# Coagnos® Fibrinogen

**REF: CG0312**

## Coagnos® Fibrinogen GB

### INTENDED PURPOSE:
Coagnos® Fibrinogen (CG0312) is intended for the quantitative determination of fibrinogen, based on the Clauss method, in human citrated plasma on Coagulyzer® Auto Pro. The Coagnos® Fibrinogen kit is indicated for professional use only. Coagnos® Fibrinogen (CG0312) is intended for the quantitative determination of fibrinogen in human plasma. Clauss[1] developed a simple method for the quantitative determination of fibrinogen by measuring the clotting time of dilute plasma after the addition of Thrombin (>30 NIH units/mL). This clot time is proportional to the fibrinogen concentration. Levels of fibrinogen can increase as a result of inflammation, pregnancy or oral contraceptive use[2]. Decreased levels can be found in certain states such as liver disease and DIC. Congenital deficiencies include afibrinogenaemia (no detectable fibrinogen), hypofibrinogenaemia (<1 mg/mL) and dysfibrinogenaemia (abnormal fibrinogen molecule).

### WARNINGS AND PRECAUTIONS:
The reagents contained in this kit are for in vitro diagnostic use only – DO NOT INGEST. Wear appropriate personal protective equipment when handling all kit components. The material safety data sheet is available for download from our homepage http://www.analyticon-diagnostics.com. Dispose of components in accordance with local regulations. Blood products have been screened and found negative (unless otherwise stated on the kit box or vial) for the presence of: Hepatitis B Antigen (HbsAg) HIV 1 antibody HIV 2 antibody HCV antibody However they should be handled with the same precautions as a human patient sample. In case any serious incident has occurred in relation to the device, please report to the manufacturer and, if applicable, to the competent authority of the country in which the users and/or the patients established themselves.

### COMPOSITION:

| Component | Content | Description | Preparation |
|---|---|---|---|
| Thrombin | 5 x 4 mL | Contains approximately 200 units bovine thrombin with stabilisers. | Reconstitute each vial with: 4 mL of purified water. Take care when pipetting to avoid contamination. Swirl gently and allow to stand for 15 minutes. Mix well immediately before use. Do not Shake. |
| Fibrinogen Calibrator | 2 x 1 mL | Contains 1 mL of lyophilised normal human plasma assayed for fibrinogen levels. | Reconstitute each vial with exactly 1 mL of purified water. Swirl gently and allow to stand for 10 minutes. Mix gently before use. Do not shake. |
| Imidazole Buffer | 2 x 25 mL | Each bottle contains an aqueous solution of 0.05M Imidazole, sodium chloride, and sodium azide (<0.1%) as a preservative pH 7.3 ±0.10. | The buffer is ready for use as packaged. |

### STORAGE, SHELF-LIFE AND STABILITY:
Unopened reagents are stable until the given expiry date when stored under conditions indicated on the vial or kit label.

| | |
|---|---|
| Thrombin | Once reconstituted, the reagent is stable for 8 hours at +15 –+30 °C, 1 week at +2 –+8 °C or 1 month at -20 °C. |
| Fibrinogen Calibrator | Once reconstituted, the reagent is stable for 4 hours at +2 –+8 °C. |
| Imidazole Buffer | Store at +2 –+8 °C once opened. |

### SAMPLE COLLECTION AND PREPARATION:
Plastic or siliconised glass should be used throughout. Blood (9 parts) should be collected into 3.2 % or 3.8 % sodium citrate anticoagulant (1 part). Separate plasma after centrifugation at 1500 x g for 15 minutes. Plasma should be kept at +2 – +8 °C or +18 – +24 °C. Testing should be completed within 4 hours of sample collection, or plasma can be stored frozen at -20 °C for 2 weeks or -70 °C for 6 months. Thaw quickly at +37 °C prior to testing. Do not keep at +37 °C for more than 5 minutes[3].

### PROCEDURE:
Refer to the appropriate Instrument Operator Manual for detailed instructions or contact Analyticon Biotechnologies AG for instrument specific application guides.

