



The American Association for Laboratory Accreditation

**R653- GENERAL REQUIREMENTS:
PROFICIENCY TESTING FOR LABORATORIES
MEETING ISO 15189 REQUIREMENTS**

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**R653: General Requirements:
Proficiency Testing
for
Medical Testing Laboratories
Meeting the
ISO 15189 Requirements**

November 2009

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Requirements

I. Proficiency Testing

Proficiency testing (PT) is a process for checking laboratory performance, usually by means of inter-laboratory data comparisons. The phrase “External Quality Assessment Schemes” is used in ISO 15189:5.6.4 to refer to PT Programs. 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 Medical Laboratory Accreditation Program (for ISO 15189 only accredited laboratories), requires successful participation in Centers for Medicare and Medicaid Services (CMS) approved PT programs and compliance with specific requirements associated with ISO 15189.

A2LA assesses compliance with proficiency testing requirements using **C615 - Proficiency Testing Assessor Checklist: A2LA Medical Testing Accreditation Program**

This document describes PT required for obtaining and maintaining A2LA Accreditation in the medical field for laboratories accredited only to ISO 15189.

The Laboratory Director has the responsibility to ensure that the laboratory has subscribed to the necessary PT programs and for monitoring the medical laboratory’s performance of the PT within those programs.

II. Proficiency Testing Conditions for Accreditation

Those medical laboratories seeking to achieve accreditation through A2LA must agree to comply with the following requirements:

- Notify A2LA of the approved program or programs in which it chooses to participate to meet these requirements and designate the program(s) for each specialty, subspecialty and analyte or test to determine compliance with these requirements if the laboratory participates in more than that one PT program approved by CMS.
- Laboratories will not send PT samples to other laboratories until the PT provider has released the results of the PT challenge.
- Laboratories will distribute the PT challenges among those staff that are authorized and competent to perform the testing required for the PT challenge.
- Laboratories must integrate the PT samples into the normal workload and perform testing on the PT samples in the same manner and number of times that patient samples are tested.
- Laboratories must authorize the PT provider to furnish directly to A2LA the results of the laboratory’s participation in an approved PT program at the same time the results are released to the laboratory, 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. A laboratory that refuses to authorize release of its PT results is



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no longer deemed to meet the accreditation requirements and may be subject to suspension or revocation of its accreditation for that specialty, subspecialty, analyte or test.

III. Minimum Coverage

At a minimum, PT participation is required in accordance with 42CFR493 Laboratory Requirements: Subpart H: *Participation in Proficiency Testing in Laboratories Performing Non-waived Testing {493.801(b)(1)-(6)}*, and Subpart I: *Proficiency Testing Programs for Non-waived Testing {493.901-959}*, and with the requirements cited in this document, R653 – General Requirements: Proficiency Testing for Medical Testing Laboratories Meeting ISO 15189 Requirements .

Each medical laboratory must enroll in a proficiency testing (PT) program that meets the criteria in Subpart I of 42CFR493 (see appendix A) and is approved by CMS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks accreditation. A list of CMS approved PT providers is available at <http://www.cms.hhs.gov/clia/> or on the A2LA website.

For each specialty, subspecialty and analyte or test, the medical laboratory must participate in one approved proficiency testing program or programs, for one year before designating a different program and must notify A2LA before any change in designation.

A2LA requires that laboratories conduct proficiency testing activities for both primary and secondary test systems. For primary test systems, laboratories must use available commercial PT programs approved by CMS or, if commercial PT is unavailable, internal performance verification data as described in 42CFR 493.1236(c) (1) below.

For secondary testing systems, the laboratory may opt to use internal performance verification data as described in ISO 15189, section 5.6.5 below, in lieu of commercially available PT samples.

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

- a. regular use of certified reference materials and/or internal quality control using secondary reference materials;
- b. replicate tests or calibrations using the same or different methods;
- c. re-testing of retained items.

CAUTION: Performing PT on secondary testing systems using the same PT materials obtained for the primary testing system is not acceptable.

The laboratory must review and evaluate the results obtained on proficiency testing as specified by the CMS-approved PT provider programs.

In accordance with 42CFR493.1236 The laboratory must also verify the accuracy of the following:

(1) Any analyte, or subspecialty without analytes, listed in Subpart I of the CLIA requirements 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 of the CLIA requirements, or the laboratory receives a zero score for nonparticipation, or late return of results).

