Fisher Diagnostics
a division of Fisher Scientific Company, LLC
a part of Thermo Fisher Scientific Inc.
8365 Valley Pike
Middletown, VA (USA) 22645-1905
Tel: 540 869 3200 or 800-528-0494

Certificate of Analysis

Product Name: Coagulation Control Level 2
Product Numbers: 200596CAP
Lot Number: CGL-092020

Date of Manufacture: 03/26/2020
Expiration Date: 2023-03-31
Storage: 2 - 8°C

Specification	Specification Limit	Result
Lyophilized Plasma Appearance	Yellow to buff colored solid	Complies
Appearance Reconstituted	Yellow to straw colored, clear to hazy, free of particulates when viewed against dark background	Complies
Vial to vial Variability	<= 2 %	1
Thromboplastin D	As Measured	20 S
APTT-XL	As Measured	59.6 S
Clauss Fibrinogen	As Measured	301 mg/dL
Quality Control Test Date	Report	04/01/2020
CAP Survey	Report	CGL
CAP Survey Year	Report	2020
CAP Mailing	Report	CGL-B
CAP Lot Number	Report	CGL-LA9
CAP Specimen Number	Report	CGL-09
Duplicate Specimen Number	Report	N/A

For in-vitro diagnostic use.

Specimen is off the shelf.

Methods:

All testing performed by Thermo Fisher Scientific Middletown, VA.

Clauss Fibrinogen - optical Clauss-based method using Pacific Hemostasis Fibrinogen reagent.

APTT - optical clot-based method using Pacific Hemostasis APTT XL reagent.

PT - optical clot-based method using Pacific Hemostasis Thromboplastin D/DS reagent.

Material type, fill, and container:
Specimen is provided as a 1.0 mL lyophilized plasma in a 5 mL serum container.

Reconstitution:
Allow sample to come to room temperature before reconstitution. Use 1.0 mL of high purity water. Swirl gently and let stand undisturbed for 15 minutes at room temperature. Swirl gently before use.

Stability for CAP Survey:
Manufacturer: Temp 2 - 8 °C / life 365 days
Packager: Temp 2 - 8 °C / life 365 days

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Lab unopened: Temp 2 - 8 °C / life 300 days
Lab opened: Temp 2 - 8 °C / Use immediately

Statement of compliance:
Specimen is in compliance with the CAP manufacturing specifications.

Specimen is off the shelf.

Biohazard/Hazard Information for CAP Survey:

Etiologic/Non-etiologic statement: For the purposes of this CAP Survey Specimen COA, the term etiologic means that live organisms capable of causing disease were intentionally added to this product by the manufacturer. The term non-etiologic means no live organisms were intentionally added to this product by the manufacture. Using these definitions, this product is non-etiologic. However, the product should be handled according to the Universal Precautions statement included on this COA.

Universal Precautions Statement:
Each unit of source material used in the preparation of this product has been tested by an FDA licensed method and found non-reactive for HBsAG, negative for Syphilis, and negative for antibodies to HIV and HCV. However, no known test method can offer complete assurance that product derived from human blood will not transmit hepatitis, AIDS, or other infectious diseases. This product, like all materials of human origin, should be handled as potentially infectious biological material.

Contains materials of animal origin that were procured using the latest animal testing guidelines, laws or regulations and materials were obtained from US Department of Agriculture ("USDA") approved facilities (or equivalent).

Quality Representative Date: 2020-04-15

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