

Certificate of Analysis

Product Name: ARC Cortisol Calibrator Kit
OEM Part Number: 08D15-02
OEM Lot Number: 555277
Storage: -10°C
Qty Manufactured: 1,001 Kits

Abbott List Number: 08D15-02
Abbott Commodity Number: 39-6903
Expiration Date: 2016-03-31
Package Insert No./Rev. JL840818 / R02
Test Date 10/07/2014

Description	Lot Number	Expiration Date
A Calibrator	555278	2016-03-31
B Calibrator	555279	2016-03-31
C Calibrator	555280	2016-03-31
D Calibrator	555363	2016-03-31
E Calibrator	555364	2016-03-31
F Calibrator	555365	2016-03-31

Specification	Specification Limit	Result
Low Control	2.4 - 4.8 µg/dL	3.5 Pass
Low Control	Lot Number	40851
Medium Control	14.5 - 24.1 µg/dL	19.0 Pass
Medium Control	Lot Number	40852
High control	21.0 - 37.3 µg/dL	28.1 Pass
High Control	Lot Number	40853
Reagent	Lot Number	19261UN13

For in-vitro diagnostic use.

Cortisol IgG Calibrators contain human source material. Human source material has been tested and found nonreactive for HBsAg and HIV-1 Ag or HIV-RNA, and negative for antibodies to HIV-1/HIV-2 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 accordance with Fisher Diagnostics' operating procedure.



Quality Representative

Date: 2014-10-13