R603 – General Requirements – Proficiency Testing for Clinical Testing Laboratories Meeting the CLIA Requirements

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I. Proficiency Testing

Proficiency testing (PT) is an evaluation of laboratory performance against pre-established criteria usually by means of inter-laboratory comparisons. Results from proficiency testing are an indication of a laboratory's competence and are an integral part of the assessment and accreditation process. A2LA's Clinical Laboratory Accreditation Programs for CLIA laboratories, requires successful participation in Centers for Medicare and Medicaid Services (CMS) approved PT programs. A2LA assesses compliance with proficiency testing requirements using C615 – General Checklist: Proficiency Testing for Clinical Testing Laboratories Meeting the CLIA Requirements.

This document describes PT required for obtaining and maintaining A2LA Accreditation in the Clinical field for CLIA. For specific proficiency testing requirements for a given specialty or sub-specialty, please see Appendix A and B of this document. The Laboratory Director has the responsibility to ensure that the laboratory has subscribed to the necessary PT programs and for monitoring the clinical laboratory's performance of the PT within those programs.

A2LA does not currently require participation in proficiency testing for waived testing. Although this participation is not required, this practice is recommended as enrolling in a PT program and performing PT on waived tests provides an excellent indication of the accuracy of the waived testing and can improve the quality of testing to patients.

A2LA specific requirements found in this Policy are in bold type and numbered as in **"(PT1)".**

II. Proficiency Testing Conditions for Accreditation

Those clinical laboratories seeking to achieve accreditation through A2LA must agree to comply with the CLIA requirements listed below.

1. (42 CFR 493.801) Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I (Appendix B) of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.

2. (42 CFR 493.801 a) The laboratory must—

    a. (42 CFR 493.801 a (1)) Notify HHS of the approved program or programs in which it chooses to participate to meet proficiency testing requirements of this subpart.

    b. (42 CFR 493.801 a (2)(i)) Designate the program(s) to be used for each specialty, subspecialty, and analyte or test to determine compliance with this subpart if the laboratory participates in more than one proficiency testing program approved by CMS; and

    c. (42 CFR 493.801 a (2)(ii)) For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with §493.1236(c)(1).

    d. (42 CFR 493.801 a (3)) For each specialty, subspecialty and analyte or test, participate in one approved proficiency testing program or programs, for one year before designating a different program and must notify CMS before any change in designation; and

    e. (42 CFR 493.801 a (4)) Authorize the proficiency testing program to release to HHS all data required to—

        i. (42 CFR 493.801 a (4)(i)) Determine the laboratory's compliance with this subpart; and

ii. (42 CFR 493.801 a (4)(ii)) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act.

3. (42 CFR 493.801 b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.

    a. (42 CFR 493.801 b (1)) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods. The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.

    b. (42 CFR 493.801 b (2)) The laboratory must test samples the same number of times that it routinely tests patient samples.

    c. (42 CFR 493.801 b (3)) Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications pertaining to the results of proficiency testing sample(s) until after the date by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent. Laboratories with multiple testing sites or separate locations must not participate in any communications or discussions across sites/locations concerning proficiency testing sample results until after the date by which the laboratory must report proficiency testing results to the program.

    d. (42 CFR 493.801 b (4)) The laboratory must not send proficiency testing samples or portions of proficiency testing samples to another laboratory for any analysis for which it is certified to perform in its own laboratory. Any laboratory that CMS determines intentionally referred a proficiency testing sample to another laboratory for analysis may have its certification revoked for at least 1 year. If CMS determines that a proficiency testing sample was referred to another laboratory for analysis, but the requested testing was limited to reflex, distributive, or confirmatory testing that, if the sample were a patient specimen, would have been in full conformance with written, legally accurate and adequate standard operating procedures for the laboratory's testing of patient specimens, and if the proficiency testing referral is not a repeat proficiency testing referral, CMS will consider the referral to be improper and subject to alternative sanctions in accordance with §493.1804(c), but not intentional. Any laboratory that receives a proficiency testing sample from another laboratory for testing must notify CMS of the receipt of that sample regardless of whether the referral was made for reflex or confirmatory testing, or any other reason.

    e. (42 CFR 493.801 b (5)) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event.

    f. (42 CFR 493.801 b (6)) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

4. (42 CFR 493.803 a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA.

5. (42 CFR 493.803 b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part.

6. (42 CFR 493.803 c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists:

    a. (42 CFR 493.803 c (1)) There is immediate jeopardy to patient health and safety.

    b. (42 CFR 493.803 c (2)) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance.

    c. (42 CFR 493.803 c (3)) The laboratory has a poor compliance history.

7. (42 CFR 493.807 a) If a laboratory's certificate is suspended or limited or its Medicare or Medicaid approval is cancelled or its Medicare or Medicaid payments are suspended because it fails to participate successfully in proficiency testing for one or more specialties, subspecialties, analyte or test, or voluntarily withdraws its certification under CLIA for the failed specialty, subspecialty, or analyte, the laboratory must then demonstrate sustained satisfactory performance on two consecutive proficiency testing events, one of which may be on site, before CMS will consider it for reinstatement for certification and Medicare or Medicaid approval in that specialty, subspecialty, analyte or test.

8. (42 CFR 493.807 b) The cancellation period for Medicare and Medicaid approval or period for suspension of Medicare or Medicaid payments or suspension or limitation of certification under CLIA for the failed specialty, subspecialty, or analyte or test is for a period of not less than six months from the date of cancellation, limitation or suspension of the CLIA certificate.

III. Reporting Requirements for the Release of PT Data

(PT1) Laboratories must authorize its PT provider to furnish to A2LA and CMS the results of the laboratory's participation in an approved PT program for the purpose of monitoring the laboratory's PT and for making the annual PT results, along with explanatory information required to interpret the PT results, available on a reasonable basis, upon request of any person. A laboratory that refuses to authorize release of its PT results is no longer deemed to meet the condition level requirements and is subject to full review by CMS, in accordance with 42 CFR 493, Subpart Q and may be subject to the suspension or revocation of its accreditation under 42 CFR 493.1840.

a. The laboratory must also provide to A2LA the results of any internal performance verification program in accordance with 42 CFR 493.1236(c)(1), and as outlined in their documented PT plan. The internal summary data derived from the program must be made available to the assessors during visits.

b. Detailed corrective action responses for any outlying or unacceptable results related to testing on their Scope of Accreditation must also be submitted. See Section X.

c. Laboratories that refuse to provide their PT results to CMS and A2LA will not be accredited and those that are already accredited will have their accreditation suspended until the conditions are agreed to.

d. The laboratory's scope of accreditation found on the A2LA website will be revised to reflect revocations. Failure to meet minimum participation requirements or to respond to A2LA requests for information may result in an adverse accreditation action (including suspension or revocation of accreditation or revision of the scope of accreditation). Any such adverse actions will be reported to CMS.

A2LA will provide proficiency testing data to CMS or to state regulatory agencies as required by law. Additionally, upon receiving proper written request from a member of the public, A2LA will provide PT performance data in compliance with United States Public Health Act, Section 353.

IV. Proficiency Testing Providers

Applicants and accredited clinical laboratories are required to participate in CMS approved PT programs. A list of CMS approved PT providers is available at http://www.cms.hhs.gov/clia/. If CMS-approved PT programs do not provide samples for a particular analyte or test, the laboratory must verify the accuracy of that analyte or test, and any other analyte or test not listed in 42 CFR 493 Subpart I (Appendix B) at least two times annually.

If a laboratory is notified that the PT provider for one or more of its analytes has failed to meet CMS requirements, the laboratory must notify A2LA within 30 days and provide a written recovery plan for the affected analytes.

V. Proficiency Testing Coverage and Plan

At a minimum, PT participation is required in accordance with 42 CFR 493 Subpart H (Appendix A) and Subpart I (Appendix B) as well as the requirements cited within this document. Failure to comply with the minimum PT requirements set within 42 CFR 493 will result in a condition level deficiency.

(PT2) A2LA requires that laboratories conduct proficiency testing activities for both primary and secondary test systems for non-waived testing. For primary test systems, laboratories (main, branch, hospital satellite, and mobile) must use available commercial PT programs approved by CMS or, if commercial PT is unavailable, internal performance verification data as described in 42 CFR 493.1236(c)(1). Primary test systems are those routinely used by the laboratory; secondary test systems are those used by the laboratory when the primary test system is not available.

For secondary testing systems, the laboratory may opt to use internal performance verification data as described in 42 CFR 493.1236(c) (1), in lieu of commercially available PT samples.

Internal performance verification checks include, but are not limited to, the following types of activities:

1. Regular use of certified reference materials and/or internal quality control using secondary reference materials
2. Replicate tests or calibrations using the same or different methods
3. Re-testing of retained items; and
4. Split patient samples with another laboratory

CAUTION: Performing PT on secondary testing systems using the same PT materials obtained for the primary testing system is a violation of 42 CFR 493.801(b) (1) and (2).

For those tests performed by the laboratory that are not included in Subpart I (Appendix B) of 42 CFR 493, the laboratory must establish and maintain the accuracy of its testing procedures in accordance with 42 CFR 493.1236:

a. The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H (Appendix A) of this part.

b. The laboratory must verify the accuracy of the following:

    1. Any analyte or subspecialty without analytes listed in subpart I (Appendix B) of this part that is not evaluated or scored by a CMS-approved proficiency testing program.

2. Any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I (Appendix B) of this part, or the laboratory receives a zero score for nonparticipation, or late return of results).

c. At least twice annually, the laboratory must verify the accuracy of the following:

1. Any test or procedure it performs that is not included in subpart I (Appendix B) of this part
2. Any test or procedure listed in subpart I (Appendix B) of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program

d. All proficiency testing evaluation and verification activities must be documented.

(PT3) Clinical laboratories must develop a written Proficiency Testing Plan describing how it will meet the minimum proficiency testing participation requirements described in 42 CFR 493 and this document. **(PT4)** This plan shall cover any commercially available PT and internal performance verification checks, as applicable, for each specialty, subspecialty, test, test method, and analyte. If an analyte is tested and reported by more than one method, the laboratory must participate in proficiency testing for all methods that could be utilized to test and report that analyte during that tie frame. The plan must also include notification to CMS and A2LA of the approved program or programs in which it intends to participate in to meet the requirements, and a notification of any changes to the proficiency testing plan as a result of a change in proficiency testing providers.

This plan must be submitted to A2LA with initial applications, annual reviews, and renewal applications. The laboratory's PT plan will be reviewed as part of the laboratory's regular assessment and annual review processes by A2LA assessors and staff.

VI. Before Accreditation is Granted

(PT5) Applicant clinical laboratories for A2LA accreditation must demonstrate successful participation in at least one CMS approved PT activity prior to receiving accreditation. This activity must be successfully completed for each specialty/subspecialty on the laboratory's scope of accreditation.

Applicant clinical laboratories should enroll in suitable PT programs in advance of submitting their application package to ensure that there is no delay in timely completion of the accreditation process.

VII. Successful Participation

Successful participation provides the laboratory, regulators, and customers a level of confidence that testing is being conducted in a competent, consistent and accurate manner. The results of commercial PT successful participation are compiled by the PT provider and presented to the laboratory in summary data that informs the laboratory of how its' performance compares to other laboratories using the same technology. Successful participation is calculated using a rolling time frame continuum.

