D5773

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§493.1278 Standard: Histocompatibility

(f)(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.

§493.1278 Standard: Histocompatibility

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

§493.1278(g) Guidelines

All QC records must be maintained for two years including instrument charts, graphs, printouts, transcribed data, manufacturer's assay information sheet for control and calibration materials and reagents to include typing trays, primers and/or probes. Do not dictate the acceptable format for documentation.