

	UTAK Laboratories, Inc.	FM-75-05-02
	Certificate of Analysis	Revision: C Date: 11/18/15

CERTIFICATE OF ANALYSIS

Product Information

Product Name: Immunosuppressants level 2
Product Number: 41631
Manufacture Date: 10/16
Lot Number: A7015
Expiration Date: 04/19
Intended Use: In vitro diagnostic
Homogeneity: Sufficiently homogeneous for analytical testing

Precautions

Matrix: Normal Human Whole Blood
Form: Lyophilized
Anticoagulant: Potassium Oxalate
Preservative: Sodium Fluoride
pH: 6-7
Virology: Non-reactive for HBsAg, HCV, and HIV
Microbial Growth: < 100 colony-forming units per milliliter

Storage and Stability

Storage Condition: 2-8°C (35-46°F)
Open Bottle Stability: 25 days *
Volume Per Bottle: 3 mL ± 0.1%

* Whole Blood can be aliquoted and refrozen; multiple freeze/thaw cycles are not recommended

Origin of Raw Material

Whole Blood: Biological Specialty Corp., Pool: RUN100316-WB2
Potassium Cyanate: Spectrum Chemical, Lot EW-03207TV, 100% purity
Cyclosporine A: TRC Canada, Lot 12-SSR-178-1, 95% purity
Everolimus: LC Laboratories, Lot BDE-112, >99% purity
Sirolimus: LC Laboratories, Lot ASW-117, >99% purity
Tacrolimus: LC Laboratories, Lot ATH-112, >99% purity

LC/MS/MS Reference Value

Cyclosporine A: 516 ng/mL
Everolimus: 16.0 ng/mL
Sirolimus: 16.7 ng/mL
Tacrolimus: 15.6 ng/mL

Approved by: Kevin Kopp

Quality Assurance