(3) At least twice annually, the laboratory must verify the accuracy of the following:

(a) Any test or procedure it performs that is not included in Subpart I of the CLIA requirements or for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program.

(b) All proficiency testing evaluation and performance verification activities must be documented.

IV. Documented Plan

Medical laboratories must develop a written Proficiency Testing Plan describing how it will meet the minimum proficiency testing participation requirements described in ISO 15189, and the A2LA document, “R653- General Requirements: Proficiency Testing for Medical Testing Laboratories Meeting ISO 15189 Requirements.”

ISO 15189, Section 5.6 requires that “The laboratory shall design internal quality control systems that verify the attainment of the intended quality of results.” Therefore, A2LA requires that laboratories have suitably implemented these requirements and have a documented plan of how they intend to cover the applicable PT requirements and the specialties, subspecialties analytes and tests listed on their scope of accreditation. This plan shall cover any commercially available participation and any intra- and/or inter-laboratory organized studies, as applicable. The plan must include notification to A2LA of the approved programs or programs in which it intends to participate to meet proficiency requirements.

The plan must include all methods of testing for all analytes. 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 time frame.

The medical laboratory must also be able to explain when proficiency testing is not possible for certain testing and provide a description of what the laboratory is doing in lieu of proficiency testing. This shall be included within the plan.

The plan must also address

- the handling, preparation, processing, examination of PT samples,
- the steps in the testing and reporting of results of PT testing,
- the laboratory’s process for submission of proficiency testing results to A2LA,
- that corrective action responses arising from PT errors must be submitted to A2LA within 30 days of receipt;



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- the potential for both announced and unannounced assessments to investigate PT issues;
- the frequency, scope and personnel to be challenged as part of the proficiency testing participation.

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.

This plan must be submitted to A2LA with the application for accreditation or the application for renewal of accreditation packet and reviewed by the A2LA assessor during the on-site assessments. The A2LA Conditions for Accreditation, acknowledged and signed by the laboratory director, requires that laboratories inform A2LA of any changes to this plan.

V. Testing samples

All testing of proficiency testing samples shall be conducted in the laboratory seeking initial or continued accreditation of its testing. The laboratory must not send PT samples or portions of samples to another laboratory for any analysis which it is certified to perform in its own laboratory.

Any laboratory that is determined to have intentionally referred its proficiency testing samples to another laboratory for analysis will have its accreditation revoked for no less than one year and must reapply for accreditation after the revocation.

Any laboratory that receives PT samples from another laboratory for testing must notify A2LA of the receipt of those samples.

The laboratory director and the individual testing the sample must attest that the PT samples were integrated into the routine sample workload and analyzed using the laboratory's process and procedures used for routine testing.

VI. Application to Specialties/Subspecialties on Scope

The laboratory must participate in a CMS approved PT program, at the frequency specified by the PT provider, for each specialty/subspecialty and analyte, for which accreditation is being sought and maintained.

When a specialty/subspecialty or analyte are added to or removed from a laboratory's testing capability , the laboratory must notify A2LA within 30 days of the change.



VII. Before Accreditation is Granted

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

Applicant medical 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.

VIII. Proficiency Testing Providers

Applicants and accredited medical 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/> or on the A2LA website.

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.

IX. Providing A2LA with PT Results

Laboratories must ensure that A2LA receive copies of all reports/results and the accompanying summary information at the same time as they are distributed to the participating laboratory by the approved PT providers. This requirement must be met by authorizing the PT providers to release the laboratory's PT results and summary data to A2LA.

Similarly, the laboratory must provide to A2LA the results of any internal performance verification program as outlined in their documented PT plan. The internal summary data derived from the program must be made available to the assessors during onsite visits.

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

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

The laboratory's scope of accreditation found on the A2LA web site 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).

X. 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. PT samples are integrated into
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the normal workload and tested by workers that normally provide testing services. 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 XIII.

