HORIBA Medical

INSTRUCTION FOR USE

Yumizen G FIB 2

CE

FIBRINOGEN REAGENT

Cat. No.: 1300036383 **12 x 2 ml**

PRODUCT NAME

Yumizen G FIB 2

INTENDED USE

(For In Vitro Diagnostic Use Only)

Yumizen G FIB 2 is a fibrinogen reagent used for quantitative determination of fibrinogen levels in plasma.

SUMMARY AND EXPLANATION

Fibrinogen is the final plasma protein of coagulation cascade. Its presence and intact function has a vital importance for normal blood coagulation.

Fibrinogen, produced in the liver, contains three pairs of protein chains. This soluble fibrinogen molecule is cleaved by thrombin to fibrin monomers. The formed fibrin monomers compose the fibrin fibers and then the insoluble fibrin net, which is stabilized by factor XIIIa.

PRINCIPLE

The method of Clauss measures the clotting time after adding a high concentration of thrombin to diluted plasma. The fibrinogen concentration of the plasma is inversely proportional to the clotting time.

ACTIVE INGREDIENTS

Yumizen G FIB 2 is a freeze-dried, highly purified human alpha thrombin in buffered medium with calcium and preservative.

PRECAUTIONS

- Person installing the Yumizen G FIB 2 reagent must be a trained laboratory professional!
- By calculating with inappropriate data or using the supplied data improperly, erroneous results may occur!
- Yumizen G FIB 2 due to its ingredients should be handled with care, observing the precautions recommended for biohazardous material!
- Reagent coming into contact with specimens and other materials should be handled as if capable of transmitting infection and should be disposed of with proper precautions!
- Avoid microbial contamination of the reagent or erroneous results may occur.
- Each donor unit used in the preparation of this reagent tested with HBsAg, anti-HIV 1-2, anti-HCV, anti-TP screening tests and found to be non-reactive.
- All reagents, waste and utilized disposable laboratory equipments should be considered as hazardous waste. Their handling and disposal should be done according to the valid hazardous material processing regulation.
- Do not use the reagent beyond the expiration date printed on the label!

PREPARATION

Yumizen G FIB 2 reagent is dissolved with required amount of distilled water, which is indicate on the label. Keep the reagent at room temperature (20-25°C) for at least 30 minutes for proper reconstitution. Swirl the vial gently, horizontally more times (5-10) before using it, but do not shake. Wait until the reagent reaches the working temperature!

SPECIMENS

Yumizen G FIB test requires freshly decalcified plasma.

To obtain it, mix nine parts of freshly drawn venous blood with one part trisodium citrate (3.2%; 109 mmol/L). The use of higher concentration of trisodium citrate (3.8%; 129 mmol/L) is not recommended. Mix the blood carefully and centrifuge plasma before testing. The measurement must be performed within 4 hours. Do not store the sample at 2-8°C. Refer to Clinical and Laboratory Standards Institute (CLSI) guidelines H21-A5.

INSTRUCTION FOR USE ON SEMI-AUTO ANALYSER

Yumizen G FIB 2 test is a fibrinogen test, which is suitable for manual techniques according to the protocol detailed below and for automated assays according to the instructions outlined in the instrument manual. Duplicate determinations are recommended.

Bring the sufficient volume of Yumizen G FIB 2 thrombin to room temperature.

1. Prepare 1:10 dilution of the plasma (control or patient's) with Yumizen G IMIDAZOL buffer.
2. Add 100 µl diluted plasma to the test cuvette.
3. Incubate plasma at 37°C for 2 minutes.
4. Add 50 µl Yumizen G FIB 2 reagent and simultaneously start the timer.
5. Determine the coagulation time.

Normal and pathological controls are recommended for verified measuring. Each laboratory should establish its own quality control program.

For automated analyser, please refer to the user manual.

Use only Yumizen G IMIDAZOL buffer in order to achieve correct result!

STORAGE AND STABILITY

Yumizen G FIB 2 reagent in intact vial is stable until the expiration date given on the vial, when stored at 2-8°C. Stability after opening in the original vial is shown in the table below:

T(°C)	20-25	15-19	2-8
Day	3	7	7

EXPECTED RESULTS

Yumizen G FIB 2 test results can be reported in g/l. This dimension is calculated from a log-log calibration curve.

The normal range of plasma fibrinogen by clotting assays is between 2.0-4.0 g/L. Every laboratory should determine its own normal or reference range.

The linearity range of Yumizen G FIB 2 without extra dilution on Yumizen G analysers (Yumizen G Line) is 1.0-5.0 g/L. In case of lower fibrinogen value (<1.0 g/L) it is recommended to retest the sample at 1:5 dilution. In case of higher fibrinogen value (>5.0 g/L) it is recommended to retest the sample at 1:20

LIMITATIONS

The result of Yumizen G FIB 2 test with Yumizen G FIB 2 reagent may be influenced by drugs and other pre-analytical interfering agents. The potential limits of these parameters were tested on Yumizen G analysers (Yumizen G Line) with the following result:

Heparin	Hemoglobin	Triglycerid	Bilirubin
2.0 IU/mL	6.8 g/L	10 mmol/L	340 µmol/L

PERFORMANCE CHARACTERISTICS

The reproducibility test of Yumizen G FIB 2 reagent on Yumizen G analysers (Yumizen G Line) gives the following results:

	Intra-Assay		Inter-Assay	
Sample	1	2	3	4
N	10	10	10	10
Mean (g/L)	2.54	1.26	2.60	1.37
CV (%)	2.106	1.292	3.008	3.845

MATERIALS REQUIRED BUT NOT PROVIDED[A]

- Sample diluent (Yumizen G IMIDAZOL; Cat. No.: 1300036385).
- Normal and pathological controls for quality control (Yumizen G CTRL I & II; Cat. No.: 1300036412).
- This reagent may be performed using manual, semi-automated and automated methods.
- Coagulation analyser for measuring, Horiba Medical analysers (Yumizen G line) are recommended.
- Yumizen G SORB (Cat. No.: 1300036418) for Yumizen G800 / 850 and Yumizen G1500 / 1500.

BIBLIOGRAPHY

1. CLSI: Collection, Transport and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Hemostasis Assays; Approved Guideline-Fifth Edition. CLSI document: H21-A5; 28:5; 2008.
2. CLSI: Procedure for the Determination of Fibrinogen in Plasma; Approved Guideline-Second Edition. CLSI document: H30-A2; 21:18; 2001.
3. Clauss A: Gerinnungsphysiologische Schnellmethode zur Bestimmung des Fibrinogens. Acta Haematol; 17:237; 1957.

MANUFACTURER

IVD CE

HORIBA ABX SAS
Parc Euromédecine
Rue du Caducée
BP 7290
34184 Montpellier Cedex 4
FRANCE

[a]Modification: modification of materials required.