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Intermittent Testing for Non-waived Test System

Purpose This document defines the requirements that must be met when an intermittent test is put back into production in the SCPMG Laboratory Systems.

Scope This policy applies to non-waived tests that are taken out of production for a period of time, and then reintroduced to production. The policy does not apply to waived tests.

Definition

Intermittent Testing	Tests that are taken out of production for a time (for example, seasonal testing). A test is considered to be taken out of production when (1) patient testing is not offered **AND** (2) proficiency testing or alternative assessment, as applicable, is suspended.

Policy When a test system is put back into production in the SCPMG Laboratory Systems, the following requirements must be met:

1. Proficiency testing or alternative assessment performed within 30 days prior to restarting patient testing
2. Method performance specifications verified within 30 days prior to restarting patient testing
3. Competency assessed for testing personnel within 12 months prior to restarting patient testing

For tests for which proficiency testing is required by CAP, if a proficiency testing challenge is not offered during the 30 day period prior to restarting patient testing, an alternative assessment for the test may be performed. In such a case, the SCPMG Laboratory Systems must participate in the next scheduled proficiency testing event.

Non-Controlled Documents The following non-controlled document supports this policy.

- College of American Pathologists, All Common Checklist

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Controlled Documents

The following controlled documents support this policy.

Policy
QM 5.5.2.100 version 02 – **Validation Policy for FDA Approved Non-waived Test System,**
QM 5.6.4.100 version 01 **– Proficiency Testing**
QM 5.6.4.101 version 01 **– Alternate Proficiency Testing**

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Intermittent Testing for Non-waived Test System, Continued

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New Lab Director - QMS

Initial Approval

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