XI. Unsuccessful Participation

1) Unsuccessful participation in proficiency testing occurs when the laboratory has:

- (a) Unsatisfactory performance for the same analyte in two consecutive, or two out of three testing events.
 - (b) Repeated unsatisfactory overall testing event scores for two consecutive, or two out of three testing events for the same specialty or subspecialty.
 - (c) 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.
 - (d) Failure of a laboratory performing gynecologic cytology to meet the standard at § 493.855.
2. *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.
 3. *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.
 4. *Initial Unsuccessful PT performance* refers to the first occurrence of a failure to achieve satisfactory PT testing performance.
 5. *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*.

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 XIII below).

If, however, as part of an initial or subsequent unsuccessful PT event, any of the following conditions exist:

- (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.

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

XII. Unsuccessful Cytology Proficiency Testing

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

If the laboratory that is accredited to perform cytology fails to:

- (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

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

XIII. Remedial Action

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

In addition to corrective action responses for unsuccessful PT participation, A2LA requires a corrective action response for each individual failed result of a PT analyte or sub specialty, and every instance of a failure to participate (or late participation) in PT for a given analyte or sub specialty, for every PT round in which these individual failed results are received.

A2LA will request additional documentation if the response is incomplete.



The medical 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.

To facilitate the A2LA review of PT corrective action data, laboratories must complete the *A2LA 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. This form can be provided to you in either hard copy or 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 such time as the laboratory has provided a successfully executed corrective action plan, and demonstrated satisfactory performance on a proficiency testing challenge.

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.

XIV. Immediate Jeopardy

Immediate Jeopardy (IJ) is defined as an egregious situation in which results or practices in a medical 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 enforced withdrawal of their A2LA accreditation for at least one year and until such time as full and complete corrective action, including root cause analysis is completed and assessed. At that time the laboratory will be eligible to reapply to A2LA for accreditation.

XV. Reinstatement following Adverse Action

When a laboratory has had its Scope of Accreditation limited, 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.



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- 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.
- Provide A2LA the corrective action plan and objective evidence that two proficiency testing events have been successfully completed
- Make application for reinstatement and pay any reinstatement fee and any assessor time and expenses should substantial assessor review of records or onsite surveillance visit be needed to verify that the corrective actions have been fully implemented.

Document Revision History

Date	Description
August 2008	Issued, superseding R306.

Proficiency Testing Requirements for Medical Testing Laboratories
Appendix A: Participation in Proficiency Testing for Laboratories Performing Nonwaived Testing
42 CFR 493, Subpart H

3.801 Condition: Enrollment and testing samples.

A 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 493 published on March 14, 1990 (55 FR 12363) prior to September 1, 1992, the rules of subpart are effective on September 1, 1992. For all other laboratories, the rules of this part are effective January 1, 1994.

Standard; Enrollment. The laboratory

must—
Notify HHS of the approved program or programs in which it chooses to participate to meet proficiency testing requirements of this part.

(1) 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;

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).

For each specialty, subspecialty and analyte or test, participate in one approved proficiency testing program or programs, for one year or more 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 sample portions of samples to another laboratory for any analysis which it is certified to perform at its own laboratory. Any laboratory that CMS determines intentionally referred its proficiency testing samples to another laboratory for analysis will have its certification revoked for at least one year. Any laboratory that receives proficiency testing samples from another laboratory for testing must notify CMS of the receipt of those samples.

(5) The laboratory must document the handling, preparation, processing, examination, and reporting 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 reports 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.

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Appendix A: Participation in Proficiency Testing for Laboratories Performing Nonwaived Testing
42 CFR 493, Subpart H

§ 493.803 Condition: Successful participation.

Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, 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.

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 pathology, CMS imposes sanctions, as specified in subpart R of this part.

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) There is immediate jeopardy to patient health and safety.

(b) The laboratory fails to provide CMS or a State agent with satisfactory evidence that it has taken steps to correct the problem identified in the unsuccessful proficiency testing performance.

(c) 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, subspecialty, 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 subspecialties 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 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

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correct problems associated with a proficiency testing failure. 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.

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.

Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

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 the failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous proficiency testing events.

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—

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Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

The laboratory notifies the inspecting agency and the proficiency testing program in 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

The laboratory participated in the previous proficiency testing events.

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.

(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.

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.

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 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

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frame specified by the program is satisfactory performance and results in a score of 0 for the testing event.

(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.

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.

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.

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.

Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

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 subspecialties 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.

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(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. 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. 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. 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.

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. Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. 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

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appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. 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. 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. 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 specialties of testing.

§ 493.851 Standard; Hematology.

