Certificate of Analysis

Product Information

Product Name:	SMx Urine
Product Number:	36000-SMX-U(F)
Date of Manufacture:	[Enter Date of Manufacture as MM/YY]
Lot Number:	[Enter Product Lot Number]
Expiration Date:	[Enter Product Expiration Date as YYYY-MM-DD]
Intended Use:	For laboratory use only. Suitable for use as a matrix in method development, calibrator/control/standard preparation, analyte analysis, and general laboratory applications. Not for diagnostic use or direct administration to humans.
Homogeneity:	Sufficiently homogeneous for laboratory use
COA Rev.	[Enter COA Revision Number]

Precautions

Matrix:	SMx Urine
Form:	Frozen
Anticoagulant:	N/A
Preservative:	N/A
pH:	[Enter lot specific pH recorded on manufacturing documentation]
Specific Gravity:	[Enter lot specific Specific Gravity recorded on manufacturing documentation]
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 refrozen; 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)	Enter Supplier	Enter Lot	Enter Purity
Calcium Chloride Dihydrate	Enter Supplier	Enter Lot	Enter Purity
Creatinine	Enter Supplier	Enter Lot	Enter Purity
Magnesium Sulfate	Enter Supplier	Enter Lot	Enter Purity
Potassium Chloride	Enter Supplier	Enter Lot	Enter Purity
Sodium Chloride	Enter Supplier	Enter Lot	Enter Purity
Sodium Phosphate Dibasic	Enter Supplier	Enter Lot	Enter Purity
Sodium Phosphate Monobasic	Enter Supplier	Enter Lot	Enter Purity
Urea	Enter Supplier	Enter Lot	Enter Purity
Urobilin	Enter Supplier	Enter Lot	Enter Purity

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Certification and Compliance Statements

I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging/labelling and quality control at the below mentioned site in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorization of the importing country. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP. Additional product information is available on the device labeling.

Approved by: [Enter name generated by]
Quality Assurance