

Certificate of Analysis

Product Name: ARC Troponin I Calibrator Kit
OEM Part Number: 02K41-01
OEM Lot Number: 186421
Storage: 2 - 8°C
Qty Manufactured: 283 Kits

Abbott List Number: 02K41-01
Abbott Commodity Number: 39-6199
Expiration Date: 2022-07-31
Package Insert No./Rev. G1-0348 / R05
Test Date 10 FEB 21

Description	Lot Number	Expiration Date
Calibrator A	186422	2022-08-31
Calibrator B	186423	2022-07-31
Calibrator C	186424	2022-07-31
Calibrator D	186425	2022-07-31
Calibrator E	186426	2022-07-31
Calibrator F	186427	2022-07-31

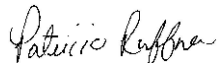
Specification	Specification Limit	Result
Calibrator B/A Ratio	>2.9	5.7 Pass
Low Control (N >= 3)	0.13 (0.10 - 0.16) ng/mL	0.13 Pass
Low Control	% CV	5.0 %
Low Control	Lot Number	TNI21071
Medium Control (N >= 3)	0.57 (0.46 - 0.69) ng/mL	0.56 Pass
Medium Control	% CV	3.0 %
Medium Control	Lot Number	TNI21072
High Control (N >= 3)	14.51 (11.60 - 17.41) ng/mL	13.75 Pass
High Control	% CV	2.0 %
High Control	Lot Number	TNI21073
Panel 1 (N >= 3)	0.30 (0.24 - 0.36) ng/mL	0.30 Pass
Panel 1	% CV	3.0 %
Panel 1	Lot Number	287687
Reagent	Lot Number	61428UN20

For in-vitro diagnostic use.

This product contains animal and human source material. Human source material has been tested and found nonreactive for HBsAg and HIV-1 NAT or HIV-1 Ag, and negative for antibodies to HIV I/II and HCV. As with all blood products, this product should be handled as potentially infectious biological material.

This lot meets all current release specifications per quality document MS.MASTER342.

The above product has been manufactured in compliance with Quality Systems Regulations, passed all Thermo Fisher final release specifications, and has met all Abbott acceptance requirements.



Quality Representative

Date: 2021-03-12