

Certificate of Approval

This is to certify that the Management System of:

MEDTOX Diagnostics, Inc., a wholly owned subsidiary of Laboratory Corporation of America Holdings

1238 Anthony Road, Burlington, NC, 27215, United States

has been approved by LRQA to the following standards:

ISO 13485:2016



Cliff Muckleroy - Area Operations Manager Americas

Issued by: Lloyd's Register Quality Assurance, Inc.

for and on behalf of: Lloyd's Register Quality Assurance Limited

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

Current issue date: 2 January 2019

Expiry date: 1 January 2022

Certificate identity number: 10162586

Original approval(s):

ISO 13485 – 29 November 2016

Approval number(s): ISO 13485 – 0078127

The scope of this approval is applicable to:

Design and Development, Manufacture and Distribution of In-Vitro Diagnostic Kits and Systems for Drugs of Abuse Testing.



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Certificate Schedule

Certificate identity number: 10162586

Location	Activities
1238 Anthony Road, Burlington, NC, 27215, United States	ISO 13485:2016 Management Processes, Sales, Design, Purchasing, Manufacturing, Testing & Packaging.
1640 Nova Lane, Burlington, NC, 27215, United States	ISO 13485:2016 Warehousing and Distribution.



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Certificate of Approval

This is to certify that the Management System of:

MEDTOX Diagnostics, Inc., a wholly owned subsidiary of Laboratory Corporation of America Holdings

1238 Anthony Road, Burlington, NC, 27215, United States

MDSAP Facility Identifier: 13-741-7965

has been audited by LRQA and found to conform to the following audit criteria:

ISO 13485:2016

Canada:

Medical Devices Regulations – Part 1- SOR 98/282

United States:

21 CFR 820

21 CFR 803

21 CFR 806

21 CFR Part 807 (Subparts A to D) – Establishment Registration and Device Listing



Cliff Muckleroy - Area Operations Manager Americas
Issued By: Lloyd's Register Quality Assurance, Inc.

Certificate Approval Number: UQA 00000324

Effective Date: 2019 January 2

Expiry Date: 2022 January 1

Certificate Issue Number: 10162585

Original Approval:

MDSAP/ ISO 13485 – 2016 November 29

Approval Number: MDSAP – 0078128

The scope of this approval is applicable to:

Design and Development, Manufacture and Distribution of In Vitro Diagnostic Kits and Systems for Drugs of Abuse Testing.



Lloyd's Register Quality Assurance, Inc. is an MDSAP authorised auditing organization.

To validate certificate authenticity visit: <http://www.lrqausa.com/help-and-support/Request-for-certificate-verification>

Certificate Schedule

Certificate Issue Number: 10162585

Location	Activities
1238 Anthony Road, Burlington, NC, 27215, United States	MDSAP 2017 Management Processes, Sales, Design, Purchasing, Manufacturing, Testing & Packaging.
1640 Nova Lane, Burlington, NC, 27215 United States MDSAP Facility Identifier: 13-741-7965-002	MDSAP 2017 Warehousing and Distribution.



Lloyd's Register Quality Assurance, Inc. is an MDSAP authorised auditing organization.

To validate certificate authenticity visit: <http://www.lrqausa.com/help-and-support/Request-for-certificate-verification>