Certificate

TÜVRheinland®

Certificate No.:	MD 687155 1140044543-40
Manufacturer:	**Artron Laboratories Inc.** 3938 North Fraser Way, Burnaby, BC, V5J 5H6, Canada
D-U-N-S No.:	20-374-8269
Certification criteria	ISO 13485:2016 Brazil RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009 Canada Medical Devices Regulations – Part 1 – SOR 98/282 United States 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D
Scope:	Design and Development, Manufacture and Distribution of Urinalysis Reagent Strips and In-vitro Diagnostic Test Kits and Analyzers used in the Detection of Cardiac Markers, Cancer, Disease status, Drugs of Abuse, Fertility Testing, Pregnancy Testing and Infectious Diseases Including Home Use, Near Patient In-vitro Diagnostic Devices

TUV Rheinland of North America, Inc., an MDSAP recognized Auditing Organization, certifies that the quality management system of the Manufacturer has been audited against and found to conform the Certification criteria for the Scope contained in this certificate. The quality management system is subject to annual surveillance audit(s).

Project No.:	50183799 002
Issue Date:	2019-02-22
Effective Date:	2019-02-22
Expiry Date:	2021-12-23

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Certification officer: Dipl.-Ing. S. Pane
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified by calling 1-888-743-4652.

TUV Rheinland of North America, Inc., 12 Commerce Road, Newtown, CT 06470, USA
Tel: (925) 249-9123, Fax: (925) 249-9124