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. Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. 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 subspecialty 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 CLIA 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, announced or unannounced testing event will be conducted on-site in each laboratory at least once each year. Laboratories will be notified the time of each announced on-site testing event at least 30 days prior to each event. Additional testing events will be conducted 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.

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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. Excused failure to appear by an individual for a retest will result in test failure with no testing remediation and limitations on slide submissions as specified in (b)(1), (b)(2), and (b)(3) of this section.

An individual is determined to have failed an 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.

An individual is determined to have failed a 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 cause of failure are reexamined until the individual is again retested with a 20-slide test set and scores at least 90 percent. Examination 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

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correct problems associated with a proficiency testing failure.
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.
Failure to achieve satisfactory performance on the same analyte in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.
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 identification.

Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.
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—
Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;
The laboratory notifies the inspecting agency and the proficiency testing program in 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—

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Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

The laboratory notifies the inspecting agency and the proficiency testing program in the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with the failure to perform tests on proficiency testing samples; and

The laboratory participated in the previous proficiency testing events.

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.

(c) 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.

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.

Failure to identify the same antibody in two consecutive or two out of three consecutive testing events is unsuccessful performance.

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.

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493.901 Approval of proficiency testing programs.

Under for a proficiency testing program to receive HHS approval, the program must be operated 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 approval 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—

Assure the quality of test samples, appropriately evaluate and score the testing results, and identify performance problems in a timely manner;

Demonstrate to HHS that it has—
The technical ability required to—
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

Distribute the samples, using rigorous quality control to assure that samples mimic real patient specimens when possible and that samples are homogeneous, except for specific specialties such as cytology, and will be available 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 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.

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any person, and include such explanatory information as may be appropriate to assist in interpretation of the proficiency testing program's results;

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 requirements of §§ 493.901 through 493.959;

Maintain records of laboratories' performance for a period of five years or such period as may be necessary for any legal proceedings; and

provide HHS with an annual report and, if needed, an interim report which identifies any previously unrecognized sources of variability such as reagents, instruments, methods, or PT samples, which adversely affect the programs' ability to evaluate laboratory performance.

493.905 Nonapproved proficiency testing programs.

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 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 subspecialties 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 antimicrobial 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 six major groups of bacteria: anaerobes, Enterobacteriaceae, gram-positive bacilli, gram-positive cocci, gram-negative cocci, and miscellaneous gram-negative 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 antimicrobial 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 principal organism and appropriate normal flora. The program must include other important emerging pathogens (as determined by HHS) and either organisms commonly

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occurring in patient specimens or opportunistic organisms. The program must include the following two types of samples; each type of sample must meet the 50 percent mixed culture criterion:

– Samples that require laboratories to report organisms that the testing laboratory considers to be a principal pathogen that is solely responsible for a described illness (including immuno-compromised patients).

– Samples that require laboratories to report organisms that the testing laboratory determines the reportable isolates, including antimicrobial susceptibility for any designated isolate; and

– Samples that require laboratories to report organisms that the testing laboratory determines the reportable isolates, including antimicrobial susceptibility for any designated isolate; and

– Samples that require laboratories to report organisms that the testing laboratory determines the reportable isolates, including antimicrobial susceptibility for any designated isolate; and

– Samples that require laboratories to report organisms that the testing laboratory determines the reportable isolates, including antimicrobial susceptibility for any designated isolate; and

– Samples that require laboratories to report organisms that the testing laboratory determines the reportable isolates, including antimicrobial susceptibility for any designated isolate; and

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– Samples that require laboratories to report organisms that the testing laboratory determines the reportable isolates, including antimicrobial susceptibility for any designated isolate; and

– Samples that require laboratories to report organisms that the testing laboratory determines the reportable isolates, including antimicrobial susceptibility for any designated isolate; and

– Samples that require laboratories to report organisms that the testing laboratory determines the reportable isolates, including antimicrobial susceptibility for any designated isolate; and

– Samples that require laboratories to report organisms that the testing laboratory determines the reportable isolates, including antimicrobial susceptibility for any designated isolate; and

– Samples that require laboratories to report organisms that the testing laboratory determines the reportable isolates, including antimicrobial susceptibility for any designated isolate; and

– Samples that require laboratories to report organisms that the testing laboratory determines the reportable isolates, including antimicrobial susceptibility for any designated isolate; and

– Samples that require laboratories to report organisms that the testing laboratory determines the reportable isolates, including antimicrobial susceptibility for any designated isolate; and

– Samples that require laboratories to report organisms that the testing laboratory determines the reportable isolates, including antimicrobial susceptibility for any designated isolate; and

– Samples that require laboratories to report organisms that the testing laboratory determines the reportable isolates, including antimicrobial susceptibility for any designated isolate; and

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
Haemophilus influenzae, 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 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 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 $1 / (1+1) \cdot 100 = 50$ percent.

