



# CERTIFICATE OF REGISTRATION

This is to certify that

## UTAK Laboratories, Inc.

25020 Avenue Tibbitts, Valencia, California 91355 USA  
D-U-N-S: 092519016

operates a

## Quality Management System

which complies with the requirements of

## ISO 13485:2016 and the requirements of the following regulatory authorities

#### Australia:

- Therapeutic Goods (Medical Devices) Regulations 2002: Schedule 3, Part 4 - Production Quality Assurance Procedure

#### Canada:

- Medical Device Regulations SOR/98-282, Part 1

#### United States:

- 21 CFR Part 803 - Medical Device Reporting
- 21 CFR Part 806 - Reports of Corrections and Removals
- 21 CFR Part 807 (Subparts A to D) - Establishment Registration and Device Listing
- 21 CFR Part 820 - Quality System Regulation

for the following scope of certification

**The manufacture and distribution of In vitro diagnostic reagents used in the detection of drugs of abuse, therapeutic drug monitoring, and trace elements for quality control purposes including laboratory use in vitro-diagnostic devices.**

Certificate No.: CERT-0107348  
File No.: 1629742  
Issue Date: 2019-06-18

Original Certification Date: 2019-06-18  
Certification Effective Date: 2019-06-18  
Certificate Expiry Date: 2022-06-17

Heather Mahon  
Global Head of Technical Services SAI Global Assurance



ISO 13485:2016

SAI Global is an MDSAP  
authorized auditing organization.



#### Registered by:

QMI-SAI Canada Limited (SAI Global), 20 Carlson Court, Suite 200, Toronto, Ontario M9W 7K6 Canada. This registration is subject to the SAI Global Terms and Conditions for Certification. While all due care and skill was exercised in carrying out this assessment, SAI Global accepts responsibility only for proven negligence. This certificate remains the property of SAI Global and must be returned to them upon request.  
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