Overview

Useful For
Assessing renal function in patients suspected of having kidney disease
Monitoring treatment response in patients with kidney disease
An index of glomerular filtration rate (GFR), especially in patients where serum creatinine may be misleading (eg, very obese, older adults, or malnourished patients)
Calculation of CKD-EPI cystatin C estimated GFR for patients where serum creatinine may be misleading (eg, very obese, older adults, or malnourished patients)

Method Name
Immunoturbidimetric

NY State Available
Yes

Specimen

Specimen Type
Serum

Specimen Required

Container/Tube:

Preferred: Serum gel
Acceptable: Red top

Specimen Volume: 0.5 mL

Collection Instructions:
1. Serum gel tubes should be centrifuged within 2 hours of collection.
2. Red-top tubes should be centrifuged and aliquoted within 2 hours of collection.

Specimen Minimum Volume
0.25 mL

Reject Due To

<table>
<thead>
<tr>
<th>Gross hemolysis</th>
<th>Reject</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gross lipemia</td>
<td>OK</td>
</tr>
<tr>
<td>Gross icterus</td>
<td>Reject</td>
</tr>
</tbody>
</table>
Specimen Stability Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum</td>
<td>Refrigerated (preferred)</td>
<td>14 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Frozen</td>
<td>30 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ambient</td>
<td>7 days</td>
<td></td>
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</tbody>
</table>

Clinical and Interpretive

Clinical Information

Cystatin C is a low-molecular weight (13,250 kDa) 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, a high concentration indicates a low GFR, while a lower concentration indicates a higher GFR, similar to creatinine.

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

The serum concentration of cystatin C is not greatly affected by body mass, age, sex, or race. Thus, in certain cases, cystatin C may be a more reliable marker of renal function (GFR) than creatinine.

GFR can be estimated (eGFR) from serum cystatin C utilizing an equation that includes the age and sex 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, much older adults, 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).(2)

The same group also developed an eGFR equation that uses serum creatinine and cystatin C, in addition to age, sex, and race.(1) This equation may be useful to average out potential confounders of creatinine versus cystatin C.

Reference Values

Cystatin C:

18-49 years: 0.63-1.03 mg/L

> or =50 years: 0.67-1.21 mg/L

0-17 years: Reference values have not been established. Refer to estimated glomerular filtration rate (eGFR).

Estimated GFR:

>60 mL/min/BSA
Adult eGFR: Estimated GFR calculated using CKD-EPI Cystatin C equation.\(^{(1)}\)

Pediatric eGFR: Estimated GFR calculated using Schwartz Cystatin C equation.\(^{(1)}\)

**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, older adults, 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 less than 3 months of age.\(^{(3)}\)

**Estimated GFR:**

Chronic kidney disease (CKD) is defined as the presence of: persistent and usually progressive reduction in GFR (GFR <60 mL/min/1.73 m\(^{2}\)) 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 (KDOQI) classification, among patients with CKD, irrespective of diagnosis, the stage of disease should be assigned based on the level of kidney function\(^{(4)}\)

<table>
<thead>
<tr>
<th>Stage</th>
<th>Description</th>
<th>GFR mL/min/BSA</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>Kidney damage with normal or increased GFR</td>
<td>90</td>
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<tr>
<td>2</td>
<td>Kidney damage with mild decrease in GFR</td>
<td>60-89</td>
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<tr>
<td>3A</td>
<td>Mild to moderate decrease in GFR</td>
<td>45-59</td>
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<tr>
<td>3B</td>
<td>Moderate to severe decrease in GFR</td>
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<tr>
<td>4</td>
<td>Severe decrease in GFR</td>
<td>15-29</td>
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<tr>
<td>5</td>
<td>Kidney failure</td>
<td>&lt;15 (or dialysis)</td>
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</tbody>
</table>

**Cautions**

The estimated glomerular filtration rate (eGFR) is not a precise measure of GFR and can be influenced by nonrenal factors such as inflammation.

**Clinical Reference**


**Performance**

**Method Description**

Cystatin C:

Serum samples from patients are mixed with latex particles coated with anti-cystatin C antibodies. Human cystatin C agglutinates with latex particles coated with the anti-cystatin C antibodies. The aggregate is determined turbidimetrically at 546 nm. (Package insert: Tina-quant Cystatin C Gen.2. Roche Diagnostics; 01/2017)


**PDF Report**

No
Test Definition: CSTCE
Cystatin C with Estimated GFR, S

Day(s) Performed
Monday through Sunday

Report Available
Same day/1 to 3 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, approved, or is exempt by the US 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

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<td>Cystatin C with Estimated GFR, S</td>
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<table>
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