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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. Proficiency testing 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 *Mycobacteriaceae* using amikacin, rifampin, isoniazid, and tobramycin, and the organism in the proficiency testing sample is an *Mycobacteriaceae*, and the laboratory reports correct responses for two of three antimicrobial agents, the laboratory's grade would be 66.67 percent.

The performance criterion for qualitative antigen tests is the presence or absence of the 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.

The performance criteria for Gram stain is the 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.

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

based 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 antimycobacterial 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 mycobacteriology, 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 it plans to include in its annual program no more 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 reported isolates and correct responses for antimycobacterial 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—

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Mycobacterium tuberculosis

Level I

Level II

Mycobacterium kansasii

Level I

Mycobacterium szulgai

Level I

Mycobacterium avium-intracellulare

Mycobacterium terrae

Level I

Mycobacterium fortuitum

For antimycobacterial susceptibility testing, the program must provide at least one sample for each testing event that includes mycobacterium tuberculosis that has a predetermined pattern of susceptibility or resistance to the common antimycobacterial agents.

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 non-acid-fast challenges which do not contain acid-fast organisms.

Evaluation of a laboratory's performance.

The program approves only those programs that assess the accuracy of a laboratory's response in accordance with paragraphs (c)(1) through (6) of this section.

The program determines the reportable organisms to be detected by acid-fast stain, isolation and identification, and for antimycobacterial 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 $1 / (1 + 1) \cdot 100 = 50$ percent.

(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 antimycobacterial agents and the laboratory reports a correct response for two of the three antimycobacterial agents, the laboratory's grade would be $2/3 \cdot 100 = 67$ percent.

(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 services offered by 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 dermatophytes to the species level;

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Those that isolate and perform identification of all organisms to the genus *Candida*; and
Those that isolate and perform identification of all organisms to the species *C. albicans*.

Program content and frequency of challenge.

An approved program for proficiency testing in parasitology, the annual program must provide a minimum of five samples per testing event. Samples must be at least three testing events at approximately equal intervals per year. The samples may be provided through mailed specimens or, at HHS' option, may be provided on-site or its designee for on-site testing. An annual program must include samples that contain organisms that are representative of the major groups of fungi: Yeast or yeastlike fungi; dimorphic fungi; dematiaceous fungi; plant pathophytes; and saprophytes, including opportunistic fungi. The specific fungi included in the samples may vary from year to year.

An approved program must, before each calendar year, furnish HHS with a description of the 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 organisms. Other important emerging pathogens (as determined by HHS) and organisms commonly occurring in patient specimens must be included periodically in the program.

An approved program may vary over time. For 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
Microsporium sp.
Acremonium sp.
Trichophyton sp.
Aspergillus fumigatus
Nocardia sp.
Blastomyces dermatitidis 1
Zygomycetes sp.

1NOTE: 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 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.

(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 $1/(1+1) \times 100 = 50$ percent.

(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 (microscopic examination of smears, mounts) and/or pinworm preparations and, if necessary, refer specimens to another

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laboratory appropriately certified in the specialty of parasitology for identification; those that identify parasites using concentration preparations and/or permanent slides.

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. 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.

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 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 paragraphs (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 the 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 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 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 $1/(1+1) \cdot 100 = 50$ percent.

(4) The criterion for acceptable performance for qualitative parasitology examinations is the presence or absence of a parasite(s).

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The score for parasitology is the number of correct responses divided by the number of samples to be tested, multiplied by 100.

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.

Types of services offered by laboratories.

In virology, there are two types of laboratories for proficiency testing purposes—

Those that only perform tests that directly detect viral antigens or structures, either in cells removed from infected tissues or free in fluid specimens; and

Those that are able to isolate and identify viruses and use direct antigen techniques.

