Appendix C

Regulations and Interpretive Guidelines for Laboratories and Laboratory Services

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Subpart H--Participation in Proficiency Testing for Laboratories Performing Nonwaived Testing

Subpart H - Guidelines - General
By law, proficiency testing (PT) programs are evaluated initially for CMS approval and annually thereafter for re-approval. After review, Central Office (CO) will issue PT program approvals and/or re-approvals. A listing of these programs with the specialties, subspecialties, and analytes for which they are approved will be provided to ROs. The RO is responsible for disseminating the approved program listing to the States within their region on an annual basis. Address questions related to the currently approved PT programs to the RO.

An approved PT program is a program that has been evaluated and found to be in compliance with the requirements of Subpart I and the applicable sections of Subpart H. When a laboratory experiences problems with PT, it resolves them with the PT program. If a PT program fails to meet the requirements of Subpart I, report all available information to the RO, which discusses the findings with CO. CO renders a decision on the termination or continued approval of the PT program, as appropriate. The Centers for Disease Control and Prevention may be requested by CO to provide technical advise.

D2000

§493.801 Condition: Enrollment and testing of samples

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

Interpretive Guidelines §493.801
Each laboratory must determine the extent of patient testing it performs. The laboratory must review the specialty, subspecialties and analytes listed in Subpart I and determine which specialty, subspecialties and analytes they must enroll in to meet this requirement. Enrollment must be in a CMS approved PT program. The surveyor should verify that the laboratory is properly enrolled in an approved PT program.
***Note:** If a laboratory has not enrolled for any or all tests that it perform that are listed in Subpart I, cite ONLY D2000, Enrollment and testing of samples; do not cite D2016, Successful Participation.*

PT requirements apply to the non-waived tests listed in Subpart I. PT is not required for waived tests. If a laboratory enrolls and participates in PT for any waived tests, do not review these PT results and do not determine compliance with any other PT requirements. Do not take enforcement action for referral of PT specimens for waived tests.

PT enrollment and participation is required, as applicable, for each certificate other than a Certificate of Waiver. A facility offering testing at more than one site, but the testing is all included under one certificate, must enroll in an approved PT program(s) for the collective tests covered under that certificate, not for each site.
A general rule is "PT enrollment per certificate".

Facilities that perform laboratory testing at multiple sites and are certified under one CLIA certificate include the following examples:

- *A hospital with satellite laboratories throughout the hospital;*
- *Different departments of the laboratory;*
- *A hospital that performs point-of-care testing;*
- *Limited public health testing performed by non-profit or Federal, State or local government laboratories; or*
- *Mobile laboratories or temporary testing sites.*

The following examples give instruction and guidance for determining compliance with the PT requirement for enrollment where a specialty, subspecialty or analyte is performed by different methods, specimen types and locations:

- *A laboratory with a single certificate must enroll in an approved PT program for each analyte listed in Subpart I that it performs. When an analyte is performed using different methodologies within the laboratory, only one enrollment is required. After the laboratory has determined which analyte to enroll for, it must participate in PT using its primary method for patient testing during the event. Other methods for the same analyte must be evaluated as required in §493.1236. If the laboratory performs unsuccessfully for an analyte and sanctions are imposed, the sanctions are applicable to the analyte, not to the test methodology. For example, if a laboratory uses three different methods to perform cholesterol measurements, it must participate in PT using the primary method at the time of the PT event. If the laboratory is unsuccessful in PT performance for cholesterol and the CLIA certificate is suspended, limited, or*

revoked for cholesterol, the laboratory would be precluded from performing cholesterol by <u>any test method</u>.

- *A laboratory with a single certificate performing testing at multiple sites under that certificate must participate in PT for each analyte listed in Subpart I that is under that certificate. The performance of PT testing events may be alternated between different sites, provided the primary method at the time of the PT event is used to perform the PT. Should the facility not perform successfully for an analyte, that analyte may not be tested at <u>any location</u> under that certificate.*

- *A multiple site laboratory, which is covered by a single certificate and participates in one PT program per analyte, must be aware that a failure in PT could lead to the revocation of its certificate for <u>all</u> sites, not just the one participating in PT.*

When problems occur that cannot be resolved with the instructions in these guidelines, gather all information available and consult with the RO for guidance and resolution.