A laboratory may have an outlier PT result that does not constitute an initial or subsequent unsuccessful PT event. In such cases, the laboratory must undertake a corrective action investigation to identify the source of error causing the PT outlier. This corrective action must be submitted to A2LA for review and documentation. See Section X.

VIII. Unsuccessful Participation

Unsatisfactory proficiency testing performance occurs when a laboratory fails to attain the minimum satisfactory score for an analyte, test, subspecialty, or specialty for a testing event.

Unsuccessful proficiency testing performance means a failure to attain the minimum satisfactory score for an analyte, test, subspecialty, or specialty for two consecutive or two of three consecutive testing events.

Initial Unsuccessful PT performance refers to the first occurrence of a failure to achieve satisfactory PT testing performance.

Subsequent Unsuccessful PT performance refers to additional occurrences of a failure to achieve satisfactory PT testing performance that results in a finding of Unsuccessful participation in proficiency testing.

Unsuccessful participation in proficiency testing occurs when the laboratory has:

1. Unsatisfactory performance for the same analyte in two consecutive, or two out of three testing events.

2. Repeated unsatisfactory overall testing event scores for two consecutive, or two out of three testing events for the same specialty or subspecialty.

3. An unsatisfactory testing event score for those subspecialties not graded by analyte (that is, bacteriology, mycobacteriology, virology, parasitology, mycology, blood compatibility, immunohematology, or syphilis serology) for the same subspecialty for two consecutive, or two out of three testing events.

4. Failure of a laboratory performing gynecologic cytology to meet the standard at § 493.855. A laboratory must also meet § 493.801 for laboratory enrollment.

For initial unsuccessful PT, laboratories must undertake corrective action to investigate, identify the root cause of and implement corrective steps to prevent the reoccurrence of the cause of the unsuccessful testing. This process may entail process revision, staff retraining, assistance of a consultant or any combination of these or other steps to develop and implement corrective actions.

If a laboratory experiences subsequent unsuccessful PT, A2LA considers this to be a condition level deficiency and will remove the testing from the scope of accreditation. The laboratory must then undergo the reinstatement process (see Section XII below).

If, however, as part of an initial or subsequent unsuccessful PT event, any of the following conditions exist, A2LA will take appropriate adverse action (restriction of the Scope of Accreditation or suspension or revocation of the Certificate of Accreditation):

1. There is immediate jeopardy to patient health and safety.

2. The laboratory fails to provide A2LA with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance.

3. The laboratory has a poor compliance history.

If a laboratory fails to provide the PT results to the PT provider within the established time frame, a score of "0" will be awarded for that PT challenge. The laboratory must cease testing for that analyte or test until successful PT can be demonstrated. Such PT non-participation and the accreditation actions resulting from that non-participation are reported to CMS by A2LA. When such adverse actions are reported to CMS, additional sanctions may be applied.

IX. Unsuccessful Cytology Proficiency Testing

All A2LA accredited laboratories that perform gynecologic cytology testing must ensure that each laboratory enrolls in a CMS-approved cytology PT program along with each individual (cytotechnologists and pathologists) that screens gynecologic cytology and re-enrolls annually thereafter.

If the laboratory that is accredited to perform cytology fails to do the following, A2LA will intermediately limit the laboratory's scope of accreditation to exclude gynecologic cytology testing:

1. Ensure that individuals engaged in the examination of gynecologic preparations are properly tested

2. Ensure that those who fail a testing event are retested; and

3. Ensure that required remedial actions is taken

4. As described in 42 CFR 493.855 (b)(1), (b)(2) or (b)(3) (Please refer to Appendix A)

This action will be communicated to the CMS Regional Office

A2LA will take appropriate adverse action (restriction of the Scope of Accreditation or suspension or revocation of the Certificate of Accreditation) and notify CMS of that adverse action.

X. Remedial Action

Remedial Actions: **(PT6)** If unacceptable results are received on a formal proficiency testing program, a detailed root cause analysis and corrective action plan must be provided to A2LA within 30 days of notification of unsuccessful PT performance.

A2LA will request additional documentation if the response is incomplete.

The clinical laboratory must also provide A2LA with the results obtained from an assayed control material (or other objective evidence) that has been tested after the Corrective Action Plan has been implemented that demonstrates that the laboratory has successfully corrected the problem. Failure to successfully analyze the sample in this "remedial" round will result in immediate revocation of the testing concerned from the laboratory's Scope of Accreditation. Such changes to the laboratory's scope of accreditation are reported to CMS. CMS may impose additional sanctions as described in 493.807(b). Please see Appendix A.

To facilitate the A2LA review of PT corrective action data, laboratories must complete the F604 – CLIA Program Proficiency Testing Data Submission Form (and include any proficiency testing data not directly reported by the PT provider), with detailed corrective actions within 30 days of receiving the report from the PT provider or their generation of any internal performance-based data as documented in the PT plan, in accordance with 42 CFR 493.1236(c)(1). This form can be provided to you in either in electronic format by contacting A2LA or can be downloaded from the A2LA web site. A2LA may confer with assessors to discuss the results of such studies and assessors will be instructed to review all data associated with these studies during each assessment.

Following a PT failure and associated corrective action, the laboratory will be required to demonstrate successful performance in the subsequent PT challenge. Failure to demonstrate successful performance on the next PT challenge will result in the outlying analyte being excluded from the scope of testing until the laboratory has provided a successful executed corrective action plan and demonstrated satisfactory performance on two consecutive proficiency testing challenges.

Repeated PT failures after remedial action may result in the revocation of the testing concerned from the laboratory's Scope of Accreditation.

Accreditation will be reinstated only upon demonstration of acceptable performance as described in Section XII of this document.

XI. Immediate Jeopardy

Immediate Jeopardy (IJ) is defined as an egregious situation in which results or practices in a clinical laboratory are, or could lead to, real or potential harm to a patient(s) or to the public and immediate action is required to correct the situation. While every unsuccessful PT event is not reason to cite IJ, each occurrence of intentional PT referral is cited as IJ.

When a laboratory intentionally sends its PT samples or portions of samples to another laboratory for any analysis which it is certified to perform in its own laboratory, this is called PT referral. Laboratories that are cited for PT referral are subject to loss of their CLIA certificate for a period of one year, and to enforced withdrawal of their A2LA Accreditation until the CLIA certificate is returned. At that time the laboratory will be eligible to reapply to A2LA for accreditation.

Such adverse actions are taken based upon intentional referral (as described in section 493.801(b)(4)) of any PT sample regardless whether the analyte is cited in 42CFR493 Subpart I or if it is not. Please refer to Appendix A.

Findings of Immediate Jeopardy, if confirmed will result in adverse accreditation actions including the limitation of the scope of accreditation, suspension of accreditation or withdrawal of accreditation. All such actions are reported to CMS where additional statutory sanctions (principle or alternative sanctions as describes in 493.1804) may be imposed.

XII. Reinstatement following Adverse Action

When a laboratory has had its Scope of Accreditation limited, or the Certificate of Accreditation suspended or revoked as the result of unsatisfactory PT performance, such restrictions or adverse actions shall be in place for a minimum of 6 months. To facilitate reinstatement, the laboratory must take the following steps to have the Scope restored or the Accreditation reaffirmed.

1. The laboratory must demonstrate sustained satisfactory performance on two consecutive proficiency testing events for the specialty, subspecialty analyte or test that resulted in the adverse action, one of which may have to be demonstrated to A2LA at the laboratory. Reinstatement (non-routine) PT cannot be applied against the normally scheduled, routine PT frequency requirements (See Section V.).

2. The laboratory should purchase its reinstatement PT samples from the PT provider for which it was enrolled for the failed analyte; however, when those samples will not be readily available, other suitable CMS-approved PT programs may be used. The laboratory must provide A2LA with a corrective action plan and objective evidence that two proficiency testing events have been successfully completed.

3. The laboratory must make application for reinstatement and pay any reinstatement fee and any assessor time and expenses should a visit be needed to verify that the corrective actions have been fully implemented.

APPENDIX A – Subpart H

42 CFR 493.801-865
SUBPART H: PARTICIPATION IN PROFICIENCY TESTING
FOR LABORATORIES PERFORMING NON-WAIVED TESTING

SUBPART H

§ 493.801 Condition: Enrollment and testing of samples.

Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.
(a) *Standard; Enrollment.* The laboratory must—
(1) Notify HHS of the approved program or programs in which it chooses to participate to meet proficiency testing requirements of this subpart.
(2)(i) Designate the program(s) to be used for each specialty, subspecialty, and analyte or test to determine compliance with this subpart if the laboratory participates in more than one proficiency testing program approved by CMS; and
(ii) For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with § 493.1236(c)(1).
(3) For each specialty, subspecialty and analyte or test, participate in one approved proficiency testing program or programs, for one year before designating a different program and must notify CMS before any change in designation; and
(4) Authorize the proficiency testing program to release to HHS all data required to—
(i) Determine the laboratory's compliance with this subpart; and
(ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act.
(b) *Standard; Testing of proficiency testing samples.*
The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens.
(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods. The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.
(2) The laboratory must test samples the same number of times that it routinely tests patient samples.
(3) Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications pertaining to the results of proficiency testing sample(s) until after the date by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent. Laboratories with multiple testing sites or separate locations must not participate in any communications or discussions across sites/locations concerning proficiency testing sample results until after the date by which the laboratory must report proficiency testing results to the program.
(4) The laboratory must not send PT samples or portions of samples to another laboratory for any analysis for which it is certified to perform in its own laboratory. Any laboratory that CMS determines intentionally referred a proficiency testing sample to another laboratory for analysis will have its certification revoked for at least one year. If CMS determines that a proficiency testing sample was referred to another laboratory for analysis, but the requested testing was limited to reflex, distributive, or confirmatory testing that, if the sample were a patient specimen, would have been in full conformance with written, legally accurate and adequate standard operating procedures for the laboratory's testing of patient specimens, and if the proficiency testing referral is not a repeat proficiency testing referral, MCS will consider the referral to be improper and subject to alternative sanctions in accordance with 493.1804(c), but not intentional. Any laboratory that receives a proficiency testing sample from

another laboratory for testing must notify CMS of the receipt of that sample regardless of whether the referral was made for reflex or confirmatory testing, or any other reason.
(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory
must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event.
6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

§ 493.803 Condition: Successful participation.

(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA.
(b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part.
(c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists:
(1) There is immediate jeopardy to patient health and safety.
(2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance.
(3) The laboratory has a poor compliance history.

§ 493.807 Condition: Reinstatement of laboratories performing nonwaived testing.

