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

§493.1271 Standard: Immunohematology

(b) Immunohematological testing and distribution of blood and blood products.

Blood and blood product testing and distribution must comply with 21 CFR 606.100(b)(12); 606.160(b)(3)(ii) and (b)(3)(v); 610.40; 640.5(a), (b), (c), and (e); and 640.11(b).

Interpretive Guidelines §493.1271(b)

Refer to the current version of 21 CFR Parts 600 through 799 for the specified sections:

- §606.100(b)(12) - Criteria for determining whether returned blood is suitable for reissue;
- §606.160(b)(3)(ii) – Visual inspection of whole blood and red blood cells during storage and immediately before distribution;
- §606.160(b)(3)(v) – Emergency release of blood, including signature of requesting physician obtained before or after release;
- §610.40 Testing for communicable diseases;
- §640.5(a) Syphilis testing;
- §640.5(b) Determination of Blood group;
- §640.5(c) Determination of Rh factor;
- §640.5(e) Inspection of whole blood during storage and immediately prior to issue; and
- §640.11(b) Inspection of RBC during storage and at the time of issue.

Probes §493.1271

If equipment and reagents are used in mobile or temporary testing sites, how are they protected from extreme temperature fluctuations when not in use (e.g., evenings, weekends, and holidays)?