

DATE:

NVLAP LAB CODE:

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

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**Instructions:** Please check the method for which you are requesting accreditation.

***NVLAP      Test Procedure Description  
Code***

**2011 Edition Testing Criteria**

- 31/2011      Testing based on criteria 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).

**2014 Edition Testing Criteria**

- 31/2014      Testing based on criteria in 45 CFR Part 170, Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology; Final Rule (September 4, 2012).

**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.