(a) If a laboratory's certificate is suspended or limited or its Medicare or Medicaid approval is cancelled or its Medicare or Medicaid payments are suspended because it fails to participate successfully in proficiency testing for one or more specialties, subspecialties, analyte or test, or voluntarily withdraws its certification under CLIA for the failed specialty, subspecialty, or analyte, the laboratory must then demonstrate sustained satisfactory performance on two consecutive proficiency testing events, one of which may be on site, before CMS will consider it for reinstatement for certification and Medicare or Medicaid approval in that specialty, sub-specialty, analyte or test.
(b) The cancellation period for Medicare and Medicaid approval or period for suspension of Medicare or Medicaid payments or suspension or limitation of certification under CLIA for the failed specialty, subspecialty, or analyte or test is for a period of not less than six months from the date of cancellation, limitation or suspension of the CLIA certificate.

PROFICIENCY TESTING BY SPECIALTY AND SUBSPECIALTY FOR LABORATORIES PERFORMING TESTS OF MODERATE COMPLEXITY (INCLUDING THE SUB-CATEGORY), HIGH COMPLEXITY, OR ANY COMBINATION OF THESE TESTS

§ 493.821 Condition: Microbiology.

The specialty of microbiology includes, for purposes of proficiency testing, the sub-specialties of bacteriology, mycobacteriology, mycology, parasitology and virology.

§ 493.823 Standard; Bacteriology.

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.
(b) Failure to participate in a testing event is un-satisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—
(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;
(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and
(3) The laboratory participated in the previous two proficiency testing events.
(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.
(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.
(2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.
(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.825 Standard; Mycobacteriology.

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.
(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—
(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;
(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and
(3) The laboratory participated in the previous two proficiency testing events.
(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.
(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.
(2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.
(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.827 Standard; Mycology.

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.
(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—
(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;
(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and
(3) The laboratory participated in the previous two proficiency testing events.
(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.
(2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.
(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.829 Standard; Parasitology.

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.
(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—
(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;
(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and
(3) The laboratory participated in the previous two proficiency testing events.
(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.
(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.
(2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.
(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.
§ 493.831 Standard; Virology.

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.
(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—
(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;
(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and
(3) The laboratory participated in the previous two proficiency testing events.
(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.
(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.
(2) For any unsatisfactory testing events, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.
(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.833 Condition: Diagnostic immunology.

The specialty of diagnostic immunology includes for purposes of proficiency testing the subspecialties of syphilis serology and general immunology.

§ 493.835 Standard; Syphilis serology.

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.
(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—
(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;
(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and
(3) The laboratory participated in the previous two proficiency testing events.
(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.
(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.
(2) For any unacceptable testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.
(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.837 Standard; General immunology.

(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.
(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.
(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—
(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;
(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and
(3) The laboratory participated in the previous two proficiency testing events.
(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.
(e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.
(2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.
(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.
(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.839 Condition: Chemistry.

The specialty of chemistry includes for the purposes of proficiency testing the sub-specialties of routine chemistry, endocrinology, and toxicology.

§ 493.841 Standard; Routine chemistry.

(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.
(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.
(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—
(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;
(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and
(3) The laboratory participated in the previous two proficiency testing events.
(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.
(e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.
(2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.
(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.
(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.843 Standard; Endocrinology.

(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.
(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.
(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—
(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;
(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and
(3) The laboratory participated in the previous two proficiency testing events.
(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.
(e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.
(2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.
(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.
(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.845 Standard; Toxicology.

(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.
(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.
(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—
(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;
(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and
(3) The laboratory participated in the previous two proficiency testing events.
(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.
(e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake
appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.
(2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.
(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.
(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.849 Condition: Hematology.

The specialty of hematology, for the purpose of proficiency testing, is not subdivided into subspecialties of testing.

§ 493.851 Standard; Hematology.

(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.
(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.
(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—
(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;
(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and
(3) The laboratory participated in the previous two proficiency testing events.
(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.
(e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.
(2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is un-successful performance.
(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.853 Condition: Pathology.

The specialty of pathology includes, for purposes of proficiency testing, the sub-specialty of cytology limited to gynecologic examinations.

§ 493.855 Standard; Cytology: gynecologic examinations.

To participate successfully in a cytology proficiency testing program for gynecologic examinations (Pap smears), the laboratory must meet the requirements of paragraphs (a) through (c) of this section.
(a) The laboratory must ensure that each individual engaged in the examination of gynecologic preparations is enrolled in a proficiency testing program approved by CMS by January 1, 1995, if available in the State in which he or she is employed. The laboratory must ensure that each individual is tested at least once per year and obtains a passing score. To ensure this annual testing of individuals, an announced or unannounced testing event will be conducted on-site in each laboratory at least once each year. Laboratories will be notified of the time of each announced on-site testing event at least 30 days prior to each event. Additional testing events will be conducted as necessary in each State or region for the purpose of testing individuals who miss the on-site testing event and for retesting individuals as described in paragraph (b) of this section.
(b) The laboratory must ensure that each individual participates in an annual testing event that involves the examination of a 10-slide test set as described in § 493.945. Individuals who fail this testing event are retested with another 10-slide test set as described in paragraphs (b)(1) and (b)(2) of this section. Individuals who fail this second test are subsequently retested with a 20-slide test set as described in paragraphs (b)(2) and (b)(3) of this section. Individuals are given not more than 2 hours to complete a 10-slide test and not more than 4 hours to complete a 20- slide test. Unexcused failure to appear by an individual for a retest will result in test failure with resulting remediation and limitations on slide examinations as specified in (b)(1), (b)(2), and (b)(3) of this section.
(1) An individual is determined to have failed the annual testing event if he or she scores less than 90 percent on a 10-slide test set. For an individual who fails an annual proficiency testing event, the laboratory must schedule a retesting event which must take place not more than 45 days after receipt of the notification of failure.
(2) An individual is determined to have failed the second testing event if he or she scores less than 90 percent on a 10-slide test set. For an individual who fails a second testing event, the laboratory must provide him or her with documented, remedial training and education in the area of failure, and must assure that all gynecologic slides evaluated subsequent to the notice of failure are reexamined until the individual is again retested with a 20-slide test set and scores at least 90 percent. Reexamination of slides must be documented.
(3) An individual is determined to have failed the third testing event if he or she scores less than 90 percent on a 20-slide test set. An individual who fails the third testing event must cease examining gynecologic slide preparations immediately upon notification of test failure and may not resume examining gynecologic slides until the laboratory assures that the individual obtains at least 35 hours of documented, formally structured, continuing education in diagnostic cytopathology that focuses on the examination of gynecologic preparations, and until he or she is retested with a 20-slide test set and scores at least 90 percent.
(c) If a laboratory fails to ensure that individuals are tested or those who fail a testing event are retested, or fails to take required remedial actions as described in paragraphs (b)(1), (b)(2) or (b)(3) of this section, CMS will initiate intermediate sanctions or limit the laboratory's certificate to exclude gynecologic cytology testing under CLIA, and, if applicable, suspend the laboratory's Medicare and Medicaid payments for gynecologic cytology testing in accordance with subpart R of this part.

§ 493.857 Condition: Immunohematology.

The specialty of Immunohematology includes four subspecialties for the purposes of proficiency testing: ABO group and D (Rho) typing; unexpected antibody detection; compatibility testing; and antibody identification.

§ 493.859 Standard; ABO group and D (Rho) typing.

(a) Failure to attain a score of at least 100 percent of acceptable responses for each analyte or test in each testing event is unsatisfactory analyte performance for the testing event.
(b) Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance.
(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—
(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;
(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and
(3) The laboratory participated in the previous two proficiency testing events.
(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.
(e)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.
(2) For any unacceptable analyte or unsatisfactory testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.
(f) Failure to achieve satisfactory performance for the same analyte in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.
(g) Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.861 Standard; Unexpected antibody detection.

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.
(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—
(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;
(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and
(3) The laboratory participated in the previous two proficiency testing events.
(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.
(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.
(2) For any unsatisfactory testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.
(e) Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.863 Standard; Compatibility testing.

(a) Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—
(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;
(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and
(3) The laboratory participated in the previous two proficiency testing events.
(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.
(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.
(2) For any unsatisfactory testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.
(e) Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.865 Standard; Antibody identification.

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.
(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—
(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;
(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and
(3) The laboratory participated in the previous two proficiency testing events.
(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.
(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.
(2) For any unsatisfactory testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.
(e) Failure to identify the same antibody in two consecutive or two out of three consecutive testing events is unsuccessful performance.
(f) Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

APPENDIX B – Subpart I

42 CFR 493.901-959
SUBPART I: PROFICIENCY TESTING PROGRAMS
FOR NON-WAIVED TESTS

SUBPART I

§ 493.901 Approval of proficiency testing programs.

In order for a proficiency testing program to receive HHS approval, the program must be offered by a private nonprofit organization or a Federal or State agency, or entity acting as a designated agent for the State. An organization, Federal, or State program seeking approval or reapproval for its program for the next calendar year must submit an application providing the required information by July 1 of the
current year. The organization, Federal, or State program must provide technical assistance to laboratories seeking to qualify under the program, and must, for each specialty, subspecialty, and analyte or test for which it provides testing—
(a) Assure the quality of test samples, appropriately evaluate and score the testing results, and identify performance problems in a timely manner;
(b) Demonstrate to HHS that it has—
(1) The technical ability required to—
(i) Prepare or purchase samples from manufacturers who prepare the samples in conformance with the appropriate good manufacturing practices required in 21 CFR parts 606, 640, and 820; and
(ii) Distribute the samples, using rigorous quality control to assure that samples mimic actual patient specimens when possible and that samples are homogeneous, except for specific subspecialties such as cytology, and will be stable within the time frame for analysis by proficiency testing participants;
(2) A scientifically defensible process for determining the correct result for each challenge offered by the program;
(3) A program of sufficient annual challenge and with the frequency specified in §§ 493.909 through 493.959 to establish that a laboratory has met minimum performance requirements;
(4) The resources needed to provide Statewide or nationwide reports to regulatory agencies on individual's performance for gynecologic cytology and on individual laboratory performance on testing events, cumulative reports and scores for each laboratory or individual, and reports of specific laboratory failures using grading criteria acceptable to HHS. These reports must be provided to HHS on a timely basis when requested;
(5) Provisions to include on each proficiency
testing program report form used by the laboratory to record testing event results, an attestation statement that proficiency testing samples were tested in the same manner as patient specimens with a signature block to be completed by the individual performing the test as well as by the laboratory director;
(6) A mechanism for notifying participants of the PT shipping schedule and for participants to notify the proficiency testing program within three days of the expected date of receipt of the shipment that samples have not arrived or are unacceptable for testing. The program must have provisions for replacement of samples that are lost in transit or are received in a condition that is unacceptable for testing; and
(7) A process to resolve technical, administrative, and scientific problems about program operations;
(c) Meet the specific criteria for proficiency testing programs listed by specialty, subspecialty, and analyte or test contained in §§ 493.901 through 493.959 for initial approval and thereafter provide HHS, on an annual basis, with the information necessary to assure that the proficiency testing program meets the criteria required for approval; and
(d) Comply with all applicable packaging, shipment, and notification requirements of 42 CFR part 72.

§ 493.903 Administrative responsibilities.

