D3035
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§493.1105 Standard: Retention requirements

(a)(3)(ii) Immunohematology records, blood and blood product records, and transfusion records as specified in 21 CFR 606.160(b)(3)(ii), (b)(3)(iv), (b)(3)(v), and (d).

Interpretive Guidelines §493.1105(a)(3)(ii)

Refer to the current version of 21 CFR Part 606.160 for the specified section.

Non-transfusion related immunohematology patient testing and quality control (QC) records, such as instrument function checks, maintenance, and temperature records, must be retained for at least 2 years.

Other immunohematology patient and QC records related to transfusion testing, including but not limited to, donor processing, compatibility testing, and transfusion reaction investigations, must be retained for the time frame stated at 21 CFR §606.160(d). This also includes the visual inspection of whole blood and red blood cells during storage and immediately before distribution [21 CFR §606.160(b)(3)(ii)], record of reissue, including records of proper temperature maintenance [21CFR §606.160(b)(3)(iv)], and emergency release of blood, including signature of requesting physician obtained before or after release [21 CFR §606.160(b)(3)(v)].