

FIBRINOGEN ASSAY



Coagulation
Marker

The Fibrinogen Assay is ideally suited to meet the growing demands of clinical laboratories requiring high throughput, precise test results. Published studies show Fibrinogen measurement has increased beyond its original limited role in coagulation to encompass a wide range of clinical conditions associated with elevated levels of fibrinogen including inflammation, trauma, surgery and pregnancy.¹⁻⁵

Diazyme's Fibrinogen Assay is a cost effective dual vial liquid stable immunoturbidimetric reagent system intended for the *in vitro* quantitative determination of fibrinogen levels in citrated human plasma.

DIAZYME FIBRINOGEN ASSAY ADVANTAGES

- Diazyme's immunoturbidimetric method improves analytical performance by measuring fibrinogen antigen
- Assay is traceable to WHO reference materials 09/242
- Measuring range: 100 to 900 mg/dL
- Fast test results (10 minutes) for a rapid turnaround time
- Liquid stable format requires no reagent preparation
- Wide range of instrument parameters available for simplifying implementation

REGULATORY STATUS

510(k) Cleared

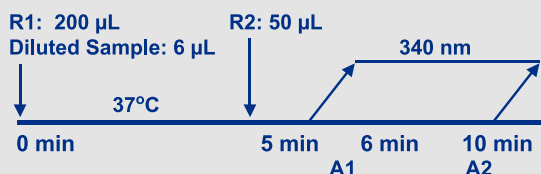
FIBRINOGEN ASSAY

Dual Vial
Liquid Stable

ASSAY SPECIFICATIONS

Method	Immunoturbidimetric Assay
Sample Type & Volume	Citrated human plasma 6 µL The sample is diluted 1:20 with saline
Method Correlation	Deming Regression: (Total of 3 sites) N = 176 y-intercept = 1.80 Slope = 0.989 R ² = 0.9973 Sample Range: 107.5-870.0
Linearity	100 to 900 mg/dL
LOB	2.2 mg/dL
LOD	5.1 mg/dL
LOQ	12.9 mg/dL
Calibration Levels	3-Point Calibration
Reagent On-Board Stability	Opened: 20 days when stored at 2-8°C

Fibrinogen Assay Procedure*



*Analyzer Dependent

Parameter questions for Fibrinogen Assay should be addressed to Diazyme technical support. Please call 858.455.4768 or email support@diazyme.com

1. Reinhart W, "Fibrinogen – marker or mediator for vascular disease." *Vascular Medicine*. 2003; 8: 211-216.
2. Wu, Alan H. B. *Tietz Clinical Guide to Laboratory Tests, Fourth Edition*, 2005.
3. Verhovsek M, Moffat K, Hayward G. Laboratory testing for fibrinogen abnormalities. *American Journal of Hematology*; 2008.
4. Acharya S, Dimichele DM (November 2008). "Rare inherited disorders of fibrinogen". *Haemophilia : the Official Journal of the World Federation of Hemophilia* 14 (6): 1151-8.
5. Page RC, Schroeder HE (March 1976). "Pathogenesis of inflammatory peri-odontal disease. A summary of current work". *Lab. Invest.* 34 (3): 235-49.

ASSAY PRECISION

The precision of the Diazyme Fibrinogen Assay was evaluated according to CLSI EP5-A2 guidelines. In the study, 6 citrated plasma samples containing at least one sample close to the very low end of the AMR and one sample close to the very high end of the AMR were tested with 2 runs per day in duplicates over 20 working days with three lots of reagents.

Sample	N	Mean (mg/dL)	Within-Run (CV %)	Between-Run (CV %)	Between-Lot (CV %)	Between-Day (CV %)	Total (CV %)
P1	240	453.4	2	2	4	2	5
P2	240	333.4	2	2	3	2	5
P3	240	208.6	1	2	3	2	5
P4	240	107.3	2	2	3	3	5
P5	240	706.8	2	2	4	3	5
P6	240	823.9	2	2	4	3	5

ASSAY INTERFERENCE

To determine the level of interference from the substances present in plasma, the Diazyme Fibrinogen Assay was used to test three plasma samples with "low", "medium", and "high" Fibrinogen 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:	176 mg/dL	Hemoglobin:	1000 mg/dL
Bilirubin:	40 mg/dL	Rheumatoid Factor:	220 IU/mL
Bilirubin Conjugated:	40 mg/dL	Triglycerides:	1000 mg/dL

The common therapeutic substances of Acetylsalicylic Acid, Na2-Cefoxitin, Ibuprofen, fibrin degradation product and coagulation inhibitors such as warfarin, dabigatran, hirudin, rivaroxaban, and argatroban, heparin showed no significant interference (< ± 10%) up to the concentrations summarized below.

Acetylsalicylic Acid:	2.78 mM	Rivaroxaban:	7.0 µg/mL
Na2-Cefoxitin:	1554 µM	Argatroban:	20.0 µg/mL
Ibuprofen:	2438 µM	FDP:	0.5 mg/mL
Warfarin:	65 µM	Unfractionated:	
Dabigatran:	3.7 µg/mL	Heparin:	3000 U/L
Hirudin:	25 µg/mL	Low molecular weight Heparin:	3000 U/L

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