D2001

§493.801 Standard: Enrollment and testing of samples

(a) Standard: Enrollment. The laboratory must--
(1) Notify HHS of the approved program or programs in which it chooses to participate to meet proficiency testing requirements of this subpart.
(2)(i) Designate the program(s) to be used for each specialty, subspecialty, and analyte or test to determine compliance with this subpart if the laboratory participates in more than one proficiency testing program approved by CMS; and

<u>Interpretive Guidelines §493.801(a)(1)-(a)(2)(i)</u>
Note: These requirements are met when the CMS approved PT program transmits the laboratory enrollment to the CMS PT monitoring system.

D2003

§493.801 Standard: Enrollment and testing of samples

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

<u>Interpretive Guidelines §493.801(a)</u>
During the on-site survey, verify that the laboratory is enrolled in an approved program or programs for all specialty, subspecialties, and tests or analytes listed in Subpart I for which it performs patient testing.

To meet the requirements of this section, it may be necessary for a laboratory to enroll in more than one program to cover all tests listed in Subpart I for which the laboratory performs testing. The approved program in which a laboratory has enrolled may not offer every analyte that the laboratory performs. The laboratory must then enroll in an additional program(s) to cover the testing not included in the first program.

The laboratory must indicate to the PT program which specialty, subspecialty, or analyte it intends the program to grade and score for regulatory purposes. This is particularly necessary when the laboratory subscribes to multiple PT programs that contain the same analyte(s) required for regulatory purposes.

D2004

§493.801 Standard: Enrollment and testing of samples

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

Interpretive Guidelines §493.801(a)(3)
When a laboratory initially applies for CLIA certification or adds a specialty or subspecialty in the middle of the calendar year, it may change PT programs at the next PT enrollment period.

D2005

§493.801 Standard: Enrollment and testing of samples

(a)(4) Authorize the proficiency testing program to release to HHS all data required to--

Interpretive Guidelines §493.801(a)(4)
Provide laboratories with the appropriate Federal or State Agency address to which PT results must be sent. Laboratories that are accredited by a CMS approved accreditation organization must release all PT data to its accreditation organization.

(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.

Probes §493.801(a)-(b)
What procedure or test method was used? Is this a routine test method used in the laboratory? Did routine personnel perform the PT? How often were PT samples tested? How are deviations (if any) justified?

Do the PT results documented in the laboratory work records (worksheet) correlate with the results reported to the PT program?

What is the laboratory's policy for testing patient samples when PT specimens are tested more than once?

Do reports submitted to the PT program provider accurately reflect the procedure (i.e., instrument, method) used in the laboratory?

Check to see if patient samples were reported on the same day that PT samples were tested. (In a small facility, infrequent testing may necessitate the testing of PT samples without patient specimens to ensure that the the PT test results are returned on time.) Did the laboratory use the same procedure for both patient specimens and PT samples?

D2006

§493.801 Standard: Enrollment and testing of samples

(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.

Interpretive Guidelines §493.801(b)

Review testing records to determine if special handling was given to PT samples. Consider the unique requirements of many PT samples when evaluating "same manner" of testing. The laboratory should document any necessary reconstitution, longer mixing times, unit conversion of results, etc.,as required in §493.801(b)(5).

A central laboratory with more than one instrument or methodology for the same test may alternate methods or instruments from one testing event to the next as long as both are routinely used to test patient specimens. All samples for one analyte within a shipment must be tested with the same instrument.

D2007

§493.801 Standard: Enrollment and testing of samples

(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods.

D2009

§493.801 Standard: Enrollment and testing of samples

(b)(1) 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.

Interpretive Guidelines §493.801(b)(1)
Review records to assure that the analyst performing the testing and the director have signed the attestation statement certifying that PT samples were tested in the same manner as patient specimens. For moderate complexity testing, in accordance with §493.1407(e)((4)(i), the director may delegate the responsibility for signing the attestation statement to a technical consultant meeting the qualifications of §493.1409. For high complexity testing, in accordance with §493.1445(e)(4)(i), the director may delegate the responsibility for signing the attestation statement to a technical supervisor meeting the qualifications of §493.1447.

