

Certificate of Analysis

Product Name: PCT Reagent Kit (1x500), US
OEM Part Number: 06P22-37
OEM Lot Number: 29995UN18
Storage: 2 - 8°C
Qty Manufactured: 131 Kits

Abbott List Number: 06P22-37
Abbott Commodity Number: 06P2237
Expiration Date: 2019-04-30
Package Insert No./Rev. G1-0601 / R01
Test Date 2018-05-03

Description	Lot Number	Expiration Date
Microparticles	29995UN18G	2019-04-30
Conjugate	29995UN18H	2019-04-30

Specification	Specification Limit	Result
Cal A RLU Mean	Report	331 RLU
F/A Ratio	>400	7963 Pass
Low Control: Mean	0.180 - 0.220 ng/mL	0.204 Pass
Low Control: % CV	<=10 %	2 Pass
Low Control	Lot Number	952678
Medium Control: Mean	1.800 - 2.200 ng/mL	2.024 Pass
Medium Control: % CV	<=10 %	2 Pass
Medium Control	Lot Number	952679
High Control: Mean	61.600 - 78.400 ng/mL	72.483 Pass
High Control: % CV	<=10 %	3 Pass
High Control	Lot Number	952680
Calibrator	Lot Number	952672-952677

% CV is based on 18 replicates

For in-vitro diagnostic use.

PCT Reagents contain animal source material.

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

The above product has been manufactured in compliance with Fisher Diagnostics' operating procedure.



Quality Representative

Date: 2018-05-11