Diazyme’s Homocysteine 3 Reagent Enzymatic Assay features convenient ready to use reagent, calibrators and controls for the quantitative determination of total L-homocysteine in serum or plasma. Diazyme’s proprietary Enzyme Cycling methodology is an excellent choice for cost conscious laboratories of all sizes due to a wide variety of instrument specific packaging options. The assay requires minimal patient sample and provides fast, accurate and precise results. A wide variety of reliable instrument parameters means the assay is readily available for installation on most automated clinical chemistry analyzers.

**DIAZYME HOMOCYSTEINE 3 REAGENT ASSAY ADVANTAGES**

- Award winning Homocysteine recognized by the American Association of Clinical Chemistry (AACC) for outstanding contribution to scientific research
- Innovative enzyme cycling based technology for accurate and reliable results
- Excellent correlation to HPLC and immunochemical methods
- No “carry over” issues with iron or lipase reagents
- Test renal patients with confidence since there is no interference from cystathionine which affects some other less specific methods
- Wide range of instrument parameters available for facilitating and simplifying implementation
- Liquid stable format requires no reagent preparation saving time and reducing sample handling

**REGULATORY STATUS**

- 510(k) Cleared
- Health Canada Registered
- CE

**AVAILABLE INSTRUMENT SPECIFIC PACKAGING**

- **Roche**
  - Modular P
  - Integra
  - Cobas
  - Hitachi
- **Beckman**
  - Synchron
- **Siemens**
  - Dimension
ASSAY PRECISION

Precision studies were conducted according to the NCCLS EP-5 protocol. Within precisions (CV%) for three levels of Hcy controls are 2.2% for 7 μM Hcy, 3.0% for 12 μM Hcy and 1.8% for 29.5 μM Hcy. Total imprecision for three levels of Hcy controls are 4.1% for 7 μM Hcy, 5.9% for 12 μM Hcy and 4.0% for 29.5 μM Hcy.

<table>
<thead>
<tr>
<th>HCY Concentration</th>
<th>7 μM N = 40</th>
<th>12 μM N = 80</th>
<th>29.5 μM N = 80</th>
</tr>
</thead>
<tbody>
<tr>
<td>Within-Run Imprecision CV%</td>
<td>2.2</td>
<td>3.0</td>
<td>1.8</td>
</tr>
<tr>
<td>Total Imprecision CV%</td>
<td>4.1</td>
<td>5.9</td>
<td>4.0</td>
</tr>
</tbody>
</table>

ASSAY INTERFERENCE

An interference study was performed by testing a serum sample spiked with varied concentrations of endogenous substances. The following substances normally present in the serum produced less than 10% deviation when tested at the stated concentrations:

- NH4Cl: 500 μM
- NaPi: 1 mM
- NaF: 1 mM
- Triglycerides: 2500 mg/dL
- Bilirubin: 20 mg/dL
- Hemoglobin: 1200 mg/dL
- *Glutathione: 0.5 mM
- Ascorbic Acid: 10 mM
- L-Cysteine: 1 mM
- S-Adenosylmethionine (SAM): 20 μM
- **Adenosine: 100 μM
- **Cystathionine: 100 μM

* Glutathione was originally tested at 1 mM level, the interference was +13.5%. When retested at 0.5 mM level, the interference was less than 10%.
** The concentrations tested are about 5-10 times higher than the normal range of serum levels.

REFERENCE RANGE

In most of the U.S. clinical laboratories, 15 μmol/L is used as the cut-off value for normal level of Hcy for adults. In Europe, 12 μmol/L is used as the cut-off value. However, each laboratory is recommended to establish a range of normal values for the population in their region.

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