D5791

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§493.1289 Standard: Analytic systems quality assessment

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems

identified in the analytic systems specified in §§493.1251 through 493.1283.

Interpretive **Guidelines §493.1289(a)-(c)**

Quality Assessment (QA) is an ongoing review process that encompasses all facets of the laboratory's technical and non-technical functions at all location/sites where testing is performed. QA also extends to the laboratory's interactions with and responsibilities to patients, physicians, and other laboratories ordering tests, and the non-laboratory areas or the facility of which it is a part.

When the laboratory discovers an error or identifies a potential problem, actions must be taken to correct the situation. This correction process involves identification and resolution of the problem, and development of policies that will prevent recurrence. Policies for preventing problems that have been identified must be written as well as communicated to the laboratory personnel and other staff, clients, etc., as appropriate. Over time, the laboratory must monitor the corrective action(s) to ensure the action(s) taken have prevented recurrence of the original problem.

All pertinent laboratory staff must be involved in the assessment process through discussions or active participation.

QA of the Analytic System includes assessing:

- Test procedures;
- Accurate and reliable test systems, equipment, instruments, reagents, materials, and supplies;
- Specimen and reagent storage condition;
- Equipment/instrument/test/system maintenance and function checks;
- Establishment and verification of method performance specifications;
- Calibration and calibration verification;
- Control procedures;
- Comparison of test results;
- Corrective actions; and
- Test records.

For Clinical Cytogenetics, cases, the laboratory should identify increases in or excessive culture failure rates, determine the contributing factors, document efforts to reduce or

eliminate these factors and assess the effectiveness of actions taken (i.e., a decrease in the culture failure rate).

Review assessment policies, procedures and reports to verify that the laboratory has a system in place to ensure continuous improvement. Corrective action reports are one indication that the laboratory is monitoring and evaluating laboratory performance and the quality of services.

Select a sample of abnormal cytology patient reports and determine that, when available, the histopathology and cytology comparison was performed and the cytology 5-year retrospective review was performed. Ensure the laboratory documents any discrepancies and performs corrective action.

Review quality control records to determine if the laboratory's monitoring efforts are detecting control failures, shifts, and trends. If the surveyor identifies previously undetected quality control failures or omission, then the laboratory's system for monitoring and evaluating quality control may not be adequate.

For International Normalized Ratio (INR) calculation, ensure the laboratory:

- Periodically verifies, for each thromboplastin lot number in use, the correct normal prothrombin time mean and (the International Sensitivity Index (ISI) value are being used for calculating the INR value.

- Periodically verifies the accuracy of the INR calculation (manual, instrument or LIS).

To verify Prothrombin time testing with INR calculations:

- Check the accuracy of normal Prothrombin time mean calculation (manual, instrument or LIS).

- Verify the ISI used in the calculation correlates with the ISI specified in the reagent package insert. Select an abnormal low or abnormal high prothrombin time result and verify the calculation.

Probes §493.1289(a)

For clinical cytogenetics cases, does the laboratory monitor the frequency of culture failures and sub-optimal analyses?

Does the laboratory add additional maintenance procedures and/or function checks, when needed, to ensure accurate and reliable test results?

What is the laboratory's system for monitoring and evaluating test results for inconsistencies with patient information?