Diazyme’s Homocysteine 2 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 2 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

**Available Instrument Specific Packaging**

- Roche
  - Hitachi
- Beckman
  - AU Series
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.

**ASSAY SPECIFICATIONS**

<table>
<thead>
<tr>
<th>Method</th>
<th>Diazyme Patented Enzyme Cycling</th>
</tr>
</thead>
</table>
| Sample Type & Volume | • Serum  
- EDTA  
- Li-heparin  
Sample Volume 13 µL |
| Method Correlation | N = 40  
y-intercept = 1.05  
Slope = 0.94  
R² = 0.99 |
| Linear Range | Up to 50 µmol/L |
| LOD | 0.4 µmol/L |
| Calibration Levels | 5-Point Calibration |
| Reagent On-Board Stability | Opened:  
At least 60 days (Analyzer Dependent) |

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**Homocysteine 2 Reagent Assay Procedure***

R1: 240 µL  
Sample: 13 µL  
37°C  
340 nm  
5 min  
7.5 min  
10 min  
A1  
A2

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**Two Reagent System**

Parameter questions for Enzymatic Homocysteine 2 Reagent Assay should be addressed to Diazyme technical support. Please call 858.455.4768 or email support@diazyme.com