**INTENDED USE:**

In Vitro Diagnostic reagent pack for the quantitative determination of Cystatin C in serum and plasma on automated and semi-automated analysers.

**SUMMARY AND EXPLANATION:**

Cystatin C is a basic proteinase inhibitor with a low molecular mass of 13KDa that is produced at a constant rate in all nucleated cells and appears in human plasma and serum. Cystatin C is freely filtered through the glomerulus, is not secreted by the tubule or eliminated via any extra-renal route, and is almost completely absorbed and catabolized by proximal tubular cells. Therefore, the plasma concentration of Cystatin C is almost exclusively determined by the glomerular filtration rate (GFR), making Cystatin C an excellent indicator of GFR. Cystatin C has advantages over routine clinical measures of renal function. It is more accurate than plasma creatinine and the Cockroft-Gault estimation of creatinine clearance and is more reliable than the 24-h creatinine clearance. There is a growing body of evidence that suggests that it is recommended to follow GLS procedures (or similar standardized conditions) regarding specimen handling. Specimen should be collected in an appropriate sampling container, with proper specimen identification. Serum/Plasma should be separated from cells within 2 hours after collection.

**PRODUCT SPECIFICATIONS:**

<table>
<thead>
<tr>
<th>Cat. No.</th>
<th>Quantity</th>
<th>Reagent</th>
<th>Storage</th>
</tr>
</thead>
<tbody>
<tr>
<td>GL1103CC</td>
<td>1 x 100 ml</td>
<td>Reagent 1</td>
<td>2 – 8 °C</td>
</tr>
<tr>
<td></td>
<td>1 x 20 ml</td>
<td>Reagent 2</td>
<td></td>
</tr>
</tbody>
</table>

**COMPONENT COMPOSITION:**

<table>
<thead>
<tr>
<th>Component</th>
<th>Ingredients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reagent 1 Buffer</td>
<td>30 ml of Tris Buffer solution (pH 7.2), containing detergents, polyethylene glycol and 0.5% sodium azide as preservative</td>
</tr>
<tr>
<td>Reagent 2 Latex</td>
<td>5 ml of Polystyrene particles (0.5%) coated with antibodies anti-human Cystatin C serum in a glycine buffer (0.1M, pH 2.0) containing NaCl (10.15%) and bovine serum albumin (0.5%), preservative: sodium azide 0.075%</td>
</tr>
</tbody>
</table>

**TABLE:**

- **Calibrator**

<table>
<thead>
<tr>
<th>Description</th>
<th>Catlog No</th>
<th>Description</th>
<th>Catlog No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cystatin C Control set</td>
<td>GL9110</td>
<td>Photorimeter</td>
<td>N/A</td>
</tr>
<tr>
<td>Cystatin C Calibrator (5 Levels)</td>
<td>GL9107</td>
<td>General Laboratory Equipment</td>
<td>N/A</td>
</tr>
</tbody>
</table>

**TEST PROCEDURE:**

- **Materials required but not supplied:**
  - Reagents containing Sodium azide must be handled with precaution. Sodium azide can form explosive compounds when heated with organic material.
  - Take the necessary precautions required for handling all laboratory reagents.
  - Reagents containing Sodium azide must be handled with precaution. Sodium azide can form explosive azides with lead and copper plumbing.
  - Do not ingest.
  - Avoid contact with skin and eyes.
  - Do not use components past the expiry date stated on the Bottles.
  - Do not freeze Reagents.
  - Do not use components for any purpose other than described in the "Intended Use" section.
  - Do not interchange caps among components as contamination may occur and compromise test results.
  - Refer to local legal requirements for safe waste disposal.

**INSTRUMENTS:**

- Instrument applications are available upon request.

**COMPONENT COMPOSITION:**

- **Component**

  - **Ingredients**

**ESPECTED VALUES:**

- The reference interval is 0.59 – 1.03 mg/L are considered within the normal range. Each laboratory should establish its own reference ranges. Results should always be reviewed with the patient’s medical examination and history.

**PERFORMANCE CHARACTERISTICS:**

- Performance results can vary with the instrument used. Data obtained in each individual laboratory may differ from these values.

- **Linearity:**
  - Linearity was evaluated using serial dilutions, prepared with saline solution, of three pooled samples, which contained values of Cystatin C in the range of analysis, ranging from 0.05 to 8mg/L. Linear regression values of Cystatin C mg/L vs. concentration yielded correlation coefficients, r > 0.999, for all samples. Within the assay's measuring range, the deviations of measurement from theoretical values did not exceed the 10% level. In addition, the system did not show prozone phenomenon at least up to 16mg/L.

- **Interfering substances:**
  - Results of studies are as follows: Bilirubin: Less than 10% interference up to 18 mg/dL.
  - Haemoglobin: Less than 10% interference up to 5g/L

**Method Comparison:**

- Various concentrations of Cystatin C (0.5 – 8.0mg/L) were added to 43 different serum samples. The linear regression gives correlation of r value of 0.98, slope of 0.97 and r-intercept of 0.05.

**BIBLIOGRAPHY:**


**SYMBOLS:**

The following symbols are used in the labelling of Glenbio Ltd. systems:

- **N.D.** Not detected
- **LOQ** Limit of Quantification
- **RE** Reference
- **CAL** Calibrator
- **BUF** Buffer
- **CT** Content
- **REF** Reference
- **REF** Reference
- **LOT** Lot Code
- **SUB** Substrate
- **B** Buffer
- **M** Mark
- **G** GLN - Glenbio Ltd.