronic kidney disease (CKD) is defined as the presence of: persistent and usually progressive reduction in GFR (GFR <60 mL/min/1.73 m²) and/or albuminuria (>30 mg of urinary albumin per gram of urinary creatinine), regardless of GFR.

According to the National Kidney Foundation Kidney Disease Outcome Quality Initiative (K/DOQI) classification, among patients with CKD, irrespective of diagnosis, the stage of disease should be assigned based on the level of kidney function:

Stage	Description	GFR mL/min/BSA
1	Kidney damage with normal or increased GFR	90
2	Kidney damage with mild decrease in GFR	60-89
3	Moderate decrease in GFR	30-59
4	Severe decrease in GFR	15-29
5	Kidney failure	<15 (or dialysis)

Cautions

Cystatin C:

Lipemic or frozen specimens, which become turbid after thawing, may interfere with the assay.

Estimated Glomerular Filtration Rate (eGFR):

eGFR is not a precise measure of GFR and can be influenced by nonrenal factors (eg, inflammation).

Supportive Data

In a study to evaluate cystatin C as a measure of renal function in comparison to serum creatinine, 500 patients had cystatin C measured by nephelometry and glomerular filtration rate (GFR) measured by nonradiolabeled iothalamate clearance.(2) In addition, serum creatinine was measured and the patients' medical records reviewed. The correlation of 1/cystatin C with GFR (r=0.90) was significantly superior than 1/creatinine (r=0.82, p<0.05) with GFR. The superior correlation of 1/cystatin C with GFR was observed in the various clinical subgroups of patients studied (ie, subjects with no suspected renal disease, renal transplant patients, recipients of some other transplant, patients with glomerular disease, and patients with non-glomerular renal disease). Using the lower fifth percentile age-adjusted normal values for iothalamate clearance, receiver operator characteristic curves were generated. The area under the curve for 1/cystatin C was significantly greater than for 1/creatinine. These results indicate that cystatin C may be superior to serum creatinine for the assessment of GFR in a wide spectrum of patients-both those with renal disease and those without renal disease. Others have similarly found that cystatin C correlates better than serum creatinine for assessment of GFR.(3)

Clinical Reference

1. Inker LA, Schmid CH, Tighiouart H, et al: Estimating glomerular filtration rate from serum creatinine and cystatin C. N Engl J Med 2012 Jul;367(1):20-29

2. Buehrig CK, Larson TS, Bergert JH, et al: Cystatin C is superior to serum creatinine for the assessment of renal function. *J Am Soc Nephrol* 2001;12:194A
3. Grubb AO: Cystatin C - properties and use as a diagnostic marker. *Adv Clin Chem* 2000;35:63-99
4. Coll E, Botey A, Alvarez L, et al: Serum cystatin C as a new marker for noninvasive estimation of glomerular filtration rate and as a marker for early renal impairment. *Am J Kidney Dis* 2000 Jul;36(1):29-34
5. Flodin M, Jonsson AS, Hansson LO, et al: Evaluation of Gentian cystatin C reagent on Abbott Ci8200 and calculation of glomerular filtration rate expressed in mL/min/1.73 m² from the cystatin C values in mg/L. *Scand J Clin Lab Invest* 2007;67:560-567
6. Larsson A, Hansson LO, Flodin M, et al: Calibration of the Siemens cystatin C immunoassay has changed over time. *Clin Chem* 2011;57:777-778
7. Voskoboev NV, Larson TS, Rule AD, Lieske JC: Importance of cystatin C assay standardization. *Clin Chem* 2011 Aug;57(8):1209-1211
8. Nitsch D, Sandling JK, Byberg L et al: Fetal, developmental, and parental influences on cystatin C in childhood: the Uppsala Family Study. *Am J Kidney Dis* 2011 Jun;57(6):863-872
9. Voskoboev NV, Larson TS, Rule AD, Lieske JC: Analytic and clinical validation of a standardized cystatin C particle enhanced turbidimetric assay (PETIA) to estimate glomerular filtration rate. *Clin Chem Lab Med* 2012 Mar;50(9):1591-1596
10. Finney H, Newman DJ, Thakkar H, et al: Reference ranges for the plasma cystatin C and creatinine measurements in premature infants, neonates, and older children. *Arch Dis Child* 2000 Jan;82(1):71-75

Performance

Method Description

Serum sample from patient is mixed with Gentian cystatin C immunoparticles. Cystatin C from the sample and anti-cystatin C form the immunoparticles aggregate. The complex particles created absorb light, and by turbidimetry the absorption is related to cystatin C concentration via interpolation on an established standard calibration curve. (Package insert: Gentian Cystatin C Immunoassay on Cobas c501, Roche Diagnostics, Indianapolis, IN, June 2011)

PDF Report

No

Day(s) and Time(s) Test Performed

24 hours per day, 7 days per week

Analytic Time

1 day

Maximum Laboratory Time

2 days

Specimen Retention Time

7 days

Performing Laboratory Location

Rochester

Fees and Codes**Fees**

- Authorized users can sign in to [Test Prices](#) for detailed fee information.
- Clients without access to Test Prices can contact [Customer Service](#) 24 hours a day, seven days a week.
- Prospective clients should contact their Regional Manager. For assistance, contact [Customer Service](#).

Test Classification

This test has been cleared or approved by the U.S. Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

CPT Code Information

82610

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
CYSTC	Cystatin C with Estimated GFR, S	87430-5

Result ID	Test Result Name	Result LOINC Value
EGFRC	eGFR by Cystatin C	50210-4
CYSC	Cystatin C, S	33863-2