The proficiency testing program must—
(a)(1) Provide HHS or its designees and participating laboratories with an electronic or a hard copy, or both, of reports of proficiency testing results and all scores for each laboratory's performance in a format as required by

and approved by CMS for each CLIA certified specialty, subspecialty, and analyte or test within 60 days after the date by which the laboratory must report proficiency testing results to the proficiency testing program.
(2) Provide HHS with reports of PT results and scores of individual performance in cytology and provide copies of reports to participating individuals, and to all laboratories that employ the individuals, within *15* working days of the testing event;
(b) Furnish to HHS cumulative reports on an individual laboratory's performance and aggregate data on CLIA certified laboratories for the purpose of establishing a system to make the proficiency testing program's results available, on a reasonable basis, upon request

of any person, and include such explanatory information as may be appropriate to assist in the interpretation of the proficiency testing program's results;
(c) Provide HHS with additional information and data upon request and submit such information necessary for HHS to conduct an annual evaluation to determine whether the proficiency testing program continues to meet the requirements of §§ 493.901 through 493.959;
(d) Maintain records of laboratories' performance for a period of five years or such time as may be necessary for any legal proceedings; and
(e) Provide HHS with an annual report and, if needed, an interim report which identifies any previously unrecognized sources of variability in kits, instruments, methods, or PT samples, which adversely affect the programs' ability to evaluate laboratory performance.

§ 493.905 Nonapproved proficiency testing programs.

If a proficiency testing program is determined by HHS to fail to meet any criteria contained in §§ 493.901 through 493.959 for approval of the proficiency testing program, CMS will notify the program and the program must notify all laboratories enrolled of the nonapproval and the reasons for nonapproval within 30 days of the notification.

PROFICIENCY TESTING PROGRAMS BY SPECIALTY AND SUBSPECIALTY

§ 493.909 Microbiology.

The subspecialties under the specialty of microbiology for which a program may offer proficiency testing are bacteriology, mycobacteriology, mycology, parasitology and virology. Specific criteria for these sub-specialties are found at §§ 493.911 through 493.919.

§ 493.911 Bacteriology.

(a) *Types of services offered by laboratories.*
In bacteriology, for proficiency testing purposes, there are five types of laboratories:
(1) Those that interpret Gram stains or perform primary inoculation, or both; and refer cultures to another laboratory appropriately certified for the subspecialty of bacteriology for identification;
(2) Those that use direct antigen techniques to detect an organism and may also interpret Gram stains or perform primary inoculation, or perform any combination of these;
(3) Those that, in addition to interpreting Gram stains, performing primary inoculations, and using direct antigen tests, also isolate and identify aerobic bacteria from throat, urine, cervical, or urethral discharge specimens to the genus level and may also perform antimicrobial susceptibility tests on selected isolated microorganisms;
(4) Those that perform the services in paragraph (a) (3) of this section and also isolate and identify aerobic bacteria from any source to the species level and may also perform anti-microbial susceptibility tests; and
(5) Those that perform the services in paragraph (a)(4) of this section and also isolate and identify anaerobic bacteria from any source.
(b) *Program content and frequency of challenge.*
To be approved for proficiency testing for bacteriology, the annual program must provide a minimum of five samples per testing event.

There must be at least three testing events at approximately equal intervals per year. The samples may be provided to the laboratory through mailed shipments or, at HHS' option, may be provided to HHS or its designee for onsite testing. For the types of laboratories specified in paragraph (a) of this section, an annual program must include samples that contain organisms that are representative of the six major groups of bacteria: anaerobes, Enterobacteriaceae, gram-positive bacilli, gram-positive cocci, gram-negative cocci, and miscellaneous gramnegative bacteria, as appropriate. The specific organisms included in the samples may vary from year to year. The annual program must include samples for bacterial antigen detection, bacterial isolation and identification, Gram stain, and anti-microbial susceptibility testing.

(1) An approved program must furnish HHS with a description of samples that it plans to include in its annual program no later than six months before each calendar year. At least 50 percent of the samples must be mixtures of the principal organism and appropriate normal flora. The program must include other important emerging pathogens (as determined by HHS) and either organisms commonly occurring in patient specimens or opportunistic pathogens. The program must include the following two types of samples; each type of sample must meet the 50 percent mixed culture criterion:

(i) Samples that require laboratories to report only organisms that the testing laboratory considers to be a principal pathogen that is clearly responsible for a described illness (excluding immuno-compromised patients). The program determines the reportable isolates, including antimicrobial susceptibility for any designated isolate; and

(ii) Samples that require laboratories to report all organisms present. Samples must contain multiple organisms frequently found in specimens such as urine, blood, abscesses, and aspirates where multiple isolates are clearly significant or where specimens are derived from immuno-compromised patients.

The program determines the reportable isolates.

(2) An approved program may vary over time. For example, the types of organisms that might be included in an approved program over time are—

Anaerobes:
Bacteroides fragilis group
Clostridium perfringens
Peptostreptococcus anaerobius
Enterobacteriaceae
Citrobacter freundii
Enterobacter aerogenes
Escherichia coli
Klebsiella pneumoniae
Proteus mirabilis
Salmonella typhimurium
Serratia marcescens
Shigella sonnei
Yersinia enterocolitica
Gram-positive bacilli:
Listeria monocytogenes
Corynebacterium species CDC Group JK
Gram-positive cocci:
Staphylococcus aureus
Streptococcus Group A
Streptococcus Group B
Streptococcus Group D (S. bovis and enterococcus)
Streptococcus pneumoniae
Gram-negative cocci:
Branhamella catarrhalis
Neisseria gonorrhoeae
Neisseria meningitidis
Miscellaneous Gram-negative bacteria:

Campylobacter jejuni
Haemophilis influenza, Type B
Pseudomonas aeruginosa

(3) For antimicrobial susceptibility testing, the program must provide at least one sample per testing event that includes gram-positive or gram-negative strains that have a pre-determined pattern of sensitivity or resistance to the common antimicrobial agents.
(c) *Evaluation of a laboratory's performance.*
HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (c) (1) through (7) of this section.
(1) The program determines staining characteristics to be interpreted by Gram stain. The program determines the reportable bacteria to be detected by direct antigen techniques or isolation. To determine the accuracy of a laboratory's response for Gram stain interpretation, direct antigen detection,
identification, or antimicrobial susceptibility testing, the program must compare the laboratory's response for each sample with the response which reflects agreement of either 80 percent of ten or more referee laboratories or 80 percent or more of all participating laboratories.
(2) To evaluate a laboratory's response for a particular sample, the program must determine a laboratory's type of service in accordance with paragraph (a) of this section. A laboratory must isolate and identify the organisms to the same extent it performs these procedures on patient specimens. A laboratory's performance will be evaluated on the basis of its final answer, for example, a laboratory specified in paragraph (a)(3) of this section will be evaluated on the basis of the average of its scores for paragraphs (c)(3) through (c)(6) as determined in paragraph (c)(7) of this section.
(3) Since laboratories may incorrectly report the presence of organisms in addition to the correctly identified principal organism(s), the grading system must provide a means of deducting credit for additional erroneous organisms that are reported. Therefore, the total number of correct responses for organism isolation and identification submitted by the laboratory divided by the number of organisms present plus the number of incorrect organisms reported by the laboratory must be multiplied by 100 to establish a score for each sample in each testing event. For example, if a sample contained one principal organism and the laboratory reported it correctly but reported the presence of an additional organism, which was not considered reportable, the sample grade would be $\frac{1}{(1+1)} \times 100 = 50\%$.

(4) For antimicrobial susceptibility testing, a laboratory must indicate which drugs are routinely included in its test panel when testing patient samples. A laboratory's performance will be evaluated for only those antibiotics for which service is offered. A correct response for each antibiotic will be determined as described in §§ 493.911(c)
(1) using criteria such as the guidelines established by the National Committee for Clinical Laboratory Standards. Grading is based on the number of correct susceptibility responses reported by the laboratory divided by the actual number of correct susceptibility responses determined by the program, multiplied by 100. For example, if a laboratory offers susceptibility testing for *Enterobacteriaceae* using amikacin, cephalothin, and tobramycin, and the organism in the proficiency testing sample is an
Enterobacteriaceae, and the laboratory reports correct responses for two of three antimicrobial agents, the laboratory's grade would be 2/3◎100=67 percent.
(5) The performance criterion for qualitative antigen tests is the presence or absence of the bacterial antigen. The score for antigen tests is the number of correct responses divided by the number of samples to be tested for the antigen, multiplied by 100.
(6) The performance criteria for Gram stain is staining reaction, i.e., gram positive or gram negative. The score for Gram stain is the number of correct responses divided by the number of challenges to be tested, multiplied by 100.
(7) The score for a testing event in bacteriology is the average of the scores determined under paragraphs (c)(3) through (c)(6) of this section
kbased on the type of service offered by the laboratory.

§ 493.913 Mycobacteriology.

(a) *Types of services offered by laboratories.*
In mycobacteriology, there are five types of laboratories for proficiency testing purposes:
(1) Those that interpret acid-fast stains and refer specimen to another laboratory appropriately certified in the subspecialty of mycobacteriology;
(2) Those that interpret acid-fast stains, perform primary inoculation, and refer cultures to another laboratory appropriately certified in the subspecialty of mycobacteriology for identification;
(3) Those that interpret acid-fast stains, isolate and perform identification and/or anti-mycobacterial susceptibility of *Mycobacterium tuberculosis,* but refer other mycobacteria species to another laboratory appropriately certified in the subspecialty of mycobacteriology for identification and/or susceptibility tests;
(4) Those that interpret acid-fast stains, isolate and identify all mycobacteria to the extent required for correct clinical diagnosis, but refer antimycobacterial susceptibility tests to another laboratory appropriately certified in the subspecialty of mycobacteriology; and
(5) Those that interpret acid-fast stains, isolate and identify all mycobacteria to the extent required for correct clinical diagnosis, and perform antimycobacterial susceptibility tests on the organisms isolated.

(b) *Program content and frequency of challenge.*
To be approved for proficiency testing for myco-bacteriology, the annual program must provide a minimum of five samples per testing event. There must be at least two testing events per year. The samples may be provided through mailed shipments or, at HHS' option, provided to HHS or its designee for on-site testing events. For types of laboratories specified in paragraphs (a)(1) and (a) (3) through (5) of this section, an annual program must include samples that contain species that are representative of the 5 major groups (complexes) of mycobacteria encountered in human specimens. The specific mycobacteria included in the samples may vary from year to year.
(1) An approved program must furnish HHS and its agents with a description of samples that it plans to include in its annual program no later than six months before each calendar year. At least 50 percent of the samples must be mixtures of the principal mycobacteria and appropriate normal flora. The program must include mycobacteria commonly occurring in patient specimens and other important emerging mycobacteria (as determined by HHS). The program determines the reportable isolates and correct responses for anti-mycobacterial susceptibility for any designated isolate.
(2) An approved program may vary over time. For example, the types of mycobacteria that might be included in an approved program over time are—

TB
Mycobacterium tuberculosis
Mycobacterium bovis
Group I
Mycobacterium kansasii
Group II
Mycobacterium szulgai
Group III
Mycobacterium avium-intracellulare
Mycobacterium terrae
Group IV
Mycobacterium fortuitum

(3) For antimycobacterial susceptibility testing, the program must provide at least one sample per testing event that includes mycobacterium tuberculosis that has a predetermined pattern of sensitivity or resistance to the common anti-mycobacterial agents.
(4) For laboratories specified in paragraphs (a)(1) and (a)(2), the program must provide at least five samples per testing event that includes challenges that are acid-fast and challenges which do not contain acid-fast organisms.

