**Cystatin C Assay**

Dual Vial Liquid Stable

Cystatin C is an emerging renal Biomarker for eGFR and is recommended as part of the KDIGO 2012 guidelines for the early confirmation and diagnosis of Chronic Kidney Disease (CKD).\(^1\) In addition to confirming CKD at earlier stages than is possible with serum Creatinine, studies suggest that Cystatin C may help facilitate kidney disease screening efforts in the elderly, and those with diabetes, hypertension, or cardiovascular disease.\(^2\)-\(^7\) The Diazyme Cystatin C Assay is a cost effective dual vial liquid stable system which is directly traceable to (ERM/DA471/IFCC) the international standard reference material. The test utilizes Avian IGY antibodies to virtually eliminate some of the most common causes for interference in immunoassay’s.

**Diazyme Cystatin C Assay Advantages**

- Diazyme’s Cystatin C Assay uses Avian IGY antibodies which are not interfered with by rheumatoid and HAMA factors for increased reliability
- The assay is traceable to (ERM/DA471/IFCC) the international standard reference material providing increased accuracy and performance
- Liquid stable reagent, calibrator and controls are offered separately for added convenience
- A wide range of instrument parameters are offered for facilitating and simplifying implementation

**Regulatory Status**

510(k) Cleared

**Available Instrument Specific Packaging**

- Roche
  - Hitachi
- Beckman
  - Synchron
  - AU Series
- Siemens
  - Dimension

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**Innovations in Clinical Diagnostics**
ASSAY PRECISION

The precision of the Diazyme Cystatin C Assay was evaluated according to Clinical Laboratory Standards Institute (formerly NCCLS) EP5-A guideline. In the study, three samples containing Cystatin C were tested on Hitachi 917 2 runs per day in duplicates over 20 working days.

### Within Run Precision ($S_r$)

<table>
<thead>
<tr>
<th>Level</th>
<th>0.9 mg/L Cystatin C</th>
<th>2.5 mg/L Cystatin C</th>
<th>5.4 mg/L Cystatin C</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of Data Points</td>
<td>80</td>
<td>80</td>
<td>80</td>
</tr>
<tr>
<td>Mean (mg/L)</td>
<td>0.91</td>
<td>2.51</td>
<td>5.40</td>
</tr>
<tr>
<td>SD (mg/L)</td>
<td>0.03</td>
<td>0.06</td>
<td>0.11</td>
</tr>
<tr>
<td>CV%</td>
<td>3.5%</td>
<td>2.5%</td>
<td>2.0%</td>
</tr>
</tbody>
</table>

### Within Laboratory Precision ($S_T$)

<table>
<thead>
<tr>
<th>Level</th>
<th>0.9 mg/L Cystatin C</th>
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<tr>
<td>Mean (mg/L)</td>
<td>0.91</td>
<td>2.51</td>
<td>5.40</td>
</tr>
<tr>
<td>SD (mg/L)</td>
<td>0.04</td>
<td>0.08</td>
<td>0.25</td>
</tr>
<tr>
<td>CV%</td>
<td>4.6%</td>
<td>3.0%</td>
<td>4.6%</td>
</tr>
</tbody>
</table>

### ASSAY INTERFERENCE

The following substances do not interfere with this assay at the levels tested (less than 10% bias):

- Hemoglobin: up to 1000 mg/dL
- Bilirubin: up to 40 mg/dL
- Bilirubin Conjugated: up to 40 mg/dL
- Triglycerides: up to 1000 mg/dL
- Ascorbic Acid: up to 176 mg/dL
- Rheumatoid Factor: up to 1000 IU/mL

### ASSAY REFERENCE RANGE

The reference interval is 0.5 - 1.03 mg/L. However, each laboratory is recommended to establish a range of normal values for the population in their region.

### Cystatin C Assay Procedure