

Certificate of Analysis

Product Name: Roche CoaguChek XS PT Control Level 2
Product Numbers: J04580702C
Lot Number: WP9-132020

Date of Manufacture: 03/30/20
Expiration Date: 2022-06-30
Storage: 2 - 8°C

Specification	Specification Limit	Result
Appearance	White to buff-colored solid	Complies
Reconstituted Appearance	A clear, amber fluid with no particulates.	Complies
Moisture	<= 3.4 %	0.7
Control Values	CoaguChek	CoaguChek
Lot Variability	<= 4.1 %	1.6
INR Value	As Measured	3.2
CAP Lot Number	Report	WP9-LB6
CAP Specimen Number	Report	WP9-13
Mailing	Report	WP9-C
Year	Report	2020
Diluent Lot Number	Report	WP9-LA1DIL
Diluent Specimen Number	Report	WP9-DIL
QC Test Date	Report	04/03/20

For in-vitro diagnostic use.

Survey: Coagulation

Method: CoaguChek XS. All testing performed by Thermo Fisher Scientific Middletown, VA.

Material type, fill, and container: Specimen is provided as 0.3 mL lyophilized plasma in a siliconized 2 mL vial.

Diluent bulb and diluent composition: the diluent is supplied in a plastic pipette that contains a 0.410 mL solution of 99% water, <1% CaCl₂ and <0.1% stabilizer buffer.

Stability for CAP Survey:

Manufacturer: Temp 2 - 8 °C/Life 365 days

Packager: Temp 2 - 8 °C/Life 365 days

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 CAP manufacturing specifications.

Specimen is off the shelf.

Biohazard/Hazard Information for CAP Survey:

Etiologic/Non-etiological 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-etiological means no live organisms were intentionally added to this product by the manufacturer. Using these definitions this product is non-etiological.

There is no human sourced material in this product.

This product contains 0.1% sodium azide. Sodium azide under acidic conditions yields hydrazoic acid, an extremely toxic compound. Dilute with running water before discarding and flush with large amounts of water during disposal. These precautions are recommended to avoid deposits in the metal piping where explosive conditions may develop.

Traceability Statement: All specimens that contain materials of animal origin were procured using the latest animal testing guidelines, laws or regulations and materials were obtained from US Department of Agriculture ("USDA") approved facilities.



Quality Representative



Date: 2020-07-13