(c) *Evaluation of a laboratory's performance.*

HHS approves only those programs that assess the accuracy of a laboratory's response in accordance with paragraphs (c)(1) through (6) of this section.
(1) The program determines the reportable
mycobacteria to be detected by acid-fast stain, for isolation and identification, and for anti-mycobacterial susceptibility. To determine the accuracy of a laboratory's response, the program must compare the laboratory's response for each sample with the response that reflects agreement of either 80 percent of ten or more referee laboratories or 80 percent or more of all participating laboratories.
(2) To evaluate a laboratory's response for a particular sample, the program must determine a laboratory's type of service in accordance with paragraph (a) of this section. A laboratory must interpret acid-fast stains and isolate and identify the organisms to the same extent it performs these procedures on patient specimens. A laboratory's performance will be evaluated on the basis of the average of its scores as determined in paragraph (c)(6) of this section.
(3) Since laboratories may incorrectly report the presence of organisms in addition to the correctly identified principal organism(s), the grading system must provide a means of deducting credit for additional erroneous organisms reported. Therefore, the total number of correct responses submitted by the laboratory divided by the number of organisms present plus the number of incorrect organisms reported by the laboratory must be multiplied by 100 to establish a score for each sample in each testing event. For example, if a sample contained one principal organism and the laboratory reported it correctly but reported the presence of an additional organism, which was not present, the sample grade would be $\frac{1}{(1+1)} \times 100 = 50\%$.
(4) For antimycobacterial susceptibility testing, a laboratory must indicate which drugs are routinely included in its test panel when testing patient samples. A laboratory's performance will be evaluated for only those antibiotics for which susceptibility testing is routinely performed on patient specimens. A correct response for each antibiotic will be determined as described in § 493.913(c)(1). Grading is based on the number of correct susceptibility responses reported by the laboratory divided by the actual number of correct susceptibility responses as determined by the program, multiplied by 100. For example, if a laboratory offers susceptibility testing using three anti-mycobacterial agents and the laboratory reports correct response for two of the three anti-mycobacterial agents, the laboratory's grade would be $\frac{2}{3} \times 100 = 67\%$..
(5) The performance criterion for qualitative tests is the presence or absence of acid-fast organisms. The score for acid-fast organism detection is the number of correct responses divided by the number of samples to be tested, multiplied by 100.
(6) The score for a testing event in mycobacteriology is the average of the scores determined under paragraphs (c)(3) through (c)(5) of this section based on the type of service offered by the laboratory.

§ 493.915 Mycology.

(a) *Types of services offered by laboratories.*
In mycology, there are four types of laboratories for proficiency testing purposes that may perform different levels of service for yeasts, dimorphic fungi, dermatophytes, and aerobic actinomycetes:
(1) Those that isolate and identify only yeasts and/or dermatophytes to the genus level;
(2) Those that isolate and identify yeasts and/or dermatophytes to the species level;
(3) Those that isolate and perform identification of all organisms to the genus level; and
(4) Those that isolate and perform identification of all organisms to the species level.

(b) *Program content and frequency of challenge.*
To be approved for proficiency testing for mycology, the annual program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The samples may be provided through mailed shipments or, at HHS' option, may be provided to HHS or its designee for on-site testing. An annual program must include samples that contain organisms that are representative of five major groups of fungi: Yeast or yeastlike fungi; dimorphic fungi; dematiaceous fungi; dermatophytes; and saprophytes, including opportunistic fungi. The specific fungi included in the samples may vary from year to year.

(1) An approved program must, before each calendar year, furnish HHS with a description of samples that it plans to include in its annual program no later than six months before each calendar year. At least 50 percent of the samples must be mixtures of the principal organism and appropriate normal back-ground flora. Other important emerging pathogens (as determined by HHS) and organisms commonly occurring in patient specimens must be included periodically in the program.
(2) An approved program may vary over time. As an example, the types of organisms that might be included in an approved program over time are—

Candida albicans
Candida (other species)
Cryptococcus neoformans
Sporothrix schenckii
Exophiala jeanselmei
Fonsecaea pedrosoi
Microsporum sp.
Acremonium sp.
Trichophvton sp.
Aspergillus fumigatus
Nocardia sp.
Blastomyces dermatitidis 1
Zygomycetes sp.

[1]NOTE: Provided as a nonviable sample.

(c) *Evaluation of a laboratory's performance.*
HHS approves only those programs that assess the accuracy of a laboratory's response, in accordance with paragraphs (c)(1) through (5) of this section.
(1) The program determines the reportable organisms. To determine the accuracy of a laboratory's response, the program must compare the laboratory's response for each sample with the response that reflects agree-ment of either 80 percent of ten or more referee laboratories or 80 percent or more of all participating laboratories.
(2) To evaluate a laboratory's response for a particular sample, the program must determine a laboratory's type of service in accordance with paragraph (a) of this section. A laboratory must isolate and identify the organisms to the same extent it performs these procedures on patient specimens.
(3) Since laboratories may incorrectly report the presence of organisms in addition to the correctly identified principal organism(s), the grading system must deduct credit for additional erroneous organisms reported. Therefore, the total number of correct responses submitted by the laboratory divided by the number of organisms present plus the number of incorrect organisms reported by the laboratory must be multiplied by 100 to establish a score for each sample in each shipment or testing event. For example, if a sample contained one principal organism and the laboratory reported it correctly but reported the presence of an additional organism, which was not present, the sample grade would be $\frac{1}{(1+1)} \times 100 = 50\%$.
(4) The score for the antigen tests is the number of correct responses divided by the number of samples to be tested for the antigen, multiplied by 100.
(5) The score for a testing event is the average of the sample scores as determined under paragraph (c)(3) or (c)(4), or both, of this section.

§ 493.917 Parasitology.

(a) *Types of services offered by laboratories.*
In parasitology there are two types of laboratories for proficiency testing purposes—
(1) Those that determine the presence or absence of parasites by direct observation (wet mount) and/or pinworm preparations and, if necessary, refer specimens to another laboratory appropriately certified in the subspecialty of parasitology for identification;

(2) Those that identify parasites using concentration preparations and/or permanent stains.

(b) *Program content and frequency of challenge.*
To be approved for proficiency testing in parasitology, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year.
The samples may be provided through mailed shipments or, at HHS's option, may be provided to HHS or its designee for on-site testing. An annual program must include samples that contain parasites that are commonly encountered in the United States as well as those recently introduced into the United States. Other important emerging
pathogens (as determined by HHS) and parasites commonly occurring in patient specimens must be included periodically in the program.
(1) An approved program must, before each calendar year furnish HHS with a description of samples that it plans to include in its annual program no later than six months before each calendar year. Samples must include both formalinized specimens and PVA (polyvinyl alcohol) fixed specimens as well as blood smears, as appropriate for a particular parasite and stage of the parasite. The majority of samples must contain protozoa or helminths or a combination of parasites. Some samples must be devoid of parasites.
(2) An approved program may vary over time. As an example, the types of parasites that might be included in an approved program over time are—

Enterobius vermicularis
Entamoeba histolytica
Entamoeba coli
Giardia lamblia
Endolimax nana
Dientamoeba fragilis
Iodamoeba butschli
Chilomastix mesnili
Hookworm
Ascaris lumbricoides
Strongyloides stercoralis
Trichuris trichiura
Diphyllobothrium latum
Cryptosporidium sp.
Plasmodium falciparum

(3) For laboratories specified in paragraph (a)(1) of this section, the program must provide at least five samples per testing event that include challenges which contain parasites and challenges that are devoid of parasites.

(c) *Evaluation of a laboratory's performance.*
HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphhs (c)(1) through (6) of this section.
(1) The program must determine the reportable parasites. It may elect to establish a minimum number of parasites to be identified in samples before they are reported. Parasites found in rare numbers by referee laboratories are not considered in scoring a laboratory's performance; such findings are neutral. To determine the accuracy of a laboratory's response, the program must compare the laboratory's response with the response that reflects agreement of either 80 percent of ten or more referee laboratories or 80 percent or more of all participating laboratories.
(2) To evaluate a laboratory's response for a particular sample, the program must determine a laboratory's type of service in accordance with paragraph (a) of this section. A laboratory must determine the presence or absence of a parasite(s) or concentrate and identify the parasites to the same extent it performs these procedures on patient specimens.
(3) Since laboratories may incorrectly report the presence of parasites in addition to the correctly identified principal parasite(s), the grading system must deduct credit for these additional erroneous parasites reported and

not found in rare numbers by the program's referencing process. Therefore, the total number of correct responses submitted by the laboratory divided by the number of parasites present plus the number of incorrect parasites reported by the laboratory must be multiplied
by 100 to establish a score for each sample in each testing event. For example, if a sample contained one principal parasite and the laboratory reported it correctly but reported the presence of an additional parasite, which was not present, the sample grade would be $\frac{1}{(1+1)} \times 100 = 50\%$.
(4) The criterion for acceptable performance for qualitative parasitology examinations is presence or absence of a parasite(s).
(5) The score for parasitology is the number of correct responses divided by the number of samples to be tested, multiplied by 100.
(6) The score for a testing event is the average of the sample scores as determined under paragraphs (c)(3) through (c)(5) of this section.

§ 493.919 Virology.

(a) *Types of services offered by laboratories.*
In virology, there are two types of laboratories for proficiency testing purposes—
(1) Those that only perform tests that directly detect viral antigens or structures, either in cells derived from infected tissues or free in fluid specimens; and
(2) Those that are able to isolate and identify viruses and use direct antigen techniques.

(b) *Program content and frequency of challenge.*
To be approved for proficiency testing in virology, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The samples may be provided to the laboratory through mailed shipments or, at HHS's option, may be provided to HHS or its designee for on-site testing. An annual program must include viral species that are the more commonly identified viruses. The specific organisms found in the samples may vary from year to year. The annual program must include samples for viral antigen detection and viral isolation and identification.
(1) An approved program must furnish HHS with a description of samples that it plans to include in its annual program no later than six months before each calendar year. The program must include other important emerging viruses (as determined by HHS) and viruses commonly occurring in patient specimens.
(2) An approved program may vary over time. For example, the types of viruses that might be included in an approved program over time are the more commonly identified viruses such as Herpes simplex, respiratory syncytial virus, adenoviruses, enteroviruses, and cytomegaloviruses.

(c) *Evaluation of laboratory's performance.*
HHS approves only those programs that assess the accuracy of a laboratory's response in accordance with paragraphs (c)(1) through (5) of this section.
(1) The program determines the reportable viruses to be detected by direct antigen techniques or isolated by laboratories that perform viral isolation procedures. To determine the accuracy of a laboratory's response, the program must compare the laboratory's response for each sample with the response that reflects agreement of either 80 percent of ten or more referee laboratories or 80 percent or more of all participating laboratories.
(2) To evaluate a laboratory's response for a particular sample, the program must determine a laboratory's type of service in accordance with paragraph (a) of this section. A laboratory must isolate and identify the viruses to the same extent it performs these procedures on patient specimens.
(3) Since laboratories may incorrectly report the presence of viruses in addition to the correctly identified principal virus, the grading system must provide a means of deducting credit for additional erroneous viruses reported. Therefore, the total number of correct responses determined by virus culture techniques submitted by the laboratory divided by the number of viruses present plus the number of incorrect viruses reported by the laboratory must be multiplied by 100 to establish a score for each sample in each testing event. For example, if a sample contained one principal virus and the laboratory reported it correctly but reported the presence of an additional virus, which was not present, the sample grade would be $\frac{1}{(1+1)} \times 100 = 50\%$.

