Diazyme’s Vitamin B12 Assay is a cost effective four vial liquid stable reagent system intended for the in vitro quantitative determination of Vitamin B12 in human serum on automated chemistry analyzers (Roche’s Modular P and similar). Measurement of Vitamin B12 is for the assessment of Vitamin B12 sufficiency. Deficiencies in Vitamin B12 have been linked to specific forms of anemia, neurological complications and dementia.¹⁻⁵

**DIAZYMÉ VITAMIN B12 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

Precision of the Diazyme vitamin B12 assay was evaluated according to the CLSI EPS-A2 guideline on the Roche Modular P analyzer. In the study, three lots of reagents were used. For each reagent lot, 2 vitamin B12 controls (C1-2) and 10 vitamin B12 human serum samples (S1-10) were tested at the rate of two runs per day, 2 replicates per run over a period of time corresponding to 20 working days.

<table>
<thead>
<tr>
<th>Method correlation</th>
<th>Linearity</th>
<th>LOD</th>
<th>LOQ</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regular Regression: N = 99 y-intercept = -5.77 pg/mL Slope = 0.969 R² = 0.969</td>
<td>Up to 2000 pg/mL</td>
<td>63.3 pg/mL</td>
<td>30.6 pg/mL</td>
</tr>
<tr>
<td>Sample Range: 123.0 to 1969.0 pg/mL</td>
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</tr>
</tbody>
</table>

**Calibration Levels**

5-Point Calibration

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**Reagent On-Board Stability**

Opened: 4 days on board analyzer

**Vitamin B12 Assay Procedure**

For a list of validated parameters please contact Diazyme technical support at 858-455-4768 or email support@diazyme.com