D2010

§493.801 Standard: Enrollment and testing of samples

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

D2011

§493.801 Standard: Enrollment and testing of samples

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

D2013

§493.801 Standard: Enrollment and testing of samples

(b)(4) 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 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.

Interpretive Guidelines §493.801(b)(4)
The regulation refers to intentional referral of PT specimens by a laboratory for purposes of using another laboratory's results as its own. A laboratory that routinely performs only presumptive testing or screening methods and refers patient samples to another laboratory for definitive or confirmatory testing or comparison of test results must not refer PT samples to another laboratory for confirmatory testing. A laboratory must only test and report PT specimens to the degree those tests or examinations are performed for in-house patient testing.

Handle allegations of inter-laboratory communications or referral of proficiency testing specimens as a complaint and investigate using the complaint investigation procedures outlined in §6136 of the SOM.

Do not solicit a Plan of Correction from a laboratory when it has been determined that the laboratory intentionally referred its PT samples to another laboratory for analysis and submitted the other laboratory's results as its own. Immediately notify the RO recommending revocation of the certificate (a statutory requirement) and forward to the RO all documentation necessary to support the findings.

D2015

§493.801 Standard: Enrollment and testing of samples

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

Interpretive Guidelines §493.801(b)(5)
Review records to assure that the analyst performing the testing and the director have signed the attestation statement certifying that PT samples were tested in the same manner as patient specimens. For moderate complexity testing, in accordance with §493.1407(e)(4)(i), the director may delegate the responsibility for signing the attestation statement to a technical consultant meeting the qualifications of §493.1409. For high complexity testing, in accordance with §493.1445(e)(4)(i), the director may delegate the responsibility for signing the attestation statement to a technical supervisor meeting the qualifications of §493.1447. The signature of the director or technical consultant/supervisor need not be obtained prior to reporting PT results to the PT provider.

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

Interpretive Guidelines §493.801(b)(6)
"Primary" means the test system(s), assay(s) or examination(s) routinely used for patient testing at the time of the PT testing event; however, the primary method is determined after the laboratory has chosen the analyte(s) it performs for enrollment.

D2016

§493.803 Condition: Successful participation.

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

Interpretive Guidelines §493.803
Only the PT program has the capability to correct scores. These corrections will be noted in the PT monitoring system as "non-routine" scores.

No single PT enforcement protocol is universally applicable for all situations. Unique circumstances may require special considerations or actions that may not conform to the general approach outlined below. The laboratory's compliance history, its willingness to take remedial actions, and the professional judgment of surveyors, RO CLIA laboratory consultants and enforcement personnel may be factors in determining an appropriate PT enforcement plan.

Careful review of PT performance reports and other available information should always be performed to determine whether the PT results truly represent failed PT. The potential of a PT program data input error or other factors beyond the laboratory's control should be considered. If the laboratory has made a transcription error(s), it is considered erroneous PT result(s).

Absent any special circumstances (which must be documented in the case file), consider verified unsuccessful PT performance to represent unsuccessful PT participation and cite as a condition-level deficiency (use D2016 on the CMS-2567).

NOTE: The CMS PT monitoring system may NOT be used alone to determine unsuccessful participation. Surveyors must verify any unsuccessful participation

indicated in the PT monitoring system. This may be done by reviewing PT results supplied by the approved PT program (they will send copies to the surveyor if requested) or from results sent to the laboratory by the PT program.

If the unsuccessful PT participation is the first occurrence for the laboratory, and there is no immediate jeopardy to patient health or safety, notify the laboratory and require that it seek training of its personnel, obtain the necessary technical assistance to correct the problem causing the unsuccessful participation, or both. SAs may initiate training and/or technical assistance after first obtaining RO concurrence. No onsite review is required to initiate this action.

