

§493.1271 Standard: Immunohematology

(e) Investigation of transfusion reactions.

(e)(1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures.

(e)(2) The laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused.

Interpretive Guidelines §493.1271(e)(2):

Examine records of transfusion reaction investigations for completeness, accuracy, and promptness. Verify that investigations of transfusion reactions are conducted in accordance with the facility's established protocols. Records must include each step of the investigation, including conclusions and any follow-up.

Probes §493.1271(e)(2):

If problems or technical errors are identified during a transfusion reaction investigation, are corrective actions taken and, as applicable, procedures instituted to prevent a recurrence?

Did the laboratory assess the adequacy of the procedures implemented? Use D5793.

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

Interpretive Guidelines §493.1271(f)

All non-transfusion related immunohematology QC records must be retained for at least 2 years. Use D3035.

Transfusion-related immunohematology QC records, including but not limited to, donor processing, compatibility testing, and transfusion reaction investigations, must be retained for the timeframe stated at 21 CFR §606.160(d).