

requirements formerly at § 493.1105, (now at § 493.1241(c)) as relevant information necessary for proper test performance and interpretation. The test requisition requirements do not prohibit laboratories from performing the testing if the requested information is missing. Although we expect laboratories to obtain this information when possible, the potential negative impact of the missing information on the test results may be addressed or noted on the report.

*Comment:* One State health department requested modification of the requirement for recording the time of specimen receipt into the laboratory, stating we should require the time of receipt only if it is pertinent to sample integrity, test method, or procedure.

*Response:* We disagree with the commenter. Recording the date and time of specimen receipt enables the laboratory to determine the elapsed time between specimen receipt and reporting of patient test results. It also provides a mechanism to monitor transportation times for specimens referred to the laboratory. Therefore, we are retaining this requirement formerly at § 493.1107(b) (now at § 493.1242(b)).

*Comment:* One commenter stated the final rule with comment period did not require a person's name or unique identifier on the test report.

*Response:* We agree with the commenter that the final rule with comment period did not specifically require a patient's name or unique identifier as part of the test report formerly at § 493.1109. Therefore, we are adding at § 493.1291(c)(1), a requirement for the laboratory report to include the patient's name with an identification number, or a unique patient identifier and identification number to ensure positive patient identification. The patient's name alone is not a unique identifier, and when used on the test report, the patient's name must be accompanied by an identification or accession number. When a patient's name is not used for confidentiality purposes, or when the identity of the person is not known, a unique patient identifier must be submitted with the specimen. The laboratory must also use an identification number. In reviewing the report requirements formerly at § 493.1109(b), interpretation was omitted. Therefore, we are adding interpretation to the test report requirements at § 493.1291(c)(6) for those test results that require supplemental information.

*Comment:* Some commenters disagreed with requiring the name and address of the laboratory performing the

test on the test report. They believed that too much information would make the report crowded and confusing. Another comment received from a professional organization acknowledged the benefit of this requirement, but stated its application to cumulative reports causes disruption of data presentation and utility of the report and, in some cases, the information cannot reasonably be included.

*Response:* We agree the name and address of the laboratory performing the test is an essential piece of information that must be included on the test report. It provides a contact for the individual who requested or is using the test results when additional information is needed for result interpretation and patient care. If a laboratory determines its reports are crowded or confusing, it has complete latitude and responsibility to reorganize the report in a manner that will correct the problem as specified formerly at § 493.1703 (now at § 493.1299). A laboratory that generates cumulative reports may use a single character identifier (for example, an asterisk or subscript) to identify a particular reference laboratory that performed the test. This information (the name and address of the reference laboratory) may be defined on a subsequent page or on the back of the report. Laboratories may develop other formats to meet this requirement. However, we are retaining the requirement formerly at § 493.1109(b) (now at § 493.1291(c)(2)) to include the name and address of the laboratory where the test was performed.

*Comment:* One commenter questioned the appropriateness of maintaining test records in the patient's chart or medical record.

*Response:* The CLIA regulation does not preclude laboratories from storing test records in a patient's chart or medical record; however, records must include the following:

- Test analysis (including instrument printouts, if applicable).
- Identity of the personnel performing the test.

To retain this type of information in a patient's chart or medical record may be cumbersome and impractical for QA activities; however, it is at the discretion of the laboratory.

*Comment:* One commenter questioned whether computer records of reports are acceptable in lieu of paper files.

*Response:* The requirement formerly at § 493.1109(h) specifies that all test reports or an exact duplicate of each test report must be maintained by the laboratory in a manner that permits ready identification and timely accessibility. The information contained

on the test report may be manually written, generated by an electronic system, maintained on microfilm, or any other means, provided it contains all of the information that was on the original test report. Therefore, we are deleting the reference to "exact duplicate" that was contained in the former § 493.1109(h), and amending the language now at § 493.1291(j) to clarify that the laboratory must be able to retrieve a copy of the original report. We are also making a conforming change in the retention requirement for test reports (now at § 493.1105(a)(6)).

*Comment:* Many commenters stated that the removal of the subpart on laboratory information systems (LIS) was inappropriate and not logical considering the current and future direction of collection and dissemination of laboratory data. Other commenters indicated that the current method of reporting patient results and the laboratory computer system was overlooked.

*Response:* We agree with all of the commenters and are addressing some of the commenters' concerns pertaining to electronic patient and testing information by doing the following:

- Adding a requirement at § 493.1101(e) for laboratories to store and maintain records in a manner that ensures proper preservation. Proper storage of patient records that are collected in a LIS is essential for record preservation and accurate recall of patient information. Without proper storage and maintenance of records, the timeframes, identification, and the accessibility of records will not be possible.

- Incorporating a requirement at § 493.1241(e) for laboratories using LIS to ensure that the requisition information is accurately transcribed or entered. The laboratory may establish its own mechanism to meet this requirement, possibly through random checks or representative sampling of LIS patient testing information verified against that submitted on the original test request.

- Adding a requirement at § 493.1291(a) that requires laboratories to ensure patient test results are accurately and reliably sent from the point of data entry to the final report's destination in a timely manner. We are providing frequently encountered reporting scenarios that must be reviewed by the laboratory to ensure the accuracy and reliability of the transmitted patient result information.

- Requiring at § 493.1291(c) that the date of the test report be identified on the report. This date must be maintained as the date testing results