

Certificate of Analysis

Product Information

Product Name:	SMx Urine
Product Number:	36000-SMX-U(F)
Date of Manufacture:	xx/xx/xx
Lot Number:	xxxx
Expiration Date:	xx/xx
Intended Use:	In vitro diagnostic
Homogeneity:	Sufficiently homogeneous for analytical testing

Precautions

Matrix:	SMx Urine
Form:	Frozen
Anticoagulant:	N/A
Preservative:	N/A
pH:	5.03
Specific Gravity:	1.026
Virology:	Non-reactive for HBsAg, HCV, and HIV
Microbial Growth:	<100 colony-forming units per milliliter

Storage and Stability

Storage Condition:	-10°C (14°F)
Open Vial Stability:	30 days*
Vial Volume:	100 mL

^{*} The matrix may be thawed, aliquoted, and frozen; although, this product should not be exposed to multiple freeze/thaw cycles.

Origin of Raw Material

UTAK Laboratories

Analyte	Supplier	Lot#	Purity
Recombinant Albumin-Cellastim (rHSA)	TBD	XXXX	99.94%
Calcium Chloride Dihydrate	TBD	XXXX	99.9%
Creatinine	TBD	XXXX	≥98%
Magnesium Sulfate	TBD	XXXX	100%
Potassium Chloride	TBD	XXXX	100%
Sodium Chloride	TBD	XXXX	>99.5%
Sodium Phosphate Dibasic	TBD	XXXX	99.3%
Sodium Phosphate Monobasic	TBD	XXXX	>99.5%
Urea	TBD	XXXX	100%
Urobilin	TBD	XXXX	>95%