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 specimens or, at HHS's option, may be provided to HHS or its designee for on-site testing. An annual program must include viral tests 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.

An approved program must furnish HHS 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 $1/(1+1) \cdot 100 = 50$ percent.

(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 §§ 493.921 and 493.927.

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3.923 Syphilis serology.

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.

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.

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 participating laboratories. The proficiency testing program must indicate the minimum concentration, by method that will be considered as indicating a positive response. For a sample in syphilis serology the average of scores determined under paragraphs (b)(2) and (b)(3) of this section. For quantitative syphilis tests, the program must determine the correct response for each method by the distance of the response from 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:

$$\frac{\text{Number of acceptable Responses for all challenges}}{\text{Total number of all challenges}} \times 100 = \text{score}$$

§ 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-1 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 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 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 participating laboratories. The proficiency testing program must indicate the minimum concentration that will be considered as

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indicating a positive response. The score for a challenge in general immunology is either the score determined under paragraph (c)(2) or (3) of this section.

For quantitative immunology analytes or challenges, the program must determine the correct response for each analyte by the distance of the response from the target value. After the target response 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—

Challenge or test	Criteria for acceptable performance
Human antitrypsin	Target value ±3 SD.
Fetoprotein (tumor marker)	Target value ±3 SD.
Clear antibody	Target value ±2 dilutions or positive or negative
Streptolysin O	Target value ±2 dilutions or positive or negative
Human Immunodeficiency virus	Reactive or nonreactive
Component C3	Target value ±3 SD
Component C4	Target value ±3 SD
Hepatitis (HBsAg, anti-HBc, anti-HBe)	Reactive or nonreactive
.....	Target value ±3 SD
.....	Target value ±3 SD
.....	Target value ±3 SD

Challenge or test	Criteria for acceptable performance
Epidemic typhus mononucleosis	Target value ±2 dilutions or positive or negative
Rheumatoid factor	Target value ±2 dilutions or positive or negative

Rubella

Target value ±2 dilutions
 immune or nonimmune
 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:

$$\frac{\text{Number of acceptable Responses for the analyte}}{\text{Total number of Challenges for the analyte}} \times \text{Testing event} = \text{score}$$

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

$$\frac{\text{Number of acceptable Responses for all challenges}}{\text{Total number of Challenges for the analyte}} \times \text{Testing event} = \text{score}$$

§ 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

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Glucose (Excluding measurements on devices cleared by FDA for home use)
 Total
 Lactate dehydrogenase (LDH)
 LDH isoenzymes
 Magnesium
 Potassium
 Sodium
 Total Protein
 Triglycerides
 Urea Nitrogen
 Uric Acid

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:

$$\frac{\text{Number of acceptable Responses for the analyte}}{\text{Total number of Challenges for the analyte}} \times 100 = \text{Testing event score}$$

Total number of Challenges for the analyte

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

$$\frac{\text{Number of acceptable Responses for all challenges}}{\text{Total number of Challenges for the analyte}} \times 100 = \text{score}$$

Number of acceptable Responses for all challenges

§ 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 mail shipments or, at HHS' option, may be provided to HHS or its designee for on-site testing.

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

Analyte or Test

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

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.

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 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 endocrinology is the score determined under paragraph (c)(2) or (c)(3) of this section.

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 $\pm 25\%$.
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
T3 Uptake	positive or negative
Triiodothyronine	Target value ± 3 SD.
Thyroid-stimulating hormone	Target value ± 3 SD.
Thyroxine	Target value $\pm 20\%$ 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:

$$\frac{\text{Number of acceptable Responses for the analyte}}{\text{Total number of Challenges for the analyte}} \times 100 = \text{Testing event score}$$

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

$$\frac{\text{Number of acceptable Responses for all challenges}}{\text{Total number of Challenges for the analyte}} \times 100 = \text{Testing event score}$$

§ 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 a 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 mail 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

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test procedure is five serum, plasma, or dried samples.

Analyte or Test Procedure

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

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.

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 matbolites....	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:

$$\frac{\text{Number of acceptable Responses for the analyte}}{\text{Total number of Challenges for the analyte}} \times 100 = \text{Testing event score}$$

(5) To determine the overall testing event score, the number of correct responses for all

analytes must be averaged using the following formula:

$$\frac{\text{Number of acceptable Responses for all challenges}}{\text{Total number of Challenges for the analyte}} \times 100 = \text{Testing event score}$$

§ 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 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.

