

FIBRINOGEN ASSAY

Dual Vial Liquid Stable

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. The Fibrinogen Assay is ideally suited to meet the growing demands of clinical laboratories requiring high throughput, precise test results. 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.

DIAZYME FIBRINOGEN ASSAY ADVANTAGES

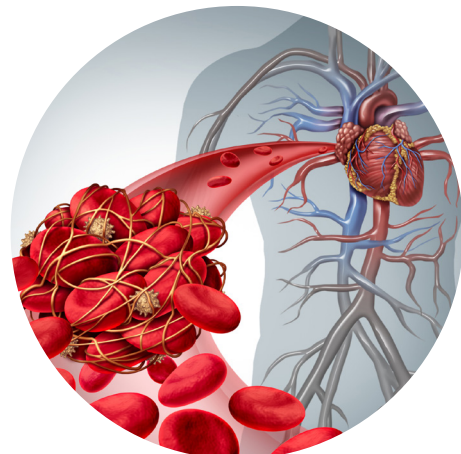
- Diazyme's immunoturbidimetric method improves analytical performance by measuring fibrinogen antigen
Improves laboratory efficiency and workflow
Reduced sample handling
- Fast test results (under 10 minutes) ideal for high throughput applications
- Liquid stable format requires no reagent preparation, saving time and reducing sample handling
- User friendly instrument specific packaging options
- Wide range of instrument parameters available for facilitating and simplifying implementation

REGULATORY STATUS

510(k) Cleared

AVAILABLE INSTRUMENT SPECIFIC PACKAGING

- Roche
- Hitachi



FIBRINOGEN ASSAY

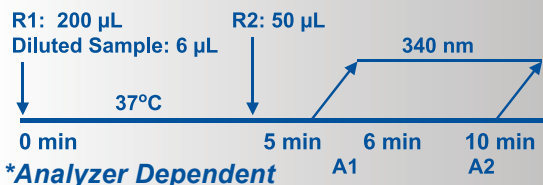
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ASSAY SPECIFICATIONS

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 = 0.9946 Sample Range: 107.5-870.0 Linear Regression: (Total of 3 sites) N = 176 y-intercept = 2.72 Slope = 0.986 R ² = 0.9946 Sample Range: 107.5-870.0
Linearity	0 - 1032.8 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: 14 days stressed at 37°C 1 month stressed at 25°C Unopened: 18 months at 2-8°C

Fibrinogen Assay Procedure*



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

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 (SD, %CV)	Between-Run (SD, %CV)	Between-Lot (SD, %CV)	Between-Day (SD, %CV)	Total (SD, %CV)
P1	240	453.4	8.0, 2%	9.4, 2%	16.2, 4%	10.6, 2%	23.0, 5%
P2	240	333.4	5.8, 2%	5.2, 2%	10.7, 3%	7.4, 2%	15.1, 5%
P3	240	208.6	3.0, 1%	3.2, 2%	6.6, 3%	4.9, 2%	9.3, 5%
P4	240	107.3	1.6, 2%	1.7, 2%	3.6, 3%	2.8, 3%	5.2, 5%
P5	240	706.8	11.9, 2%	13.9, 2%	27.1, 4%	20.1, 3%	38.4, 5%
P6	240	823.9	16.3, 2%	12.7, 2%	30.3, 4%	22.3, 3%	42.9, 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

DIAZYME LABORATORIES

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