



## CERTIFICATE OF ANALYSIS

### Product Description

Architect Cyclosporine Ppt. Rgt.	
FDI Kit Catalog No.:	4008238
FDI Kit Lot No.:	310604
ADD Purchase Order No.:	4800254951/4600563950
Abbott List No.:	1L75-55
Abbott Commodity No.:	39-6678
Total Kits Manufactured:	3074
Total Kits for FDI:	15
Total Kits for ADD:	3059
FDI Precipitation Rgt. Part No.:	4008235
FDI Precipitation Rgt. Lot No.:	310608
FDI Precipitation Rgt. Date of Manufacture (YYYY-MM-DD):	2022-04-18
FDI Precipitation Rgt. Expiration Date (YYYY-MM-DD):	2023-04-18
FDI Precipitation Rgt. Fill Volume (mL):	47.93
FDI Solubilization Rgt. Part No.:	4008236
FDI Solubilization Rgt. Lot No.:	310609
FDI Solubilization Rgt. Date of Manufacture (YYYY-MM-DD):	2022-04-14
FDI Solubilization Rgt. Expiration Date (YYYY-MM-DD):	2023-04-14
FDI Solubilization Fill Volume (mL):	14.0
FDI Cyclosporine Precipitation Rgt. Kit Expiration Date (YYYY-MM-DD):	2023-04-14
Package Insert Commodity Number/Revision:	093417.00 REV 000
Storage Conditions:	15-30 Degrees C
Shipping Conditions:	Ambient

### Product Test Results

### Specifications

Conductivity Specification (umhos): 140.27 – 254.93 @ 20 - 25° C

### Results

191.6 Pass

<b>The following testing was performed on ARCHITECT / System using</b>	<b>Reagent Kit Lot Number:</b> 85K30022
	<b>Calibrator Kit Lot Number:</b> 85K29721
	<b>Date Tested:</b> 03 May 2022

Parameter	Specifications: (Panel Lot: ACQ 353/1)	Assay Results (mean based on 3 reps)	Pass / Fail
Panel 1	114.5 – 171.7 ng/mL	125.3	Pass
Panel 2	554.8 – 832.2 ng/mL	643.5	Pass

Product meets physical inspection requirements per Abbott MS Master 342 and Master 351. Product meets requirements specified in Abbott Material Specification 39-6678. Product has been manufactured in accordance with FDI Operating Procedures. No changes have been made in the formula, manufacturing procedure or specification.

Solubilization Reagent seal integrity verified by 100% vacuum testing at ½ atm (15"Hg) vacuum for a minimum of 10 minutes.

The material meets all Quality Release Criteria and is found acceptable for Shipment to Abbott.

Quality Assurance: \_\_\_\_\_

Date: May 4, 2022

089-1119.014