

DATE:

NVLAP LAB CODE:

INFORMATION TECHNOLOGY SECURITY TESTING TEST PROCEDURE SELECTION LIST – HEALTHCARE IT TESTING

Instructions: All applicants for accreditation for Healthcare Information Technology Testing must meet the Security Testing requirements as a minimum. To become accredited for the Modular Testing category, the requirements must be met for one or more selected test procedures in addition to meeting the requirements for the Security Testing procedures.

The listed test procedures are taken from “Approved Test Procedures Version 1.1”, with each associated erratum, where applicable, effective October 24, 2010. For additional information about these test procedures, please see <<http://nist.gov/nvlap/hit-lap.cfm>>.

The test procedures are based on the technical criteria found in 45 CFR Part 170, Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology; Final Rule (July 28, 2010).

Please check the boxes for which you are requesting accreditation.

	<i>NVLAP Code</i>	<i>Test Procedure Description</i>
Security Testing		
<input checked="" type="checkbox"/>	31/S	Security Testing encompasses the following nine required test procedures: Sec. 170.302 (o) through Sec. 170.302 (w).
General Testing		
	31/G	General Testing encompasses the following sixteen test procedures: Sec.170. 302 (a) through Sec.170.302 (e), Sec. 170.302(f)(1), Sec. 170.302(f)(2),Sec. 170.302(f)(3), Sec. 170.302 (g) through 170.302 (n).
Ambulatory Testing		
	31/A	Ambulatory Testing encompasses the following ten test procedures: Sec. 170.304 (a) through Sec. 170.304 (j).
Inpatient Testing		
	31/I	Inpatient Testing encompasses the following ten test procedures: Sec.170. 306 (a) through Sec.170. 306 (c), Sec. 170.306(d)(1) and 170.306(d)(2), Sec.170. 306 (e) through Sec.170. 306 (i).

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Modular Testing

31/M	In addition to Security Testing, Modular Testing encompasses one or more test procedures from Sec. 170.302, Sec. 170.304, and Sec. 170.306. Please select the test procedures for which you are requesting accreditation.
31/M01	Sec. 170.302(a), Drug-drug, drug-allergy interaction checks
31/M02	Sec. 170.302(b), Drug formulary checks
31/M03	Sec. 170.302(c), Maintain up-to-date problem list
31/M04	Sec. 170.302(d), Maintain active medication list
31/M05	Sec. 170.302(e), Maintain active medication allergy list
31/M06	Sec. 170.302(f)(1), Vital signs
31/M07	Sec. 170.302(f)(2), Calculate body mass index
31/M08	Sec. 170.302(f)(3), Plot and display growth charts
31/M09	Sec. 170.302(g), Smoking status
31/M10	Sec. 170.302(h), Incorporate laboratory test results
31/M11	Sec. 170.302(i), Generate patient lists
31/M12	Sec. 170.302(j), Medication reconciliation
31/M13	Sec. 170.302(k), Submission to immunization registries
31/M14	Sec. 170.302(l), Public health surveillance
31/M15	Sec. 170.302(m), Patient specific education resources
31/M16	Sec. 170.302(n), Automated measure calculation
31/M17	Sec. 170.304(a), Computerized provider order entry
31/M18	Sec. 170.304(b), Electronic prescribing
31/M19	Sec. 170.304(c), Record demographics

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31/M20	Sec. 170.304(d), Patient reminders
31/M21	Sec. 170.304(e), Clinical decision support
31/M22	Sec. 170.304(f), Electronic copy of health information
31/M23	Sec. 170.304(g), Timely access
31/M24	Sec. 170.304(h), Clinical summaries
31/M25	Sec. 170.304(i), Exchange clinical information and patient summary record
31/M26	Sec. 170.304(j), Calculate and submit clinical quality measures
31/M27	Sec. 170.306(a), Computerized provider order entry
31/M28	Sec. 170.306(b), Record demographics
31/M29	Sec. 170.306(c), Clinical decision support
31/M30	Sec. 170.306(d)(1), Electronic copy of health information
31/M31	Sec. 170.306(d)(2), Electronic copy of health information (for discharge summary)
31/M32	Sec. 170.306(e), Electronic copy of discharge instructions
31/M33	Sec. 170.306(f), Exchange clinical information and patient summary record
31/M34	Sec. 170.306(g), Reportable lab results
31/M35	Sec. 170.306(h), Advance directives
31/M36	Sec. 170.306(i), Calculate and submit clinical quality measures

Complete the Application Supplement on the next pages.

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APPLICATION SUPPLEMENT

QUALITY MANUAL (see NIST Handbook 150:2006, subclauses 3.1.2 and 4.2)

Please provide NVLAP with a copy of your laboratory quality manual and supporting management system documentation, including test procedures, with your initial application and with each renewal application.

The documentation may accompany this application or may be sent at a later date; however, NVLAP will take no action on your application until the documentation is received.

ORGANIZATIONAL CHART (see NIST Handbook 150:2006, subclauses 3.1.2 and 4.1)

In addition to the organizational chart provided in response to Item 11 in the general application, attach a list of all testers and those methods in which the individual performs tests.

PROFICIENCY TESTING (see NIST Handbook 150:2006, subclause 3.4)

For Healthcare Information Technology (HIT) Testing, a proficiency written exam is required prior to the initial on-site assessment and an oral proficiency quiz is conducted as part of every on-site visit. At the end of the initial on-site, an operational proficiency test may be provided to the laboratory, which must be successfully evaluated prior to accreditation.

Proficiency written exam – If the laboratory is applying for initial accreditation, once the assessor(s) determines that the management system meets the requirements, a written exam will be provided to the applicant laboratory. This exam evaluates the laboratory personnel's technical expertise and knowledge of the governing standards and test methods applicable to the scope(s) of accreditation for which the laboratory is applying. The laboratory must successfully complete the exam for the accreditation process to continue and the on-site visit to be scheduled.

Proficiency/round-table quiz during on-site – During the on-site visit, the laboratory's personnel will be quizzed and team dynamics observed for proficiency and expertise in the technical area for which the laboratory is applying for accreditation. Staff member interaction and knowledge distribution among team members are key factors monitored by the assessors.

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Proficiency Artifact and/or Operational Exam – Once it is determined that the laboratory has satisfactorily completed the on-site visit, a proficiency artifact and/or operational exam may be required (at the end of the initial on-site assessment). The proficiency artifact and/or operational exam would be designed to evaluate the laboratory’s understanding of, and competence to apply, the Health Information Technology conformance testing methodology specific to the scope of accreditation for which the laboratory is applying. If NVLAP determines that the proficiency artifact and/or operational exam is required, then in order to become initially accredited to its requested scope of accreditation, the laboratory shall successfully complete the proficiency artifact and/or operational exam by the NVLAP-specified deadline.

ON-SITE ASSESSMENT (see NIST Handbook 150:2006, subclauses 3.2 and 3.3)

The on-site assessment for HIT laboratories is typically two days in length. Experts from several areas may quiz the laboratory personnel (see **Proficiency/round-table quiz during on-site** above) via direct interaction or teleconference during that time. If any issues arise that would warrant further technical discussions, this may add an extra half-day to the on-site, depending upon issues that need to be addressed subsequent to the oral quizzes.