(4) The performance criterion for qualitative antigen tests is presence or absence of the viral antigen. The score for the antigen tests is the number of correct responses divided by the number of samples to be tested for the antigen, multiplied by 100.
(5) The score for a testing event is the average of the sample scores as determined under paragraph (c)(3) and (c)(4) of this section.

§ 493.921 Diagnostic immunology.

The subspecialties under the specialty of immunology for which a program may offer proficiency testing are syphilis serology and general immunology. Specific criteria for these sub-specialties are found at §§ 493.923 and 493.927.

§ 493.923 Syphilis serology.

(a) *Program content and frequency of challenge.*
To be approved for proficiency testing in syphilis serology, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The samples may be provided through mailed shipments or, at HHS' option, may be provided to HHS or its designee for on-site testing. An annual program must include samples that cover the full range of reactivity from highly reactive to non-reactive.

(b) *Evaluation of test performance.*
HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (b)(1) through (4) of this section.
(1) To determine the accuracy of a laboratory's response for qualitative and quantitative syphilis tests, the program must compare the laboratory's response with the response that reflects agreement of either 80 percent of ten or more referee laboratories or 80 percent or more of all participating laboratories. The proficiency testing program must indicate the minimum concentration, by method that will be considered as indicating a positive response.
The score for a sample in syphilis serology is the average of scores determined under paragraphs (b)(2) and (b)(3) of this section.
(2) For quantitative syphilis tests, the program must determine the correct response for each method by the distance of the response from the target value. After the target value has been established for each response, the appropriateness of the response must be determined by using fixed criteria. The criterion for acceptable performance for quantitative syphilis serology tests is the target value ◎1 dilution.
(3) The criterion for acceptable performance for qualitative syphilis serology tests is reactive or non-reactive.
(4) To determine the overall testing event score, the number of correct responses must be averaged using the following formula:

$$\frac{Number\ of\ Acceptable\ Responses\ for\ All\ Challenges}{Total\ Number\ of\ All\ Challenges} \times 100 = Testing\ Event\ Score$$

§ 493.927 General immunology.

(a) *Program content and frequency of challenge.*
To be approved for proficiency testing for immunology, the annual program must provide a minimum of five samples per testing event.
There must be at least three testing events at approximately equal intervals per year. The annual program must provide samples that cover the full range of reactivity from highly reactive to non-reactive. The samples may be provided through mailed shipments or, at HHS' option, may be provided to HHS or its designee for on-site testing.

(b) *Challenges per testing event.*

The minimum number of challenges per testing event the program must provide for each analyte or test procedure is five. Analytes or tests for which laboratory performance is to be evaluated include:

Analyte or Test Procedure
Alpha-l antitrypsin
Alpha-fetoprotein (tumor marker)
Antinuclear antibody
Antistreptolysin O
Anti-human immunodeficiency virus (HIV)
Complement C3
Complement C4
Hepatitis markers (HBsAg, anti-HBc,
HBeAg)
IgA
IgG
IgE
IgM
Infectious mononucleosis
Rheumatoid factor
Rubella

(c) *Evaluation of a laboratory's analyte or test performance.*
HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (c)(1) through (5) of this section.
(1) To determine the accuracy of a laboratory's response for quantitative and qualitative immunology tests or analytes, the program must compare the laboratory's response for each analyte with the response that reflects agreement of either 80 percent of ten or more referee laboratories or 80 percent or more of all participating laboratories. The proficiency testing program must indicate the minimum concentration that will be considered as indicating a positive response. The score for a sample in general immunology is either the score determined under paragraph (c)(2) or (3) of this section.
(2) For quantitative immunology analytes or tests, the program must determine the correct response for each analyte by the distance of the response from the target value. After the target value has been established for each response, the appropriateness of the response must be determined by using either fixed criteria or the number of standard deviations (SDs) the response differs from the target value.

Criteria for Acceptable Performance
The criteria for acceptable performance are—

Analyte or test	**Criteria for acceptable performance**
Alpha-1 antitrypsin	Target value ±3 SD.
Alpha-fetoprotein (tumor marker)	Target value ±3 SD.
Antinuclear antibody	Target value ±2 dilutions or positive or negative.
Antistreptolysin O	Target value ±2 dilution or positive or negative.
Anti-Human Immunodeficiency virus	Reactive or nonreactive.
Complement C3	Target value ±3 SD.
Complement C4	Target value ±3 SD.
Hepatitis (HBsAg, anti-HBc, HBeAg)	Reactive (positive) or nonreactive (negative).
IgA	Target value ±3 SD.
IgE	Target value ±3 SD.
IgG	Target value ±25%.
IgM	Target value ±3 SD.
Infectious mononucleosis	Target value ±2 dilutions or positive or negative.

Rheumatoid factor	Target value ±2 dilutions or positive or negative.
Rubella	Target value ±2 dilutions or immune or nonimmune or positive or negative.

(3) The criterion for acceptable performance
for qualitative general immunology tests is positive or negative.
(4) To determine the analyte testing event score, the number of acceptable analyte responses must be averaged using the following formula:

$$\frac{Number\ of\ Acceptable\ Responses\ for\ the\ Analyte}{Total\ Number\ of\ Challenges\ for\ the\ Analyte} \times 100 = Analyte\ Score\ for\ the\ Testing\ Event$$

(5) To determine the overall testing event score, the number of correct responses for all analytes must be averaged using the following formula:

$$\frac{Number\ of\ Acceptable\ Responses\ for\ All\ Challenges}{Total\ Number\ of\ All\ Challenges} \times 100 = Testing\ Event\ Score$$

§ 493.929 Chemistry.

The subspecialties under the specialty of chemistry for which a proficiency testing program may offer proficiency testing are routine chemistry, endocrinology, and toxicology. Specific criteria for these subspecialties are listed in §§ 493.931 through 493.939.

§ 493.931 Routine chemistry.

(a) *Program content and frequency of challenge.*
To be approved for proficiency testing for routine chemistry, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The annual program must provide samples that cover the clinically relevant range of values that would be expected in patient specimens. The specimens may be provided through mailed shipments or, at HHS' option, may be provided to HHS or its designee for on-site testing.

(b) *Challenges per testing event.*
The minimum number of challenges per testing event a program must provide for each analyte or test procedure listed below is five serum, plasma or blood samples.

Analyte or Test Procedure
Alanine aminotransferase (ALT/SGPT)
Albumin
Alkaline phosphatase
Amylase
Aspartate aminotransferase (AST/SGOT)
Bilirubin, total
Blood gas (pH, pO2, and pCO2)
Calcium, total
Chloride
Cholesterol, total
Cholesterol, high density lipoprotein
Creatine kinase
Creatine kinase, isoenzymes
Creatinine
Glucose (Excluding measurements on devices
cleared by FDA for home use)

Iron, total
Lactate dehydrogenase (LDH)
LDH isoenzymes
Magnesium
Potassium
Sodium
Total Protein
Triglycerides
Urea Nitrogen
Uric Acid

(c) *Evaluation of a laboratory's analyteor test performance.*
HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (c)(1) through (5) of this section.
(1) To determine the accuracy of a laboratory's response for qualitative and quantitative chemistry tests or analytes, the program must compare the laboratory's response for each analyte with the response that reflects agree-ment of either 80 percent of ten or more referee laboratories or 80 percent or more of all participating laboratories. The score for a sample in routine chemistry is either the score determined under paragraph (c)(2) or (3) of this section.
(2) For quantitative chemistry tests or analytes, the program must determine the correct response for each analyte by the distance of the response from the target value. After the target value has been established for each response, the appropriateness of the response must be determined by using either fixed criteria based on the percentage difference from the target value or the number of standard deviations (SDs) the response differs from the target value.

Criteria for Acceptable Performance
The criteria for acceptable performance are—

Analyte or test	**Criteria for acceptable performance**
Alanine aminotransferase (ALT/SGPT)	Target value ±20%.
Albumin	Target value ±10%.
Alkaline phosphatase	Target value ±30%.
Amylase	Target value ±30%.
Aspartate aminotransferase (AST/SGOT)	Target value ±20%.
Bilirubin, total	Target value ±0.4 mg/dL or ±20% (greater).
Blood gas pO2	Target value ±3 SD.
pCO2	Target value ±5 mm Hg or ±8% (greater).
pH	Target value ±0.04.
Calcium, total	Target value ±1.0 mg/dL.
Chloride	Target value ±5%.
Cholesterol, total	Target value ±10%.
Cholesterol, high density lipoprotein	Target value ±30%.
Creatine kinase	Target value ±30%.
Creatine kinase isoenzymes	MB elevated (presence or absence) or Target value ±3SD.
Creatinine	Target value ±0.3 mg/dL or ±15% (greater).
Glucose (excluding glucose performed on monitoring devices cleared by FDA for home use)	Target value ±6 mg/dl or ±10% (greater).

Iron, total	Target value ±20%.
Lactate dehydrogenase (LDH)	Target value ±20%.
LDH isoenzymes	LDH1/LDH2 (+ or −) or Target value ±30%.
Magnesium	Target value ±25%.
Potassium	Target value ±0.5 mmol/L.
Sodium	Target value ±4 mmol/L.
Total Protein	Target value ±10%.
Triglycerides	Target value ±25%.
Urea nitrogen	Target value ±2 mg/dL or ±9% (greater).
Uric acid	Target value ±17%.

(3) The criterion for acceptable performance for qualitative routine chemistry tests is positive or negative.
(4) To determine the analyte testing event score, the number of acceptable using the following formula:

$$\frac{Number\ of\ Acceptable\ Responses\ for\ the\ Analyte}{Total\ Number\ of\ Challenges\ for\ the\ Analyte} \times 100 = Analyte\ Score\ for\ the\ Testing\ Event$$

(5) To determine the overall testing event score, the number of correct responses for all analytes must be averaged using the following formula:

$$\frac{Number\ of\ Acceptable\ Responses\ for\ All\ Challenges}{Total\ Number\ of\ All\ Challenges} \times 100 = Testing\ Event\ Score$$

§ 493.933 Endocrinology.

(a) *Program content and frequency of challenge.*
To be approved for proficiency testing for endocrinology, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The annual program must provide samples that cover the clinically relevant range of values that would be expected in patient specimens. The samples may be provided through mailed shipments or, at HHS' option, may be provided to HHS or its designee for on-site testing.

(b) *Challenges per testing event.*
The minimum number of challenges per testing event a program must provide for each analyte or test procedure is five serum, plasma, blood, or urine samples.

