**Sensitivity: The lower limit of detection is 0.4 µmol/L.**

Elevated levels of tHcy are also linked with Alzheimer’s and result in inflammation and plaque formation, which may cause injuries to arterial vessels due to its irritant nature, disease [1-3]. Excess homocysteine (Hcy) in the bloodstream has emerged as an important risk factor in the assessment of cardiovascular disease [4,5].

**Elevated level of total Homocysteine (tHcy) has emerged as an important risk factor in the assessment of cardiovascular disease [1-3].** Excess homocysteine (Hcy) in the bloodstream has emerged as an important risk factor in the assessment of cardiovascular disease. The test has been developed to determine homocysteine concentrations within a measuring range from 3 – 50 µmol/L. Samples with values higher than 50 µmol/L should be diluted 1:2 with distilled water and rerun. Multiply results by 2.

**TEST PRINCIPLE**

\[ \text{Hcy} + \text{SAM} \rightarrow \text{Methionine} + \text{SAH} \]

<table>
<thead>
<tr>
<th>COMPONENTS</th>
<th>CONCENTRATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>S-Adenosylmethionine (SAM)</td>
<td>0.1 mM</td>
</tr>
<tr>
<td>NADH</td>
<td>&gt; 0.2 mM</td>
</tr>
<tr>
<td>TCEP</td>
<td>&gt; 0.5 mM</td>
</tr>
<tr>
<td>2-Oxoglutarate</td>
<td>5.0 mM</td>
</tr>
<tr>
<td>Glutamate dehydrogenase</td>
<td>10 KU/L</td>
</tr>
<tr>
<td>SAH hydrolase</td>
<td>3.0 KU/L</td>
</tr>
<tr>
<td>Adenosine deaminase</td>
<td>5.0 KU/L</td>
</tr>
<tr>
<td>Hcy methyltransferase</td>
<td>5.0 KU/L</td>
</tr>
</tbody>
</table>

**TESTPREPARATION**

The reagents are ready to use.

**REAGENT STABILITY AND STORAGE**

Conditions: Protect from light. Close immediately after use. Avoid contamination. Do not freeze!

Storage: at 2 – 8 °C

Stability: Up to the expiration date

Discard hemolysed, turbid or severely lipemic specimens.

**SAMPLE STABILITY AND STORAGE**

Serum, Heparin plasma, or EDTA plasma can be used in the Homocysteine assay. Centrifuge blood sample immediately after collection! If immediate centrifugation is not possible, collected blood specimens should be kept on ice and centrifuged within an hour.

**SAMPLE COLLECTION AND HANDLING**

Addition of 3-deazaadenosine to inhibit Hcy production in red cells has been suggested. However, the DIALAB Hcy assay cannot use samples containing 3-deazaadenosine since it inhibits one of the key enzymes used in the assay.

**REF**

Phone: +43 (0) 2236 660910-0, Fax: +43 (0) 2236 660910-30, e-mail: office@dialab.at

Hondastrasse, Objekt M55, IZ NOE-Sued, 2351 Wiener Neudorf, Austria.
### Precision

#### Within run precision, n=20

<table>
<thead>
<tr>
<th>Sample</th>
<th>Mean [µmol/L]</th>
<th>SD [µmol/L]</th>
<th>CV [%]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample 1</td>
<td>7.08</td>
<td>0.33</td>
<td>4.61</td>
</tr>
<tr>
<td>Sample 2</td>
<td>12.4</td>
<td>0.24</td>
<td>1.91</td>
</tr>
<tr>
<td>Sample 3</td>
<td>16.2</td>
<td>0.51</td>
<td>3.12</td>
</tr>
<tr>
<td>Sample 4</td>
<td>26.9</td>
<td>0.66</td>
<td>2.47</td>
</tr>
</tbody>
</table>

#### Inter run precision, n=30

<table>
<thead>
<tr>
<th>Sample</th>
<th>Mean [µmol/L]</th>
<th>SD [µmol/L]</th>
<th>CV [%]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample 1</td>
<td>7.32</td>
<td>0.44</td>
<td>5.98</td>
</tr>
<tr>
<td>Sample 2</td>
<td>11.3</td>
<td>0.57</td>
<td>5.08</td>
</tr>
<tr>
<td>Sample 3</td>
<td>14.4</td>
<td>0.81</td>
<td>5.61</td>
</tr>
<tr>
<td>Sample 4</td>
<td>27.7</td>
<td>0.72</td>
<td>2.61</td>
</tr>
</tbody>
</table>

### Specificity/Interferences

The following substances normally present in the serum produced less than 10% deviation when tested at levels equal to the concentrations listed below.

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

Patients who are taking methotrexate, carbamazepine, phenytoin, nitrous oxide, anticonvulsants, or 6-azauridine triacetate may have higher levels of homocysteine due to metabolic interference with homocysteine metabolism.

S-adenosylhomocysteine (SAH) will cause a significant positive interference. However, SAH is either not detectable or at very low concentrations in normal plasma and should not cause concern.

Automated chemistry analyzers use on-board routine wash steps to prevent reagent carry-over by reagent probes. However, the efficiency of the routine reagent probe wash varies and additional wash steps may be needed.

### Method Comparison

Correlation studies were performed by testing 40 serum samples in comparison with an existing commercial Hcy assay method. Linear regression gives the following equation:

\[ y = 0.94 \times + 1.05; R^2 = 0.99 \]

### Calibration

The assay requires the use of an Homocysteine Standard or Calibrator.

We recommend the Dialab Homocysteine Calibrator Set (5 levels).

### Quality Control

Homocysteine controls should be used to validate the performance of Hcy reagents.

We recommend the Dialab Homocysteine Control Set (4 levels).

Each laboratory should establish corrective action in case of deviations in control recovery.

### Automation

Special adaptations for automated analyzers can be made on request.

### WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic use by suitably qualified laboratory personnel only.
2. Do not ingest! Avoid contact with skin, eyes and mucous membranes.
3. Contains sodium azide which may react with lead or copper plumbing to form explosive compounds. Flush drains with copious amounts of water when disposing of this reagent.
4. Do not mix reagents of different lots.
5. Take the necessary precautions for the use of laboratory reagents.
6. Additional safety information concerning storage and handling of this product is provided within the Material Safety Data Sheet for this product.

### Waste Management

Please refer to local legal requirements.

### REFERENCES