(Rev. 166, Issued: 02-03-17, Effective: 03-03-17, Implementation: 03-03-17)

### §493.1289 Standard: Analytic systems quality assessment

(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff.

#### **Interpretive** Guidelines §493.1289(b)

Verify that the laboratory has a system in place to monitor and evaluate test results for inconsistencies with patient information, and for correlation between test results. For example, a laboratory could multiply the hemoglobin result by a factor of 3, to see if the result is equal to the hematocrit. If the laboratory has auto-validation in it's Laboratory Information System (LIS), verify that the laboratory is taking steps to reduce the likelihood of sample-switching errors, for example, when the creatinine result is significantly different from the patient's previous creatinine test results, or if the MCV is significantly different from the patient's previous test results and the patient did not receive a blood transfusion.

#### Probes §493.1289(b)

How does the laboratory address multiple failed or sub-optimal cultures that have been submitted from one client?

How does the laboratory use the review of all normal or negative gynecologic specimens received within the previous 5 years to assess the analytic system and communicate findings to the staff?

(c) The laboratory must document all analytic systems assessment activities.

## **Interpretive Guidelines §493.1289(c)**

The steps taken by the laboratory to identify and correct problems and prevent their recurrence must be documented. All laboratory policies amended due to its QA activities must also be noted.

# POSTANALYTIC SYSTEMS