Analyte or Test
Cortisol
Free Thyroxine
Human Chorionic gonadotropin (excluding urine pregnancy tests done by visual color comparison categorized as waived tests)
T3 Uptake
Triiodothyronine
Thyroid-stimulating hormone
Thyroxine

(c) *Evaluation of a laboratory's analyte or test performance.*
HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (c)(1) through (5) of this section.
(1) To determine the accuracy of a laboratory's response for qualitative and quantitative endocrinology tests or analytes, a program must compare the laboratory's response for each analyte with the response that reflects

agree-ment of either 80 percent of ten or more referee laboratories or 80 percent or more of all participating laboratories.
The score for a sample in endocrinology is either the score determined under paragraph (c)(2) or (c)(3) of this section.
(2) For quantitative endocrinology tests or analytes, the program must determine the correct response for each analyte by the distance of the response from the target value. After the target value has been established for each response, the appropriateness of the response must be determined by using either fixed criteria based on the percentage difference from the target value or the number of standard deviations (SDs) the response differs from the target value.

Criteria for Acceptable Performance
The criteria for acceptable performance are—

Analyte or test	**Criteria for acceptable performance**
Cortisol	Target value ±25%.
Free Thyroxine	Target value ±3 SD.
Human Chorionic Gonadotropin (excluding urine pregnancy tests done by visual color comparison categorized as waived tests)	Target value ±3 SD positive or negative.
T3 Uptake	Target value ±3 SD.
Triiodothyronine	Target value ±3 SD.
Thyroid-stimulating hormone	Target value ±3 SD.
Thyroxine	Target value ±20% or 1.0 mcg/dL (greater).

(3) The criterion for acceptable performance for qualitative endocrinology tests is positive or negative.
(4) To determine the analyte testing event score, the number of acceptable analyte responses must be averaged using the following formula:

$$\frac{Number\ of\ Acceptable\ Responses\ for\ the\ Analyte}{Total\ Number\ of\ Challenges\ for\ the\ Analyte} \times 100 = Analyte\ Score\ for\ the\ Testing\ Event$$

(5) To determine the overall testing event score, the number of correct responses for all analytes must be averaged using the following formula:

$$\frac{Number\ of\ Acceptable\ Responses\ for\ All\ Challenges}{Total\ Number\ of\ All\ Challenges} \times 100 = Testing\ Event\ Score$$

§ 493.937 Toxicology.

(a) *Program content and frequency of challenge.*
To be approved for proficiency testing for toxicology, the annual program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The annual program must provide samples that cover the clinically relevant range of values that would be expected in specimens of patients on drug therapy and that cover the level of clinical significance for the particular drug. The samples may be provided through mailed shipments or, at HHS' option, may be provided to HHS or its designee for on-site testing.

(b) *Challenges per testing event.*
The minimum number of challenges per testing event a program must provide for each analyte or test procedure is five serum, plasma, or blood samples.

Analyte or Test Procedure
Alcohol (blood)

Blood lead
Carbamazepine
Digoxin
Ethosuximide
Gentamicin
Lithium
Phenobarbital
Phenytoin
Primidone
Procainamide
(and metabolite)
Quinidine
Theophylline
Tobramycin
Valproic Acid

(c) *Evaluation of a laboratory's analyte or test performance.*

HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (c)(1) through (4) of this section.

(1) To determine the accuracy of a laboratory's responses for quantitative toxicology tests or analytes, the program must compare the laboratory's response for each analyte with the response that reflects agreement of either 80 percent of ten or more referee laboratories or 80 percent or more of all participating laboratories. The score for a sample in toxicology is the score determined under paragraph (c)(2) of this section.

(2) For quantitative toxicology tests or analytes, the program must determine the correct response for each analyte by the distance of the response from the target value. After the target value has been established for each response, the appropriateness of the response must be determined by using fixed criteria based on the percentage difference from the target value.

Criteria for Acceptable Performance

The criteria for acceptable performance are:

Analyte or test	**Criteria for acceptable performance**
Alcohol, blood	Target Value ±25%.
Blood lead	Target Value ±10% or 4 mcg/dL (greater).
Carbamazepine	Target Value ±25%.
Digoxin	Target Value ±20% or ±0.2 ng/mL (greater).
Ethosuximide	Target Value ±20%.
Gentamicin	Target Value ±25%.
Lithium	Target Value ±0.3 mmol/L or ±20% (greater).
Phenobarbital	Target Value ±20%
Phenytoin	Target Value ±25%.
Primidone	Target Value ±25%.
Procainamide (and metabolite)	Target Value ±25%.
Quinidine	Target Value ±25%.
Tobramycin	Target Value ±25%.
Theophylline	Target Value ±25%.
Valproic Acid	Target Value ±25%.

(3) To determine the analyte testing event score, the number of acceptable analyte responses must be averaged using the following formula:

$$\frac{Number\ of\ Acceptable\ Responses\ for\ the\ Analyte}{Total\ Number\ of\ Challenges\ for\ the\ Analyte} \times 100 = Analyte\ Score\ for\ the\ Testing\ Event$$

(5) To determine the overall testing event score, the number of correct responses for all analytes must be averaged using the following formula:

$$\frac{Number\ of\ Acceptable\ Responses\ for\ All\ Challenges}{Total\ Number\ of\ All\ Challenges} \times 100 = Testing\ Event\ Score$$

§ 493.941 Hematology (including routine hematology and coagulation).

(a) *Program content and frequency of challenge.*
To be approved for proficiency testing for hematology, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The annual program must provide samples that cover the full range of values that would be expected in patient specimens. The samples may be provided through mailed shipments or, at HHS' option, may be provided to HHS and or its designee for on-site testing.

(b) *Challenges per testing event.*
The minimum number of challenges per testing event a program must provide for each analyte or test procedure is five.

Analyte or Test Procedure
Cell identification or white blood cell differential
Erythrocyte count
Hematocrit (excluding spun microhematocrit)
Hemoglobin
Leukocyte count
Platelet count
Fibrinogen
Partial thromboplastin time
Prothrombin time

(1) An approved program for cell identification may vary over time. The types of cells that might be included in an approved program over time are—

Neutrophilic granulocytes
Eosinophilic granulocytes
Basophilic granulocytes
Lymphocytes
Monocytes
Major red and white blood cell abnormalities Immature red and white blood cells

(2) White blood cell differentials should be limited to the percentage distribution of cellular elements listed above.

(c) *Evaluation of a laboratory's analyte or test performance.*
HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (c) (1) through (5) of this section.
(1) To determine the accuracy of a laboratory's responses for qualitative and quantitative hematology tests or analytes, the program must compare the laboratory's response for each
analyte with the response that reflects agree-ment of either 80 percent of ten or more referee laboratories or 80 percent or more of all participating laboratories. The score for a sample in hematology is either the score determined under paragraph (c) (2) or (3) of this section.
(2) For quantitative hematology tests or analytes, the program must determine the correct response for each analyte by the distance of the response from the target value. After the target value has been established for each

response, the appropriateness of the response is determined using either fixed criteria based on the percentage difference from the target value or the number of standard deviations (SDs) the response differs from the target value.

Criteria for Acceptable Performance
The criteria for acceptable performance are:

Analyte or test	**Criteria for acceptable performance**
Cell identification	90% or greater consensus on identification.
White blood cell differential	Target ±3SD based on the percentage of different types of white blood cells in the samples.
Erythrocyte count	Target ±6%.
Hematocrit (Excluding spun hematocrits)	Target ±6%.
Hemoglobin	Target ±7%.
Leukocyte count	Target ±15%.
Platelet count	Target ±25%.
Fibrinogen	Target ±20%.
Partial thromboplastin time	Target ±15%.
Prothrombin time	Target ±15%.

(3) The criterion for acceptable performance
for the qualitative hematology test is correct cell identification.
(4) To determine the analyte testing event score, the number of acceptable analyte responses must be averaged using the following formula:

$$\frac{Number\ of\ Acceptable\ Responses\ for\ the\ Analyte}{Total\ Number\ of\ Challenges\ for\ the\ Analyte} \times 100 = Analyte\ Score\ for\ the\ Testing\ Event$$

(5) To determine the overall testing event score, the number of correct responses for all analytes must be averaged using the following formula:

$$\frac{Number\ of\ Acceptable\ Responses\ for\ All\ Challenges}{Total\ Number\ of\ All\ Challenges} \times 100 = Testing\ Event\ Score$$

§ 493.945 Cytology; gynecologic examinations.

a) *Program content and frequency of challenge.*
(1) To be approved for proficiency testing for gynecologic examinations (Pap smears) in cytology, a program must provide test sets composed of 10- and 20-glass slides. Proficiency testing programs may obtain slides for test sets from cytology laboratories, provided the slides have been retained by the laboratory for the required period specified in
§§ 493.1105(a)(7)(i)(A) and 493.1274(f)(2). If slide preparations are still subject to retention by the laboratory, they may be loaned to a proficiency testing program if the program provides the laboratory with documentation of the loan of the slides and ensures that slides loaned to it are retrievable upon request. Each test set must include at least one slide representing each of the response categories described in paragraph (b)(3)(ii)(A) of this section, and test sets should be comparable so that equitable testing is achieved within and between proficiency testing providers.
(2) To be approved for proficiency testing in gynecologic cytology, a program must provide announced and unannounced on-site testing for each individual at least once per year and must provide an initial retesting event for each individual within 45 days after notification of test failure and subsequent retesting events within 45 days after completion of remedial action described in § 493.855.

(b) *Evaluation of an individual's performance.*

HHS approves only those programs that assess the accuracy of each individual's responses on both 10- and 20-slide test sets in which the slides have been referenced as specified in paragraph (b)(1) of this section.
(1) To determine the accuracy of an individual's response on a particular challenge (slide), the program must compare the individual's response for each slide preparation with the response that reflects the pre-determined consensus agreement or confirmation on the diagnostic category, as described in the table in paragraph (b)(3)(ii)(A) of this section. For all slide preparations, a 100% consensus agreement among a minimum of three physicians certified in anatomic pathology is required. In addition, for pre-malignant and malignant slide preparations, confirmation by tissue biopsy is required either by comparison of the reported biopsy results or reevaluation of biopsy slide material by a physician certified in anatomic pathology.
(2) An individual qualified as a technical supervisor under § 493.1449 (b) or (k) who routinely interprets gynecologic slide preparations only after they have been examined by a cytotechnologist can either be tested using a test set that has been screened by a cytotechnologist in the same laboratory or using a test set that has not been screened. A technical supervisor who screens and interprets slide preparations that have not been previously examined must be tested using a test set that has not been previously screened.
(3) The criteria for acceptable performance are determined by using the scoring system in paragraphs (b)(3) (i) and (ii) of this section.
(i) Each slide set must contain 10 or 20 slides with point values established for each slide preparation based on the significance of the relationship of the interpretation of the slide to a clinical condition and whether the participant in the testing event is a cytotechnologist qualified under §§ 493.1469 or 493.1483 or functioning as a technical supervisor in cytology qualified under § 493.1449 (b) or (k) of this part.
(ii) The scoring system rewards or penalizes the participants in proportion to the distance of their answers from the correct response or target diagnosis and the penalty or reward is weighted in proportion to the severity of the lesion.
(A) The four response categories for reporting proficiency testing results and their descriptions are as follows:

Category	**Description**
A	Unsatisfactory for diagnosis due to:
	(1) Scant cellularity.
	(2) Air drying.
	(3) Obscuring material (blood, inflammatory cells, or lubricant).
B	Normal or Benign Changes—includes:
	(1) Normal, negative or within normal limits.
	(2) Infection other than Human Papillomavirus (HPV) (e.g., Trichomonas vaginalis, changes or morphology consistent with Candida spp., Actinomyces spp. or Herpes simplex virus).
	(3) Reactive and reparative changes (e.g., inflammation, effects of chemotherapy or radiation).
C	Low Grade Squamous Intraepithelial Lesion—includes:
	(1) Cellular changes associated with HPV.
	(2) Mild dysplasia/CIN-1.
D	High Grade Lesion and Carcinoma—includes:
	(1) High grade squamous intraepithelial lesions which include moderate dysplasia/CIN-2 and severe dysplasia/carcinoma in-situ/CIN-3.
	(2) Squamous cell carcinoma.
	(3) Adenocarcinoma and other malignant neoplasms.