The laboratory will submit an acceptable plan of remedial action, listing projected completion dates and other pertinent information, for its training and/or technical assistance efforts. Follow-up is necessary to verify that the laboratory has carried out its plan. Satisfactory participation in the next PT event would provide verification that the laboratory's remedial action, training and/or technical assistance were successful. The remedial action plan should demonstrate that the laboratory will correct its problems within 3 months, although special circumstances may be considered. When a laboratory refuses to take acceptable training and/or technical assistance actions (including failure to submit an acceptable plan of remedial action, or failure to complete its plan), sanction action will be initiated.

When the unsuccessful PT participation is not the first such occurrence for the laboratory, and there is no issue of immediate jeopardy, cite as a condition-level deficiency and take appropriate enforcement action. For immediate jeopardy cases the procedures in Subpart R apply. For non-immediate jeopardy situations, enforcement procedures should be completed within 90 days from the date that the unsuccessful PT was first identified. In immediate jeopardy situations, enforcement procedures should be completed within 23 days from the date unsuccessful participation of PT is first identified.

Example:
A laboratory scores 60% on a testing event in mycobacteriology. On the next testing event, the laboratory fails to participate in mycobacteriology. The citations are §§493.825(b), 493.825(e), and 493.803.

Example:
A laboratory scores 60% on uric acid PT samples. On the next testing event, the laboratory scores 40% on the same analyte. The citations are §§493.841(a), 493.841(f), and 493.803. When recommending to the RO that a laboratory be subject to sanctions, submit copies of the laboratory's testing event or analyte score(s) that were unsatisfactory and the correct responses provided by the PT program. Also, enclose copies of any correspondence sent to or received by the laboratory concerning its PT performance.

When recommending to the RO that a laboratory be subject to sanctions, submit copies of the laboratory's testing event or analyte score(s) that were unsatisfactory and the correct responses provided by the PT program. Also, enclose copies of any correspondence sent or received by the laboratory concerning its PT performance.

D2017

§493.807 Condition: Reinstatement of laboratories performing nonwaived testing after failure to participate

(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 Non-Waived Tests

§493.821 Condition: Microbiology.

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

D2020

§493.823 Standard; Bacteriology.

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

D2021

§493.823 Standard; Bacteriology.

(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.

D2025

§493.823 Standard; Bacteriology.

(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.

D2026

§493.823 Standard; Bacteriology.

(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.

D2028

§493.823 Standard; Bacteriology.

(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.

D2029

§493.825 Standard; Mycobacteriology.

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

D2030

§493.825 Standard; Mycobacteriology.

(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.

D2034

§493.825 Standard; Mycobacteriology.

(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.

D2035

§493.825 Standard; Mycobacteriology.

(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.

D2037

§493.825 Standard; Mycobacteriology.

(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.

D2038

§493.827 Standard; Mycology.

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

D2039

§493.827 Standard; Mycology.

(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.

D2043

§493.827 Standard; Mycology.

(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.

D2044

§493.827 Standard; Mycology.

(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.

D2046

§493.827 Standard; Mycology.

(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.

D2047

§493.829 Standard; Parasitology.

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

D2048

§493.829 Standard; Parasitology.

(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.

D2052

§493.829 Standard; Parasitology.

(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.

D2053

§493.829 Standard; Parasitology.

(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.

D2055

§493.829 Standard; Parasitology.

(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.

D2056

§493.831 Standard; Virology.

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

D2057

§493.831 Standard; Virology.

(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.

D2061

§493.831 Standard; Virology.

(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.

D2062

§493.831 Standard; Virology.

(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.

D2064

§493.831 Standard; Virology.

(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.

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§493.833 Condition: Diagnostic immunology.

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

D2066

§493.835 Standard; Syphilis serology.

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

D2067

§493.835 Standard; Syphilis serology.

(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.

D2071

§493.835 Standard; Syphilis serology.

(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.

D2072

§493.835 Standard; Syphilis serology.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.
(2) For any unacceptable testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

D2074

§493.835 Standard; Syphilis serology.

(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.

D2075

§493.837 Standard; General immunology.

