SIEMENS Healthineers

Dade® Data-Fi® Abnormal Fibrinogen Control Plasma
Data-Fi FIBRINOGEN CONTROL

CE 0197

Revision bar indicates update to previous version.

Control for Dade® Fibrinogen Determination Reagents

Intended Use

Data-Fi FIBRINOGEN CONTROL is a control derived from human plasma. It is used to assess accuracy and precision of Fibrinogen with Dade® Thrombin Reagent and Dade® Fibrinogen Determination Reagents in the low range.

Summary and Explanation

Fibrinogen is a large protein (M.W. 340,000), which is the most abundant clotting factor in plasma[1]. The normal range has been estimated to extend from as low as 150 mg/dL to as high as 500 mg/dL, but is typically considered to be 200 to 400 mg/dL[2]. Following removal of two small peptides by thrombin, fibrinogen is converted to fibrin, the major structural protein component of the clot. Fibrinogen assays are often performed in laboratory evaluation of hemostatic disorders. A number of fibrinogen abnormalities of varying severity have been identified, both congenital and acquired. Afibrinogenemia is usually a severe disorder resulting in frequent bleeding episodes. Patients with low levels of fibrinogen (hypofibrinogenemia) or with abnormal protein (dysfibrinogenemia) are usually asymptomatic, but a mild bleeding problem or a tendency to thrombosis is sometimes observed[3]. More recently, abnormally high levels of fibrinogen have been shown to be a risk factor for coronary heart disease and stroke[4].

Reagents

Reagent	Description	Storage	Stability
Dade® Data-Fi® Abnormal Fibrinogen Control Plasma Data-Fi FIBRINOGEN CONTROL	Lyophilized reagent containing: • human plasma[a] • Stabilizer: • Bovine serum albumin • Buffer	2–8 °C May be used up to the expiry date indicated on the label if stored unopened.	2–8 °C: reconstituted, 16 hours

[a] from pooled plasma collected from selected healthy blood donor

Warnings and Precautions

For *in-vitro* diagnostic use only.

For laboratory professional use.

According to EU regulation 2017/746, any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the EU Member State in which the user and/or patient is established.

Safety data sheets (MSDS/SDS) available on siemens-healthineers.com/sds.

CAUTION! POTENTIAL BIOHAZARD
Each donor or donor unit was tested and found to be negative for human immunodeficiency virus (HIV) 1 and 2, hepatitis B virus (HBV) and hepatitis C virus (HCV) using either tests that are CE marked or FDA approved for this purpose. Because no known test can offer complete assurance of the absence of infectious agents, all human derived products should be handled with appropriate caution.

CAUTION!
This device contains material of animal origin and should be handled as a potential carrier and transmitter of disease.

Dispose of hazardous or biologically contaminated materials according to the practices of your institution. Discard all materials in a safe and acceptable manner and in compliance with all government requirements.

Summary of Safety and Performance (SSP) is available in the European database on medical devices (see Eudamed public website: https://ec.europa.eu/tools/eudamed). In case Eudamed is not available, SSP can be delivered by Siemens Healthineers on request.

Preparing Reagents

Reconstitute each vial with 1.0 mL distilled water. Close the vial again and let stand at least 15 minutes at 15 to 25 °C, until the contents have dissolved. Carefully agitate the contents (swirling motion) to mix. Do not shake. Mix carefully once more before using.

Note: Do not use distilled water containing preservatives.

Indication of deterioration: lack of vacuum upon opening vial or inability to obtain reproducible values.

Procedure

Materials Provided

REF	Contents		
B4233-22	Dade® Data-Fi® Abnormal Fibrinogen Control Plasma Data-Fi FIBRINOGEN CONTROL Table of Assigned Values	10 × →	1 mL

Materials Required but not Provided

Item	Description
Coagulation analyzers[b], such as:	• Atellica® COAG 360 System • SYSMEX CA-500/CA-600 series • SYSMEX CA-1500 System • SYSMEX CS-2000i/CS-2100i System • SYSMEX CS-2500 System • SYSMEX CS-5100 System

[b] Availability of analyzers may vary by country.

Please note that the applications on other analyzers can be validated by the instrument manufacturer in accordance with the requirements of the REGULATION (EU) 2017/746 under their responsibility as long as the intended purpose and performance are not modified.

The reconstituted control plasma is to be used in the same manner as freshly obtained patient plasma. The lot-dependent target value is indicated in the enclosed Table of Assigned Values. For checking accuracy and precision, Data-Fi FIBRINOGEN CONTROL Plasma is used together with Dade® Thrombin

Reagent (Atellica® COAG 360 System only) or Dade® Fibrinogen Determination Reagents according to the instructions in the applicable Instructions for Use.

Limitations

The lot-dependent target value is indicated in the enclosed Table of Assigned Values. The target value indicated has been determined with Siemens Healthineers reagents in photo-optical coagulation analyzers and a manual method and corresponds to the mean value of at least 20 determinations carried out in three different assays in Siemens Healthineers laboratories. Deviations in the execution of the test or in the coagulation analyzers, etc. used may lead to values that deviate from those indicated. Therefore, each laboratory should determine its own target value.

Performance Characteristics

Data-Fi FIBRINOGEN CONTROL will perform according to the results and within the limits described when used as a control for Dade® Fibrinogen Determination Reagents.

Studies indicate that inter-laboratory variation using this control should result in CV of approximately 10 % for Dade® Fibrinogen Determination Reagents. If laboratory control preparations are to be used for effective quality assurance in coagulation tests, then each laboratory should determine the mean value and the standard deviation for its own measuring procedures in order to maintain an appropriate aid for monitoring its own quality control.

Technical Assistance

For customer support, contact your local technical support provider or distributor.

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References

1. Biggs R, Rizza C eds. Human blood coagulation, haemostasis and thrombosis. 3rd Ed. Oxford: Blackwell Scientific Publications; 1984: 26.
2. Huseby R, Bang N. in: Thrombosis and bleeding disorders. Bang N, Beller F, Deutsch E, Mammen E, eds. New York: Academic Press; 1971: 222.
3. Thompson A, Harker L. Manual of hemostasis and thrombosis. Philadelphia: F.A. Davis Co.; 1983: 113.
4. Wilhelmsen L, Svärdsudd K, Korsan-Bengtsen K, et al. Fibrinogen as a risk factor for stroke and myocardial infarction. N Engl J Med. 1984; 311: 501-5.

Definition of Symbols

The following symbols may appear on the product labeling:

	Do not reuse		Use By
LOT	Batch Code	REF	Catalogue Number
	Caution		Manufacturer
EC REP	Authorized representative in the European Community		Contains sufficient for <n> tests
	Biological Risks	IVD	*In Vitro* Diagnostic Medical Device
	Temperature Limitation		Consult instruction for Use
	Non-sterile		CE marking of conformity
CE 0197	CE marking of conformity with notified body ID number. Notified body ID number can vary.	CONTENTS	Contents
	Reconstitution volume	LEVEL	Level
	Keep away from sunlight and heat	WARNING	Warning
DANGER	Danger	RxOnly	Prescription device (US only)
UDI	Device Identification (UDI) barcode	REACH xx/xx/xx	REACH Authorization Number

Legal Information

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