Diazyme’s Homocysteine 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 required minimal patient sample volume and provides fast, accurate and precise results.

**DIAZYME HOMOCYSTEINE ASSAY ADVANTAGES**

- Award winning Homocysteine enzymatic assay recognized by the American Association of Clinical Chemistry (AACC)
- 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
- Available in 2 or 3 reagent format
- Liquid stable format requires no reagent preparation
- Wide range of instrument parameters available for simplifying implementation

**REGULATORY STATUS**

510(k) Cleared; EU: [CE];
Health Canada Registered
ASSAY SPECIFICATIONS

<table>
<thead>
<tr>
<th>Method</th>
<th>Diazyme Patented Enzyme Cycling</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample Type &amp; Volume</td>
<td>Serum, Plasma, - EDTA, - Li-heparin</td>
</tr>
<tr>
<td></td>
<td>Sample Volume 13 μL</td>
</tr>
<tr>
<td>Method Correlation</td>
<td>N = 40 y-intercept = 1.05 Slope = 0.94 R² = 0.99</td>
</tr>
<tr>
<td>Linearity</td>
<td>Up to 50 μmol/L</td>
</tr>
<tr>
<td>LOD</td>
<td>0.4 μmol/L</td>
</tr>
<tr>
<td>Calibration Levels</td>
<td>5-Point Calibration</td>
</tr>
<tr>
<td>Reagent On-Board Stability*</td>
<td>Opened: At least 60 days when stored at 2-8°C</td>
</tr>
</tbody>
</table>

Precision studies were tested with HCY Enzymatic Assay on OLYMPUS AU400

*Analyzer Dependent

Parameter questions for Homocysteine Enzymatic Assay should be addressed to Diazyme technical support. Please call 858.455.4768 or email support@diazyme.com

ASSAY PRECISION

Precision studies were conducted according to the NCCLS EP-5 protocol. Four HCY serum samples containing 7.0, 12.0, 15.6 and 29.0 μM HCY were tested.

<table>
<thead>
<tr>
<th>HCY Concentration</th>
<th>7 μM</th>
<th>12 μM</th>
<th>15.6 μM</th>
<th>29 μM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Within-Run Imprecision CV% N = 20</td>
<td>4.5</td>
<td>1.87</td>
<td>3.04</td>
<td>2.4</td>
</tr>
<tr>
<td>Total Imprecision CV% N = 30</td>
<td>5.87</td>
<td>4.88</td>
<td>5.51</td>
<td>2.57</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:

- Bilirubin: 40 mg/dL
- Triglycerides: 1000 mg/dL
- Hemoglobin: 500 mg/dL
- Bilirubin Conjugate: 40 mg/dL
- Ascorbic Acid: 10 mM
- Cystathionine: 100 μM**

**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.¹ ² 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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