D5777

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

§493.1281 Standard: Comparison of test results

(b) The laboratory must have a system to identify and assess patient test results that appear inconsistent with the following relevant criteria, when available:

(b)(1) Patient age.

(b)(2) Sex.

(b)(3) Diagnosis or pertinent clinical data.

(b)(4) Distribution of patient test results.

(b)(5) Relationship with other test parameters.

Interpretive Guidelines §493.1281(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.

For automated laboratories, inconsistent patient results may be evaluated through the use of verified LIS supported logic, patient distribution test results, verified automated test comparison logic programs and individual test repeat criteria.

Probes §493.1281(b)

How does the laboratory obtain sufficient information to enable an evaluation of test results with clinically relevant patient information?

Does the laboratory have procedures to assess and evaluate patient test results for inconsistencies?

For example:

- Hemoglobin and Hematocrit (MCHC value exceeds reference range);
- BUN and Creatinine comparison;
- Albumin and Total Protein;
- Correlation of urine culture with urine microscopic; and
- Alkaline phosphatase with orthopedic surgical patients and/or pediatric patients; and
- Correlation of microscopic sediment findings with macroscopic results, such as, the presence of protein with casts, positive occults blood with red cells, and positive leukocyte esterase with white cells.

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(c) The laboratory must document all test result comparison activities

Interpretive Guidelines §493.1281(c)

The actual measurement(s) of test results and comparison activities must be recorded. Acceptable formats for documentation may vary. Cite documentation deficiencies at §493.1281(a) or §493.1281(b). Use D5775 or D5777, as appropriate.