Interpretive Guidelines: §493.837
Analytes or tests for which laboratory PT performance is to be evaluated:

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

Note: If a laboratory performs both a quantitative and a qualitative procedure of a test or analyte, it may choose which to enroll in to fulfill the enrollment requirement. It need not enroll in both quantitative and qualitative PT for the same analyte.

(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.

D2076

§493.837 Standard; General immunology.

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

D2077

§493.837 Standard; General immunology.

(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.

D2081

§493.837 Standard; General immunology.

(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.

D2082

§493.837 Standard; General immunology

(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.

D2084

§493.837 Standard; General immunology

(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.

D2085

§493.837 Standard; General immunology

(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.

Analytes or tests for which laboratory PT performance is to be evaluated which include serum, plasma or blood samples:

Alanine aminotransferase (ALT/SGPT)
Albumin
Alkaline phosphatase
Amylase
Aspartate aminotransferase (AST/SGOT)
Bilirubin, total
Blood gas (pH, pO_2, and pCO_2)
Calcium, total
Chloride
Cholesterol, total
Cholesterol, high density lipoprotein
Creatine kinase
Creatine kinase isoenzymes
Creatinine
Glucose (Excluding measurements on devices cleared by FDA specifically for home use)
Iron, total
Lactate dehydrogenase (LDH)
LDH isoenzymes
Magnesium
Potassium
Sodium
Total Protein
Triglycerides
Urea Nitrogen
Uric Acid

D2087

§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.

D2088

§493.841 Standard; Routine chemistry.

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

D2089

§493.841 Standard; Routine chemistry.

(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.

D2093

§493.841 Standard; Routine chemistry.

(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.

D2094

§493.841 Standard; Routine chemistry.

(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.

D2096

§493.841 Standard; Routine chemistry.

(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.

D2097

§493.841 Standard; Routine chemistry.

(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.

D2098

§493.843 Standard; Endocrinology.

Analytes or tests for which laboratory PT performance is to be evaluated which include serum, plasma, blood, or urine:

Cortisol
Free Thyroxine
Human Chorionic Gonadotropin (Excluding color comparison tests for urine specimens)
T_3 Uptake
Triiodothyronine
Thyroid-stimulating hormone
Thyroxine

Note: If the laboratory performs the same analyte on different specimen types, it may choose which specimen type to enroll in PT. The laboratory need not enroll for each specimen type of the same analyte.

(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.

D2099

§493.843 Standard; Endocrinology.

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

D2100

§493.843 Standard; Endocrinology.

(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.

D2104

§493.843 Standard; Endocrinology.

(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.

D2105

§493.843 Standard; Endocrinology.

(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.

D2107

§493.843 Standard; Endocrinology.

(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.

D2108

§493.843 Standard; Endocrinology.

(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.

D2109

§493.845 Standard; Toxicology.

Analytes or tests for which laboratory PT performance is to be evaluated which include serum, plasma, or blood:

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

(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.

D2110

§493.845 Standard; Toxicology.

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

D2111

§493.845 Standard; Toxicology.

(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.

D2115

§493.845 Standard; Toxicology.

(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.

D2116

§493.845 Standard; Toxicology.

(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.

D2118

§493.845 Standard; Toxicology.

(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.

D2119

§493.845 Standard; Toxicology.

(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.

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§493.849 Condition: Hematology.

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

Analytes or tests for which laboratory PT performance is to be evaluated:

*Cell identification **or** white blood cell differential (chosen by the laboratory)*
Erythrocyte count
Hematocrit (excluding spun microhematocrit)
Hemoglobin
Leukocyte count
Platelet count
Fibrinogen
Partial thromboplastin time
Prothrombin time

D2121

§493.851 Standard; Hematology.

(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

D2122

§493.851 Standard; Hematology.

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

D2123

§493.851 Standard; Hematology.

(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.

D2127

§493.851 Standard; Hematology.

(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.

D2128

§493.851 Standard; Hematology.

(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.

D2130

§493.851 Standard; Hematology.

(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

D2131

§493.851 Standard; Hematology.

(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.

D2132

§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.

D2133

§493.855 Standard; Cytology: gynecologic examinations.

