

CERTIFICATE OF ANALYSIS

UrichemTRAK Control

Product Name:	Urichem TRAK Bulk Pack Level 1	
Kit Part Number:	10011401	
Kit Lot Number:	UC22091	
Expiration Date:	2022-09-30	
Storage Temperature:	2°C to 8 °C	

Item:	Lot Number	Date of Dispense	Expiration Date
Level 1	UC22091	2020-09-17	2022-09-30
Level 2	UC22092	2020-10-05	2022-09-30

	Visual Inspection	Homogeneity (Glucose)	Microbial
Specification:	Clear, Clean Colorless to Yellow Liquid	≤ 1.00%	No Growth
Level 1 results	Clear, Clean Colorless Liquid	-0.25%	No Growth
Level 2 results	Clear, Clean Colorless Liquid	0.03%	No Growth

The above listed material met all the manufacturer's release specifications/criteria and was manufactured in accordance with United States Good Manufacturing Practices.

Components of the control which are derived from human source material have been tested using FDA accepted methods and found non-reactive for Hepatitis B Surface antigen (HBsAg), Hepatitis C (HCV), HIV-1 and HIV-2.

SMY 01/08/2021

Quality Approval

Date

10010700CoA-6
Effective Date: 06/19/15

Legal Entity: Microgenics Corporation

Thermo Fisher Scientific
46500 Kato Road
Fremont, CA 94538 USA

Phone: 510-979-5000
Fax: 510-979-5002
Toll Free: 800-232-3342

Template: 10020092TMP, Rev. 1
Effective Date: 08/11/16