FIBRINOGEN CLAUSS Liquid

THROMBIN REAGENT FOR FIBRINOGEN ASSAY

Method CLAUSS + Factor Diluent

Code MFIB108IL **Packaging 10 x 2 ml**

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INTENDED USE

It is intended to use in the quantitative determination of fibrinogen in plasma samples. FOR IN-VITRO DIAGNOSTIC USE ONLY.

SUMMARY AND PRINCIPLE

The thrombin clotting time fibrinogen assay is based on the method originally described by Clauss. In the presence of high concentrations of thrombin, the time required for clot formation in dilute plasma is inversely proportional to the fibrinogen concentration.

REAGENTS

Store all unopened reagents at 2-8°C.
Materials provided:
Liquid Stable Thrombin Reagent (for Fbg assay)

NOTE:

Fibrinogen Reference Plasma, and Imidazole Buffered Saline can also be purchased separately.

Composition:

Liquid Stable Thrombin Reagent (for Fbg assay):
Liquid buffered bovine thrombin. Ready for use. Store unopened vials at + 2 to + 8°C. Stability after use: 12 month at + 2 to +8°C. Do not freeze. Before use, mix by inverting.

SPECIMEN COLLECTION

Mix nine parts of freshly collected patient blood with one part of 0.11 or 0.13 mol/l (3.2 or 3.8%) sodium citrate. Avoid hemolysis and contamination by tissue fluids.
Samples that have less than 90%of the expected fill volume should be rejected. Centrifuge the blood specimen for a minimum of 10 minutes at 1000 rcf. Test within 2 hours if samples are held at 22-24°C. For more details on specimen collection and storage, see NCCLS Document H21-A3.2

TEST PROCEDURE

The Liquid Stable Fibrinogen Assay Kit and individual components are suitable for use with manual, mechanical or photo-optical methods of end-point clot detection.

Manual:

- Prepare a minimum of five different dilutions of the reconstituted Fibrinogen Reference Plasma in IBS. Dilute plasma at least 1:3 to minimize interfering factors.
- Dilute quality control and patient samples 1:10 in IBS.
- Prewarm 0.2 mL of each dilution to 37°C for 3 minutes.
- Add 0.1 mL of Liquid Stable Thrombin Reagent to prewarmed dilution and time clot formation. Do not prewarm Thrombin.
- The frequency of curve preparation is partially determined by the method of clot detection used. Always prepare a new curve with each change in reagent lots, instrumentation, or when controls no longer fall within established ranges.

Automatic:

Refer to the appropriate Instrument's Operator's Manual for the complete assay procedure instructions.

RESULTS

Plasma diluted 1:10 represents 100% of the assigned value. The dilution factor indicates the relationship between the 1:10 dilution and other dilutions.

Example Only:
Standard = 304 mg/dL fibrinogen

Dilution	Dilution Factor	Fibrinogen mg/dl	Mean CT seconds
1:3.5	10/3.5 = **2.9**	312x2.9 = **905**	**5.8**
1:5	10/5 = **2**	312x2 = **624**	**7.3**
1:10	10/10 = **1**	312x1 = **312**	**13.4**
1:15	10/15 = **0.67**	312x0.67 = **209**	**20.8**
1:35 3	10/35 = **0.29**	312x0.29 = **90**	**49.2**

Calculate the mean of duplicate clotting times to the nearest 0.1 second. Use all five of the calibrator points to construct a log-log curve that plots fibrinogen
concentration vs. clotting time. Draw the straight line of best fit. Examine the curve and, if necessary, omit non-linear points. The final curve must consist of at least three consecutive points.
Find the clotting time of quality control and patient samples on the curve and read the corresponding fibrinogen value. If clotting times for the 1:10 dilution fall outside the linear curve, prepare 1:5 or 1:20 dilutions as needed. If the sample is diluted 1:5, divide the result from the standard curve by 2; if the sample was diluted 1:20, multiply the curve result by 2 to get the final result.

LIMITATIONS

Blood must be immediately added to trisodium citrate anticoagulant and gently mixed. EDTA and heparin are unsuitable anticoagulants.
Hemolysis can cause clotting factor activation and end point detection interference. Icteric and lipemic specimens may also be inappropriate for end point detection methods.
The sample should only contact nonwettable surfaces.
The ratio of blood to anticoagulant is usually 9:1 and results in a citrate concentration of 10.9 to 12.9 mmol/L.
This concentration must be adjusted for patients with hematocrits above 55%. See NCCLS Document H21-A3.1,2
Freezing and thawing of plasma that contains residual cells will generate damaged cell membranes that can affect results.
Acute inflammatory reactions can elevate circulating Factor I (fibrinogen).
High Fibrinogen Degradation Products (FDP) may prolong clotting times, especially when the fibrinogen level is below 150 mg/dL.
In patients with qualitative fibrinogen abnormalities, the thrombin clotting time assay may indicate decreased fibrinogen. The quantitative fibrinogen results may be normal on these same samples if tested by other methods.
Heparin does not interfere at therapeutic levels. However, very high heparin levels may cause low fibrinogen results. Batroxobin enzyme can be substituted for thrombin in this assay if heparin interference is suspected.
High paraprotein levels, thrombin antibodies, and drugs that activate the fibrinolytic system can interfere with fibrinogen assays.
The Liquid Stable Fibrinogen Assay Kit and individual components are designed to work at 37° C. Ensure that all heating elements are functioning properly.

EXPECTED VALUES

Laboratories should establish a normal reference interval for fibrinogen measurements. Generally, the normal reference interval is 200 to 400 mg/dL (2.0 to 4.0 g/L).

PERFORMANCE CHARACTERISTICS

Accuracy:

A low, a normal, and a high fibrinogen plasma were tested in multiple laboratories using Liquid Stable Fibrinogen Assay Kit. The results were compared to results obtained using other manufacturer's reagents in multiple labs.

Sample	Fibrinogen	N =	All Reagents	N =
Low	144 mg/dl	10	163 mg/dl	195
Normal	294 mg/dl	10	297 mg/dl	195
High	488 mg/dl	16	474 mg/dl	390

Precision:

A low, a normal, and a high fibrinogen plasma were tested on multiple days using Liquid Stable Fibrinogen Assay Kit on a photo-optical instrument. Ten standard curves were determined on each test day, for a total of 30 standard curves. The percent CV was determined to be 5.9% (low), 3.4% (normal), and 2.9% (high).

REFERENCES

Clauss A. : Acta Haemat. 17, 237-245 (1957)
National Committee for Clinical Laboratory Standards: Collection, Transport and Processing of blood specimens for coagulation testing and performance of coagulation assays 2nd edition. Approved guideline. NCCLS Document H21-A2 Villanova PA, (1991)
National Committee for Clinical Laboratory Standards: Procedure for determining fibrinogen in plasma. Approved guideline. NCCLS Document H30-A, Villanova PA., (1994)
Musgrave K.A., Bick R.L.: Quality Assurance in the Hemostasis Laboratory,
Bick R.L., et al, editors: Hematology: Clinical and Laboratory Practice Vol. 2, 1309 -1315 Mosby, St Louis, MO. (1993)
Palpereti G., Cocchieri S., Poggi M. et al: Oral Anticoagulant Therapy Control; Evidence that the INR Expression Improves the interlaboratory Comparabilità of results. The Bologna Oral Anticoagulant Control Exercise. Thromb Haemostasis 58: 905-910 (1987)

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