(a) The laboratory must ensure that each individual engaged in the examination of gynecologic preparations is enrolled in a proficiency testing program approved by CMS by January 1, 1995, if available in the State in which he or she is employed.

D2134

§493.855 Standard; Cytology: gynecologic examinations.

The laboratory must ensure that each individual is tested at least once per year and obtains a passing score.
To ensure this annual testing of individuals, an announced or unannounced testing event will be conducted on-site in each laboratory at least once each year. Laboratories will be notified of the time of each announced on-site testing event at least 30 days prior to each event. Additional testing events will be conducted as necessary in each State or region for the purpose of testing individuals who miss the on-site testing event and for retesting individuals as described in paragraph (b) of this section.

D2136

§493.855 Standard; Cytology: gynecologic examinations.

(b) The laboratory must ensure that each individual participates in an annual testing event that involves the examination of a 10-slide test set as described in §493.945.

D2137

§493.855 Standard; Cytology: gynecologic examinations.

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.

D2138

§493.855 Standard; Cytology: gynecologic examinations.

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.

D2141

§493.855 Standard; Cytology: gynecologic examinations.

Unexcused failure to appear by an individual for a retest will result in test failure with resulting remediation and limitations on slide examinations as specified in (b)(1), (b)(2), and (b)(3) of this section.

D2142

§493.855 Standard; Cytology: gynecologic examinations.

(1) An individual is determined to have failed the annual testing event if he or she scores less than 90 percent on a 10-slide test set.

D2143

§493.855 Standard; Cytology: gynecologic examinations.
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.

D2144

§493.855 Standard; Cytology: gynecologic examinations.

(2) An individual is determined to have failed the second testing event if he or she scores less than 90 percent on a 10-slide test set.

D2145

§493.855 Standard; Cytology: gynecologic examinations.

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

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D2146

§493.855 Standard; Cytology: gynecologic examinations.

must assure that all gynecologic slides evaluated subsequent to the notice of failure are reexamined until the individual is again retested with a 20-slide test set and scores at least 90 percent.

D2147

§493.855 Standard; Cytology: gynecologic examinations.

Reexamination of slides must be documented.

D2148

§493.855 Standard; Cytology: gynecologic examinations.

(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.

D2149

§493.855 Standard; Cytology: gynecologic examinations.

An individual who fails the third testing event must cease examining gynecologic slide preparations immediately upon notification of test failure and

D2150

§493.855 Standard; Cytology: gynecologic examinations.

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.

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§493.855 Standard; Cytology: gynecologic examinations.

(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.

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§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.

Analytes or tests for which laboratory PT performance is to be evaluated:

ABO group (excluding subgroups)
D(Rho) typing
Unexpected antibody detection
Compatibility testing
Antibody identification

D2153

§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.

D2154

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

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

D2155

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

(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.

D2159

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

(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.

D2160

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

(e)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.
(2) For any unacceptable analyte or unsatisfactory testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

D2162

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

(f) Failure to achieve satisfactory performance for the same analyte in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

D2163

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

(g) Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

D2164

§493.861 Standard; Unexpected antibody detection.

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

D2165

§493.861 Standard; Unexpected antibody detection.

(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.

D2169

§493.861 Standard; Unexpected antibody detection.

(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.

D2170

§493.861 Standard; Unexpected antibody detection.

(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.

D2172

§493.861 Standard; Unexpected antibody detection.

(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.

D2173

§493.863 Standard; Compatibility testing.

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

D2174

§493.863 Standard; Compatibility testing.

(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.

D2178

§493.863 Standard; Compatibility testing.

(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.

D2179

§493.863 Standard; Compatibility testing.

(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.

D2181

§493.863 Standard; Compatibility testing.

(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.

D2182

§493.865 Standard; Antibody identification.

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

D2183

§493.865 Standard; Antibody identification.

(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.

D2187

§493.865 Standard; Antibody identification.

(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.

D2188

§493.865 Standard; Antibody identification.

(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.

D2190

§493.865 Standard; Antibody identification.

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

D2191

§493.865 Standard; Antibody identification.

(f) Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.
