

## **D2000**

**(Rev. 140, Issued: 05-29-15, Effective: 05-29-15, Implementation: 05-29-15)**

### **§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 that offers modules containing at least three (3) testing events annually (excluding mycobacteriology, which only needs to contain two (2) testing events annually) with a minimum of five (5) samples per event

(§§493.909 – 493.459). The surveyor should verify that the laboratory is properly enrolled in an approved PT program.

**NOTE:** If a laboratory has not enrolled for one or more tests that it performs and the tests are listed in Subpart I, cite ONLY D2000, Enrollment and testing of samples; do **not** cite D2016, Successful Participation.

PT requirements apply to the nonwaived tests listed in Subpart I, except for PT referral which applies to PT for all testing (waived, nonwaived, tests listed in Subpart I and tests not listed in Subpart I).

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, with testing 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 PT 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 limited for cholesterol, the laboratory would be precluded from performing cholesterol by **any test method**.

- A multisite laboratory that performs testing at the various sites under a single 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 rotated between different sites, provided the primary method at the time of the PT event is used to perform the PT. All samples from the testing event must be evaluated at **a single site**. Should the facility not perform successfully for an analyte, that analyte may not be tested at **any location** under that certificate.
- A laboratory with multiple sites **covered by a single certificate that participates in one PT program per analyte, must be aware that a failure in PT could lead to the limitation or revocation of its certificate for all sites for the failed analyte, subspecialty, or specialty, 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.