

Certificate of Analysis

Product Name: Roche CoaguChek XS PT Control Level 2
Product Numbers: 04580702
Lot Number: 441692

Date of Manufacture: 02/05/19
Expiration Date: 2021-05-31
Storage: 2 - 8°C

Specification	Specification Limit	Result
Appearance	White to buff-colored solid	Complies
Appearance: Reconstituted	A clear, amber fluid with no particulates.	Complies
Imprint on vial bottom	"B"NNN	B692
Moisture	<= 3.4 %	0.6
Control Values	CoaguChek	CoaguChek
Lot Variability	<= 4.1 %	2.0
INR Value	2.7 - 3.3	2.6
Bulk Plasma Supplier Lot Number*	Report	34540
CoaguChek Strip Lot Number	Report	286 321 80
CoaguChek Code Chip Number	Report	307

For in-vitro diagnostic use.

Roche Product Number: 04580702001

Stability: Unopened vials are stable until the expiration date indicated above when stored at 2-8 °C.

Traceability Statement: The serum-based material used in this product is from farms certified to be free of transmissible spongiform encephalitis (TSE).

* The Pel-Freez COA for the Bulk Plasma lot is attached.



Quality Representative

Date: 2019-05-07