DIAZYME LABORATORIES

FOLATE ASSAY

Four Vial Liquid Stable

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

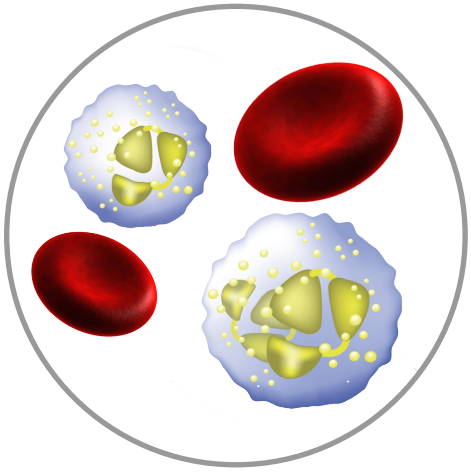
REGULATORY STATUS

510(k) Cleared

CE

AVAILABLE INSTRUMENT SPECIFIC PACKAGING

- **Roche**
  - Hitachi



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ASSAY SPECIFICATIONS

Method	FemtoQuant™ Enzyme Immunoassay
Sample Type & Volume	• Serum Sample Volume 25 µL
Method Correlation	Linear Regression: N = 141 y-intercept = 0.287 Slope = 0.941 R^2 = 0.968 Sample Range: 2.07-19.85
Linearity	Up to 20.00 ng/mL
LOD LOB LOQ	0.91 ng/mL 0.27 ng/mL 2.0 ng/mL
Calibration Levels	5-Point Calibration
On-Board Stability	Opened: 4 days when stored at 2-8°C

*Folate 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. *Steinberg SE. Mechanisms of folate homeostasis. Am J Physiol 1984; 246(9):G319-24.*
2. *Appling DR. Compartmentation of folate-mediated one-carbon metabolism in eukaryotes. FASEB J 1991; 5(12):2645-51.*
3. *Burtis CA, Ashwood ER, eds. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia, PA: WB Saunders;1999:1693-5.*
4. *McPherson RA, Pincus MR, eds. Erythrocytic Disorders. Henry's Clinical Diagnosis and Management. 21st ed. Philadelphia, PA: WB Saunders; 2006:(31).*
5. *Kones R. Folic acid, 1991: an update, with new recommended daily allowances. South Med J 1990; 83(12):1454-8.*
6. *Spiegelstein, O., Lu, X., Le, X.C., Troen, A., Selhub, J., Melnyk, S., James, S.J. and Finnell, R.H. 2003. Effects of dietary folate intake and folate binding protein-1 (Folbp1) on urinary speciation of sodium arsenate in mice. Toxicol. Lett. 145: 167-174. 55: 13-36.*
7. *Mangoni, A.A. 2006. Folic acid, inflammation, and atherosclerosis: false hopes or the need for better trials? Clin. Chim. Acta 367: 11-19.*
8. *Reynolds, E. 2006. Vitamin B12, folic acid, and the nervous system. Lancet Neurol. 5: 949-960.*

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.

Samples	Mean ng/mL	Within-Run (SD, %CV)	Between-Run (SD, %CV)	Total (SD, %CV)
Serum 1	3.4	0.2, 6.4%	0.1, 1.7%	0.2, 7.2%
Serum 2	4.8	0.2, 4.6%	0.1, 4.5%	0.4, 7.4%
Serum 3	5.8	0.3, 4.9%	0.2, 3.3%	0.4, 7.5%
Serum 4	8.9	0.4, 4.1%	0.4, 4.0%	0.6, 6.4%
Serum 5	12.3	0.5, 3.9%	0.4, 4.3%	0.7, 5.8%
Serum 6	15.1	0.6, 3.8%	0.5, 3.5%	0.8, 5.4%
Serum 7	16.8	0.8, 4.6%	0.5, 2.8%	1.1, 6.8%
Con 1	4.4	0.2, 3.7%	0.2, 4.3%	0.3, 7.4%
Con 2	11.2	0.5, 4.5%	0.4, 3.9%	0.8, 7.0%

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 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	ibuprofen:	50 mg/L
metronidazole:	200 mg/L	ampicillin-Na:	1000 mg/L
theophylline:	10 mg/L	cyclosporine:	5 mg/L
phenylbutazone:	40 mg/L	doxycyclin:	50 mg/L
acetaminophen:	200 mg/L	levodopa:	20 mg/L
cefoxitin:	660 mg/L	methyldopa:	20 mg/L
acetylcystein:	566 mg/L		
rifampicin:	60 mg/L		

The following across-reactivities were found:

amethopterin:	9.3%
aminopterin:	3.9%
folinic acid:	7.8%

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