

§493.1291 Standard: Test report

(e) The laboratory must, upon request, make available to clients a list of test methods employed by the laboratory and, as applicable, the performance specifications established or verified as specified in §493.1253. In addition, information that may affect the interpretation of test results, for example test interferences, must be provided upon request. Pertinent updates on testing information must be provided to clients whenever changes occur that affect the test results or interpretation of test results.

Interpretive Guidelines §493.1291(e)

When the laboratory changes methods, establishes a new procedure or refers tests to another laboratory, the laboratory must make the updated information concerning parameters such as patient preparation, preservation of specimens, specimen collection, or new “normal” ranges or units of measure available to its clients.

§493.1291(e) Probes

How does the laboratory keep its clients informed about tests offered, methods used, and specimen requirements?

What means does the laboratory use to provide interpretation of results to its clients?