

D5821

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§493.1291 Standard: Test report

(k) When errors in the reported patient test results are detected, the laboratory must do the following:

Interpretive Guidelines §493.1291(k)

Errors in test results may include incorrect patient identification, test results, reference or normal ranges, interpretive information, or other significant information. See D5625 for specific guidance regarding certain amended cytology reports.

(k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors.

Interpretive Guidelines §493.1291(k)(1)

When determining whether the laboratory gave prompt notification of test and/or reporting errors to the authorized person(s), their agent (if applicable), and others who are identified as responsible for using the test results on the requisition, consider whether

contact information was provided to the laboratory, when the error was identified, when the authorized person was notified, and the extent of the error (e.g., clinically significant results reported on the wrong patient).

Probes §493.1291(k)(1)

What mechanism(s) does the laboratory use for notifying the authorized person(s) of the corrected values?

(k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results.

Interpretive Guidelines §493.1291(k)(2)

Corrected reports, either hard copy or electronic, must clearly indicate both the corrected results(s) and the fact that the report is a corrected report. The corrected reports should be promptly sent to the authorized person, their agent (if applicable) and others who are identified as responsible for using the test results on the requisition.

For corrected reports in Cytology, use D5659.

Probes §493.1291(k)(2)

How does the laboratory ensure that incorrect original results are not reissued verbally, in writing or electronically?

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(k)(3) Maintain duplicates of the original report, as well as the corrected report.

Interpretive Guidelines §493.1291(k)(3)

The laboratory must have a system for maintaining copies of the original and corrected reports. Computer-generated reports or electronically stored copies are acceptable.

Copies of all reports, including corrected reports, provided by the referral laboratory must be maintained by both the referral and referring laboratories for the required time periods.

Probes §493.1291(k)(3)

For laboratories that maintain the patient's medical record as the test report, what is the mechanism for differentiating between the incorrect original report and the corrected report?