Diazyme’s Folate Assay is a cost effective four vial liquid stable reagent system intended for the in vitro quantitative determination of folate in human serum on automated chemistry analyzers. Folate deficiency can be caused by low dietary intake, malabsorption due to gastrointestinal diseases, inadequate utilization due to enzyme deficiencies or folate antagonist therapy, drugs such as alcohol and oral contraceptives, and excessive folate demand, such as during pregnancy. Because deficiencies of both vitamin B12 and folate can lead to megaloblastic (macrocytic) anemia, appropriate treatment requires differential diagnosis of the deficiency; thus, both vitamin B12 and folate values are needed.¹⁻⁸

**DIAZYME FOLATE ASSAY ADVANTAGES**

- Improves Laboratory efficiency and workflow
- Fast test results for a rapid turnaround time
- 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

**AVAILABLE INSTRUMENT SPECIFIC PACKAGING**

- Roche
  - Hitachi
**ASSAY PRECISION**

The precision of the Diazyme Folate Assay was evaluated according to CLSI EP5-A2 guideline. In the study, eight serum samples and 2 levels of serum based controls were tested in duplicates per run, 2 runs per day for 20 days.

<table>
<thead>
<tr>
<th>Samples</th>
<th>Mean ng/mL</th>
<th>Within-Run (SD, %CV)</th>
<th>Between-Run (SD, %CV)</th>
<th>Total (SD, %CV)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum 1</td>
<td>3.4</td>
<td>0.2, 6.4%</td>
<td>0.1, 1.7%</td>
<td>0.2, 7.2%</td>
</tr>
<tr>
<td>Serum 2</td>
<td>4.8</td>
<td>0.2, 4.6%</td>
<td>0.1, 4.5%</td>
<td>0.4, 7.4%</td>
</tr>
<tr>
<td>Serum 3</td>
<td>5.8</td>
<td>0.3, 4.9%</td>
<td>0.2, 3.3%</td>
<td>0.4, 7.5%</td>
</tr>
<tr>
<td>Serum 4</td>
<td>8.9</td>
<td>0.4, 4.1%</td>
<td>0.4, 4.0%</td>
<td>0.6, 6.4%</td>
</tr>
<tr>
<td>Serum 5</td>
<td>12.3</td>
<td>0.5, 3.9%</td>
<td>0.4, 4.3%</td>
<td>0.7, 5.8%</td>
</tr>
<tr>
<td>Serum 6</td>
<td>16.1</td>
<td>0.6, 3.8%</td>
<td>0.5, 3.5%</td>
<td>0.8, 5.4%</td>
</tr>
<tr>
<td>Serum 7</td>
<td>16.8</td>
<td>0.8, 4.6%</td>
<td>0.5, 2.6%</td>
<td>1.1, 6.8%</td>
</tr>
<tr>
<td>Con 1</td>
<td>4.4</td>
<td>0.2, 3.7%</td>
<td>0.2, 4.3%</td>
<td>0.3, 7.4%</td>
</tr>
<tr>
<td>Con 2</td>
<td>11.2</td>
<td>0.5, 4.5%</td>
<td>0.4, 3.9%</td>
<td>0.8, 7.0%</td>
</tr>
</tbody>
</table>

**ASSAY INTERFERENCE**

To determine the level of interference from the substances present in plasma, the Diazyme Folate Assay was used to test three human serum samples with “low”, “medium”, and “high” Folate concentrations spiked with various concentrations of endogenous substances following the CLSI EP7-A2. The following endogenous substances do not interfere with this assay at the levels tested (less than 10% bias).

- Ascorbic Acid: 44 mg/dL
- Bilirubin: 15 mg/dL
- Bilirubin Conjugated: 7.5 mg/dL
- Hemoglobin: 200 mg/dL
- Triglycerides: 1000 mg/dL

The following common therapeutic substances showed no significant interference (< ± 10%) up to the concentrations summarized below.

- acetylsalicylic Acid: 1000 mg/L
- metronidazole: 200 mg/L
- theophylline: 10 mg/L
- phenylbutazone: 40 mg/L
- acetylaminoophen: 200 mg/L
- cefoxitin: 660 mg/L
- acetylcyostein: 566 mg/L
- rifampicin: 60 mg/L

The following across-reactivities were found:

- amethopterin: 9.3%
- aminopterin: 3.9%
- folic acid: 7.8%