

Certificate of Analysis

Product Information

Product Name:	SMx Oral Fluid
Product Number:	35400-SMX-OF(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 Oral Fluid
Form:	Frozen
Anticoagulant:	N/A
Preservative:	ProClin 300
pH:	7.10
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.





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Origin of Raw Material UTAK Laboratories

Analyte	Supplier	Lot#	Purity
α-Amylase	TBD	XXXX	>98%
Amino-Acid Standard	TBD	xxxx	>98%
Calcium Chloride	TBD	xxxx	>98%
Cholesterol	TBD	xxxx	>98%
Disodium Phosphate	TBD	XXXX	>98%
Human Gamma Globulin	TBD	XXXX	>98%
Magnesium Sulfate	TBD	XXXX	>98%
Mucin	TBD	XXXX	>98%
Potassium Chloride	TBD	xxxx	>98%
Proclin 300	TBD	XXXX	>98%
Sodium Bicarbonate	TBD	XXXX	>98%
Sodium Chloride	TBD	XXXX	>98%

