CLINICAL AND LABORATORY STANDARDS INSTITUTE®

3rd Edition

CLSI AUTO11™

Information Technology Security of *In Vitro* Diagnostic Instruments and Software Systems

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A standard for global application developed through the Clinical and Laboratory Standards Institute consensus process.

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CLSI AUTO11-Ed3
September 2024
Replaces CLSI AUTO11-A2

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Abstract

Clinical and Laboratory Standards Institute AUTO11—*Information Technology Security of* In Vitro *Diagnostic Instruments and Software Systems* specifies technical and operational requirements and technical implementation procedures related to security of *in vitro* diagnostic (IVD) systems (devices, analytical instruments, data management systems, etc.) installed at a health care delivery organization (HDO). The intended users for CLSI AUTO11 are medical device and IVD system manufacturers, users (eg, laboratory personnel), and information technology management of HDOs.

Clinical and Laboratory Standards Institute (CLSI). *Information Technology Security of* In Vitro *Diagnostic Instruments and Software Systems*. 3rd ed. CLSI standard AUTO11 (ISBN 978-1-68440-252-6 [Print]; ISBN 978-1-68440-253-3 [Electronic]). Clinical and Laboratory Standards Institute, USA, 2024.

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Suggested Citation

CLSI. *Information Technology Security of* In Vitro *Diagnostic Instruments and Software Systems.* 3rd ed. CLSI standard AUTO11. Clinical and Laboratory Standards Institute; 2024.

Previous Editions:
October 2006, October 2014

CLSI AUTO11-Ed3

ISBN 978-1-68440-252-6 (Print)

ISBN 978-1-68440-253-3 (Electronic)

ISSN 1558-6502 (Print)

ISSN 2162-2914 (Electronic)

Volume 44, Number 25

Committee Membership

Consensus Council

The Consensus Council sets priorities for CLSI standards development and votes on Final Draft documents to confirm that process requirements have been met. Consensus Council members are listed on the CLSI website: https://clsi.org/standards-development/consensus-council/

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Acknowledgment

CLSI, the Consensus Council, and the Document Development Committee on Information Technology Security of *In Vitro* Diagnostic Instruments and Software Systems gratefully acknowledge the following volunteers for their important contributions to the revision of CLSI AUTO11:

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PRINT ISBN 978-1-68440-252-6

ELECTRONIC ISBN 978-1-68440-253-3

CLSI AUTO11-Ed3