Analyte or Test Procedure

- Cell identification or white blood cell differential
- Erythrocyte count
- Hematocrit (excluding spun microhematocrit)
- Hemoglobin
- Leukocyte count

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Platelet count
Fibrinogen
Partial thromboplastin time
Prothrombin time

An approved program for cell identification that vary over time. The types of cells that must be included in an approved program over time are—

- Eosinophilic granulocytes
- Monophilic granulocytes
- Poliphilic granulocytes
- Lymphocytes
- Neutrophils
- Platelets
- Red blood cells
- White blood cells

White blood cell differentials should be based on the percentage distribution of cellular elements listed above.

Evaluation of a laboratory's analyte or test performance.

ISO 15189 approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (c) (1) through (5) of this section.

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 agreement of either 80 percent of ten or more referee laboratories or 80 percent or more of all participating laboratories. The score for a laboratory 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	Identification
White blood cell differential	Target $\pm 3SD$ based on the percentage of different types of white blood cells in the samples
Erythrocyte count	Target $\pm 6\%$.
Hematocrit (Excluding spun hematocrits)	Target $\pm 6\%$.
Hemoglobin	Target $\pm 7\%$.
Leukocyte count	Target $\pm 15\%$.
Platelet count	Target $\pm 25\%$.
Fibrinogen	Target $\pm 20\%$.
Partial thromboplastin time	Target $\pm 15\%$.
Prothrombin time	Target $\pm 15\%$.

(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:

$$\frac{\text{Number of acceptable Responses for the analyte}}{\text{Total number of Challenges for the analyte}} \times 100 = \text{Testing event score}$$

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

$$\frac{\text{Number of acceptable Responses for all challenges}}{\text{Total number of Challenges for the analyte}} \times 100 = \text{Testing event score}$$

§ 493.945 Cytology; gynecologic examinations.

a) Program content and frequency of challenges.

(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

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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.

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 include an initial retesting event for each individual within 45 days after notification of failure and subsequent retesting events within 45 days after completion of remedial action described in § 493.855.

Evaluation of an individual's performance.

§ 493.1449 approves only those programs that assess the accuracy of each individual's responses on 10- and 20-slide test sets in which the slides have been referenced as specified in paragraph (b)(1) of this section.

To determine the accuracy of an individual's response on a particular challenge (e.g., (A) through (D)), the program must compare the individual's response for each slide preparation to the response that reflects the predetermined 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 75% consensus agreement among a minimum of three physicians certified in anatomic pathology is required. In addition, for pre-pregnant 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., <i>Trichomonas vaginalis</i> , changes or morphology consistent with <i>Candida</i> spp., <i>Actinomyces</i> spp. or Herpes simplex virus). (3) <i>Reactive and reparative changes</i> (e.g., inflammation, effects of chemotherapy or radiation)
C	Low Grade Squamous Intraepithelial
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 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

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...t value on that slide is calculated as minus (¥5). Each slide is scored individually in the same manner. The individual's score for the testing event is determined by adding the points achieved for each slide preparation, dividing by the total points for the testing event and multiplying by 100.

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

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

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 designee for on-site testing.

(c) *Challenges per testing event.*

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

Analyte or Test Procedure

ABO group (excluding subgroups)

D (Rho) typing

Unexpected antibody detection

Compatibility testing

Antibody identification

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Evaluation of a laboratory's analyte or test performance.

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

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 challenge in immunohematology is either the score determined under paragraph (d)(2) or (3) of this section.

Criteria for acceptable performance.

Criteria for acceptable performance are—

Analyte or test	Criteria for acceptable performance
Group	100% accuracy.
(b) typing	100% accuracy.
Unexpected antibody	80% accuracy.
Antibody identification	80% accuracy.
Stability testing	100% accuracy.
Antibody identification	80% accuracy.

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:

$$\frac{\text{Number of acceptable responses for the analyte} \times 100}{\text{Total number of challenges for the analyte}} = \text{Analyte score for the testing Event}$$

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

$$\frac{\text{Number of acceptable responses for all challenges} \times 100}{\text{Total number of all challenges}} = \text{Testing event score}$$