

VITAMIN B12 ASSAY

Four Vial Liquid Stable

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

DIAZYME VITAMIN B12 ASSAY ADVANTAGES

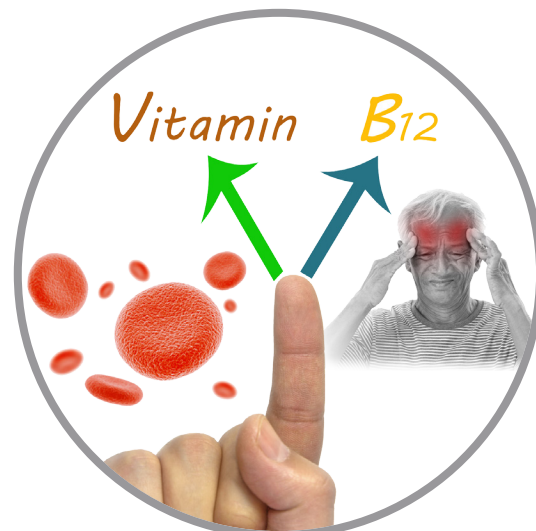
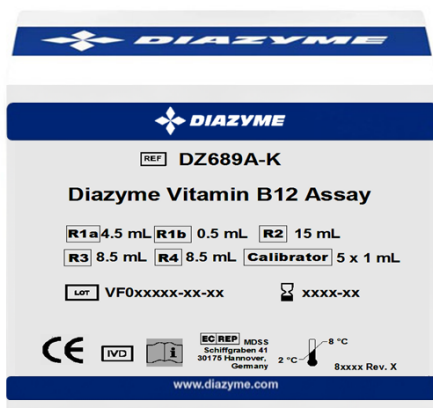
- Improves laboratory efficiency and workflow
- Fast test results for a rapid turnaround time
- Wide range of instrument parameters available for facilitating and simplifying implementation
- Liquid stable format requires no reagent preparation, saving time and reducing sample handling

REGULATORY STATUS

510(k) Cleared 

AVAILABLE INSTRUMENT SPECIFIC PACKAGING

- Roche
- Hitachi



VITAMIN B12 ASSAY

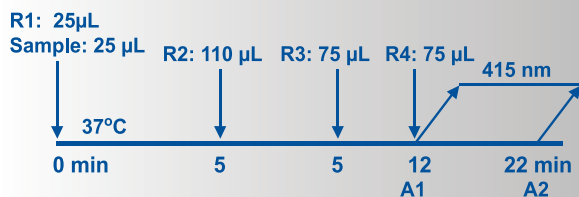
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ASSAY SPECIFICATIONS

Method	FemtoQuant™ Enzyme Immunoassay
Sample Type & Volume	• Human Serum Sample Volume 25 µL
Method Correlation	Regular Regression: N = 99 y-intercept = -5.77 pg/mL Slope = 0.969 R ² = 0.969 Sample Range: 123.0 to 1969.0 pg/mL
Linearity	Up to 2000 pg/mL
LOD LOB LOQ	63.3 pg/mL 30.6 pg/mL 96.7 pg/mL
Calibration Levels	5-Point Calibration
Reagent On-Board Stability	Opened: 4 days on board analyzer

Vitamin B12 Assay Procedure*



*Analyzer Dependent

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

1. Dai Z, Koh WP. B-vitamins and bone health—a review of the current evidence. *HYPERLINK "http://www.ncbi.nlm.nih.gov/pubmed/24494042" to "Dermato-endocrinology."*, 2015, 7, 3322-46.
2. Hunt A, Harrington D, Robinson S. Vitamin B12 deficiency. *BMJ*, 2014, 349, 5226.
3. Yamada K. Cobalt: its role in health and disease. *Met Ions Life Sci.*, 2013, 13, 295-320.
4. Kumar N. Neurologic aspects of cobalamin (B12) deficiency. *Handb Clin Neurol.*, 2014, 120, 915-26.
5. Chawla J, Kvamberg D. Hydrosoluble vitamins. *Handb Clin Neurol.*, 2014;120:891-914.

ASSAY PRECISION

Precision of the Diazyme vitamin B12 assay was evaluated according to the CLSI EP5-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.

	Mean pg/mL	Within-Run		Between-Run		Total	
		SD	%CV	SD	%CV	SD	%CV
C1	249.2	18.8	7.5%	8.2	3.3%	22.4	9.0%
C2	488.0	23.1	4.7%	13.7	2.8%	28.4	5.8%
S1	243.6	19.9	8.2%	6.7	2.8%	22.6	9.3%
S2	346.2	20.4	5.9%	14.7	4.2%	25.1	7.3%
S3	541.1	35.2	6.5%	3.3	0.6%	38.7	7.2%
S4	741.3	26.3	3.5%	25.9	3.5%	41.1	5.5%
S5	961.3	30.9	3.2%	26.4	2.7%	41.0	4.3%
S6	1166.6	31.7	2.7%	25.5	2.2%	43.7	3.7%
S7	1385.0	39.0	2.8%	35.2	2.5%	52.7	3.8%
S8	1572.1	37.4	2.4%	4.6	2.6%	55.2	3.5%
S9	1743.5	40.3	2.3%	37.9	2.2%	62.0	3.6%
S10	1883.6	42.6	2.3%	39.9	2.1%	58.4	3.1%

ASSAY INTERFERENCE

Interference studies were conducted according to the CLSI EP7-A2 guidelines. The acceptance criterion was set at 10% or less deviation between the spiked sample and the control. The assay's results were not significantly affected by the following substances:

Acetaminophen:	20.0 mg/dL	Hemoglobin:	200 mg/dL
Acetyl salicylic acid:	60.0 mg/dL	Heparin:	3.0 U/mL
Ampicillin:	5.3 mg/dL	Ibuprofen:	50.0 mg/dL
Ascorbic acid:	176 mg/dL	Lidocaine:	1.2 mg/dL
Biotin:	100.0 ng/mL	Lithium acetate:	2.2 mg/dL
Carbamazepine:	3.0 mg/dL	Noradrenalin:	4.0 µg/mL
Cefotaxime:	180.0 mg/dL	Rifampicin:	5.0 mg/dL
Chloramphenicol:	5.0 mg/dL	Theophylline:	4.0 mg/dL
Conjugated bilirubin:	20 mg/dL	Total protein:	8.5 g/dL
Creatinine:	30.0 mg/dL	Triglycerides:	450 mg/dL
Digoxin:	6.1 ng/mL	Urea:	300.0 mg/dL
Ethanol:	400.0 mg/dL	Uric acid:	20.0 mg/dL
Ethosuximide:	25.0 mg/dL	Valproic acid:	50.0 mg/dL
Free bilirubin:	20 mg/dL	Vancomycin:	10.0 mg/dL
Furosemide:	6.0 mg/dL		

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