D5207

(Rev. 140, Issued: 05-29-15, Effective: 05-29-15, Implementation: 05-29-15)

§493.1234 Standard: Communications

The laboratory must have a system in place to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results.

Interpretive Guidelines §493.1234

Such communication could entail problems with the descriptions they have provided to authorized individuals about proper specimen collection or shipment. For example, the laboratory's system for identifying and documenting communication problems should be able to capture instances in which there is a need to request additional information concerning patient specimens. If the laboratory does not receive the appropriate specimen or patient information needed to perform the tests, the laboratory should assess whether the information that is currently being made available to authorized individuals concerning patient preparation and specimen handling requirements is adequate.

The laboratory's system for identifying and documenting communications problems should be able to capture instances where testing was affected. These instances could be due to the lack of necessary patient information from the authorized person, improper specimen collection, improper handling and transport of the specimens to the laboratory,

etc. If the appropriate specimen(s) and/or patient information needed to perform the requested tests is not being received by the laboratory, an assessment should be made to determine whether the information that is currently made available to authorized persons

concerning patient preparation, specimen collection and handling requirements, is

adequate.