§ 493.1281 Standard: Comparison of test results.

(2) For renal allotransplantation and combined organ and tissue transplants in which a kidney is to be transplanted, have available results of final crossmatches before the kidney is transplanted.

(3) For nonrenal transplantation, if HLA testing and final crossmatches were not performed prospectively because of an emergency situation, the laboratory must document the circumstances, if known, under which the emergency transplant was performed, and records of the transplant must reflect any information provided to the laboratory by the patient’s physician.

(g) Documentation. The laboratory must document all control procedures performed, as specified in this section.

§ 493.1282 Standard: Corrective actions.

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur:

1. Test systems do not meet the laboratory’s verified or established performance specifications, as determined in §493.1253(b), which include but are not limited to—
   (i) Equipment or methodologies that perform outside of established operating parameters or performance specifications;
   (ii) Patient test values that are outside of the laboratory’s reportable range of test results for the test system; and
   (iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory’s patient population.

2. Results of control or calibration materials, or both, fail to meet the laboratory’s established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

3. The criteria for proper storage of reagents and specimens, as specified under §493.1252(b), are not met.

§ 493.1283 Standard: Test records.

(a) The laboratory must maintain an information or record system that includes the following:

1. The positive identification of the specimen.
2. The date and time of specimen receipt into the laboratory.
3. The condition and disposition of specimens that do not meet the laboratory’s criteria for specimen acceptability.