### INTERPRETATION OF RESULTS:
Expected values for fibrinogen in healthy adults are 150-350 mg/dL (1.5-3.5 g/L)[4,5].

### LIMITATIONS:
Heparin levels >0.6 units/mL and fibrinolytic degradation products >100 mg/mL may cause falsely low fibrinogen quantitation. If values fall outside the standard curve values for the patient samples, re-assay using an appropriate dilution to bring values into the standard range.

### QUALITY CONTROL:
Each laboratory should establish a quality control program. Normal and abnormal control plasmas should be tested prior to each batch of patient samples, to ensure satisfactory instrument and operator performance. If controls do not perform as expected, patient results should be considered invalid. Analyticon Biotechnologies AG supplies the following controls available for use with this product:

REF CG0361 Coagnos® Special Control N
REF CG0362 Coagnos® Special Control P
REF CG0351 Coagnos® Routine Control N
REF CG0352 Coagnos® Routine Control P

### REFERENCE VALUES:
Reference values can vary between laboratories depending on the techniques and systems in use. For this reason each laboratory should establish its own normal range. Using the Coagulyzer® Auto Pro, normal values ranging from 2.34 – 3.82 g/L are typical.

### PERFORMANCE CHARACTERISTICS:
The following performance characteristics have been determined by Analyticon Biotechnologies AG or their representatives using a Coagulyzer® Auto Pro instrument. Each laboratory should establish its own performance data.

**Precision**
Precision was performed according to CLSI guideline EP05-A3: Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – Third Edition, 2008.

| Sample | Mean | Repeatability | | Within-device | |
|---|---|---|---|---|---|
| | | SD | CV [%] | SD | CV [%] |
| Fibrinogen Concentration [g/L] | 3.02 | 0.15 | 4.84 | 0.34 | 11.40 |
| | 1.43 | 0.11 | 7.85 | 0.17 | 12.03 |
| | 0.89 | 0.07 | 7.64 | 0.10 | 11.70 |

**Linearity**
The method is designed to give a linear standard curve from 0.66 – 9.54 g/L Fibrinogen.

**Interferences**
Coagnos® Fibrinogen is insensitive to Heparin levels of up to 3 U/ml. Using a 10% interference threshold, there is no significant interference from Haemoglobin at concentrations up to 500 mg/dL. Using a 10% interference threshold, there is no significant interference from conjugated Bilirubin at concentrations up to 36 mg/dL for Coagnos® Fibrinogen. Lipid interference testing demonstrates that lipid levels do not directly affect the clot time of the reagent up to 250 mg/dL. Lipid concentrations in excess of this might prevent clot detection.

**Method comparison**
Comparison of fibrinogen concentrations were determined using Coagnos® Fibrinogen on Coagulyzer® Auto Pro and Siemens® Fibrinogen with Dade® Thrombin® reagent on a Sysmex® CS-5100 system on 103 samples. The following correlations were obtained:

Coagnos® Fibrinogen (g/L) = 0.983x + 0.107 r2 = 0.97 n = 103

### SYMBOLS

| | |
|---|---|
| IVD | In vitro diagnostics product |
| CE | The product complies with European legislation |
| | Follow the instructions for use ! |
| | Use by |
| | Permitted storage temperature range |
| | Read warnings and precautions in instructions for use ! |
| LOT | Batch identification number |
| REF | Item number |
| | Manufacturer |

### BIBLIOGRAPHY:


1. Clauss A (1957) Gerinnungsphysiologische Schnell-methode zur Bestimmung des Fibrinogens, *Acta Haematol*,**17**:237-246
2. Shaw TS (1977) Assays for Fibrinogen and its Derivatives CRC, *Crit. Rev. Clin. Lab. Sci*, **8**:145-192.
3. Clinical and Laboratory Standards Institute (2008) Collection, Transport and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Haemostasis Assays: Approved Guideline, 5th edn. CLSI: H21-A5
4. Scully RE *et al*. (1980) Normal Reference Laboratory Values, *New England Journal Medcine*, **302**(37):37-48.
5. Okuno T, Selenko V (1972) Plasma fibrinogen determination by automated thrombin time, *American Journal of Medical Technology,* **38**(6):196-201



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