(B) In accordance with the criteria for the scoring system, the charts in paragraphs (b)(3)(ii)(C) and (D) of this section, for technical supervisors and cytotechnologists, respectively, provide a maximum of 10 points for a correct response and a maximum of minus five (¥5) points for an incorrect response on a 10-slide test set. For example, if the correct response on a slide is ''high grade squamous intraepithelial lesion'' (category ''D'' on the scoring system chart) and an examinee calls it ''normal or negative'' (category ''B'' on the scoring system chart), then the examinee's point value on that slide is calculated as minus five (¥5). Each slide is scored individually in

the same manner. The individual's score for the testing event is determined by adding the point value achieved for each slide preparation, dividing by the total points for the testing event and multiplying by 100.
(C) Criteria for scoring system for a 10-slide test set. (See table at (b)(3)(ii)(A) of this section for a prescription of the response categories.)

For technical supervisors qualified under § 493.1449(b) or (k):

Examinee's response:	**A**	**B**	**C**	**D**
Correct response category:				
A	10	0	0	0
B	5	10	0	0
C	5	0	10	5
D	0	-5	5	10

(D) Criteria for scoring system for a 10-slide test set. (See table at paragraph (b)(3)(ii)(A) of this section for a description of the response categories.)

For cytotechnologists qualified under §§ 493.1469 or 493.1483:

Examinee's response:	**A**	**B**	**C**	**D**
Correct response category:				
A	10	0	5	5
B	5	10	5	5
C	5	0	10	10
D	0	-5	10	10

(E) In accordance with the criteria for the scoring system, the charts in paragraphs (b)(3)(ii)(F) and (G) of this section, for technical supervisors and cytotechnologists, respectively, provide maximums of 5 points for a correct response and minus ten (¥10) points for an incorrect response on a 20-slide test set.
(F) Criteria for scoring system for a 20-slide test set. (See table at paragraph (b)(3)(ii)(A) of this section for a description of the response categories.)

For technical supervisors qualified under § 493.1449(b) or (k):

Examinee's response:	**A**	**B**	**C**	**D**
Correct response category:				
A	5	0	0	0
B	2 .5	5	0	0
C	2 .5	0	5	2 .5
D	0	-10	2 .5	5

(G) Criteria for scoring system for a 20-slide test set. (See table at (b)(3)(ii)(A) of this section for a description of the response categories.)

For cytotechnologists qualified under §§ 493.1469 or 493.1483:

Examinee's response:	**A**	**B**	**C**	**D**
Correct response category:				
A	5	0	2 .5	2 .5
B	2 .5	5	2 .5	2 .5
C	2 .5	0	5	5
D	0	-10	5	5

§ 493.959 Immunohematology.

(a) *Types of services offered by laboratories.*

In immunohematology, there are four types of laboratories for proficiency testing purposes—

(1) Those that perform ABO group and/or D (Rho) typing;

(2) Those that perform ABO group and/or D (Rho) typing, and unexpected antibody detection;

(3) Those that in addition to paragraph (a)(2) of this section perform compatibility testing; and

(4) Those that perform in addition to paragraph (a)(3) of this section antibody identification.

(b) *Program content and frequency of challenge.*

To be approved for proficiency testing for immunohematology, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The annual program must provide samples that cover the full range of interpretation that would be expected in patient specimens. The samples may be provided through mailed shipments or, at HHS' option, may be provided to HHS or its designee for on-site testing.

(c) *Challenges per testing event.*

The minimum number of challenges per testing event a program must provide for each analyte or test procedure is five.

Analyte or Test Procedure

ABO group (excluding subgroups)

D (Rho) typing

Unexpected antibody detection

Compatibility testing

Antibody identification

(d) *Evaluation of a laboratory's analyte or test performance.*

HHS approves only those programs that assess the accuracy of a laboratory's response in accordance with paragraphs (d)(1) through (5) of this section.

(1) To determine the accuracy of a laboratory's response, a program must compare the laboratory's response for each analyte with the response that reflects agreement of either 100 percent of ten or more referee laboratories or 95 percent or more of all participating laboratories except for unexpected antibody detection and antibody identification. To determine the accuracy of a laboratory's response for unexpected antibody detection and antibody identification, a program must compare the laboratory's response for each analyte with the response that reflects agreement of either 95 percent of ten or more referee laboratories or 95 percent or more of all participating laboratories. The score for a sample in immunohematology is either the score determined under paragraph (d)(2) or (3) of this section.

(2) *Criteria for acceptable performance.*

The criteria for acceptable performance are—

Analyte or test	**Criteria for acceptable performance**
ABO group	100% accuracy.
D (Rho) typing	100% accuracy.
Unexpected antibody detection	80% accuracy.
Compatibility testing	100% accuracy.
Antibody identification	80% accuracy.

(3) The criterion for acceptable performance for qualitative immunohematology tests is positive or negative.

(4) To determine the analyte testing event score, the number of acceptable analyte responses must be averaged using the following formula:

$$\frac{Number\ of\ Acceptable\ Responses\ for\ the\ Analyte}{Total\ Number\ of\ Challenges\ for\ the\ Analyte} \times 100 = Analyte\ Score\ for\ the\ Testing\ Event$$

(5) To determine the overall testing event score, the number of correct responses for all analytes must be averaged using the following formula:

$$\frac{Number\ of\ Acceptable\ Responses\ for\ All\ Challenges}{Total\ Number\ of\ All\ Challenges} \times 100 = Testing\ Event\ Score$$

APPENDIX C – PT Scoring and Frequency Quick Reference

QUICK REFERENCE

PT SCORING AND FREQUENCY FROM APPENDIX A 42CFR 493.801-865 AND APPENDIX B 42CFRPT SCORING AND FREQUENCY APPENDIX A 42CFR 493.801-865 AND APPENDIX B 42CFR SUBPART I

SPECIALTY	SUBSPECIALTY	SCORING R603 Appendix A	FREQUENCY/DESCRIPTION R603 Appendix B
MICROBIOLOGY			
	Bacteriology	At least 80% and Must be for 2 consecutive testing events or 2 out of 3 consecutive events	5 samples per testing event 3 testing events / year
	Mycobacteriology	At least 80% and Must be for 2 consecutive testing events or 2 out of 3 consecutive events	5 samples per testing event 2 testing events / year
	Mycology	At least 80% and Must be for 2 consecutive testing events or 2 out of 3 consecutive events	5 samples per testing event 3 testing events / year
	Parasitology	At least 80% and Must be for 2 consecutive testing events or 2 out of 3 consecutive events	5 samples per testing event 3 testing events / year
	Virology	At least 80% and Must be for 2 consecutive testing events or 2 out of 3 consecutive events	5 samples per testing event 3 testing events / year
DIAGNOSTIC IMMUNOLOGY			
	Syphilis serology	At least 80% and Must be for 2 consecutive testing events or 2 out of 3 consecutive events	5 samples per testing event 3 testing events / year
	General immunology	At least 80% and Must be for 2 consecutive testing events or 2 out of 3	5 samples per testing event 3 testing events / year

SPECIALTY	SUBSPECIALTY	SCORING R603 Appendix A	FREQUENCY/DESCRIPTION R603 Appendix B
		consecutive events	
CHEMISTRY			
	Routine chemistry	At least 80% and Must be for 2 consecutive testing events or 2 out of 3 consecutive events	5 samples per testing event 3 testing events / year
	Endocrinology	At least 80% and Must be for 2 consecutive testing events or 2 out of 3 consecutive events	5 samples per testing event 3 testing events / year
	Toxicology	At least 80% and Must be for 2 consecutive testing events or 2 out of 3 consecutive events	5 samples per testing event 3 testing events / year 5 serum, 5 plasma, 5 blood
HEMATOLOGY			
	Hematology (routine hematology and coagulation)	At least 80% and Must be for 2 consecutive testing events or 2 out of 3 consecutive events	5 samples per testing event 3 testing events / year
PATHOLOGY			
	Cytology: gynecologic exams	Each individual engaged in gyn preparation tested 1/yr and obtains passing score. Must score at least 90% 10-slide sets and 20 slide set. Work must be reviewed after two failures until a retest is taken and passed. Failure of three test sets must cease examining.	10-slide test set. If fails read another 10-slide test set. If fail then 20-slide test set. 10 slides in 2 hrs, 20 slides in 4 hrs.
IMMUNOHEMATOLOGY			
	ABO GROUP AND D (Rho) TYPING	Failure to obtain score of at least	5 samples per testing event

SPECIALTY	SUBSPECIALTY	SCORING R603 Appendix A	FREQUENCY/DESCRIPTION R603 Appendix B
		100%	3 testing events / year
	Unexpected antibody detection	At least 80% and Must be for 2 consecutive testing events or 2 out of 3 consecutive events	5 samples per testing event 3 testing events / year
	Compatibility testing	At least 100% and Must be for 2 consecutive testing events or 2 out of 3 consecutive events	5 samples per testing event 3 testing events / year
	Antibody Identification	At least 80% and Must be for 2 consecutive testing events or 2 out of 3 consecutive events	5 samples per testing event 3 testing events / year

DOCUMENT REVISION HISTORY

Date	Description
03/07/20	➢ Integrated into Qualtrax ➢ Added Table of Contents ➢ Updated Header/Footer to current version ➢ Updated format and font for consistency ➢ Added Qualtrax hyperlinks
04/09/21	➢ Updated table and calculation formats in Appendix B ➢ Updated format ➢ Updated Table of ContentsAdded A2LA PT requirements identifiers ➢ Updated section II ➢ Grammatical and Editorial changes ➢ Remove repetitive information throughout the document ➢ Updated clause 493.1236 in section III ➢ Added references to Appendix A and B throughout the document ➢ Moved "Proficiency Testing Providers" and "Reporting Requirements for the Release of PT Data" sections ➢ Combined previous section VII with "Reporting Requirements for the Release of PT Data"
02/25/22	➢ Updated appendix c ➢ Updated table of contents ➢ Updated section IX ➢ Updated section VIII ➢ Removed extra document history