

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0452541	(X3) Date Survey Completed 03/26/2025
Name of Provider or Supplier Osborne County Memorial Hospital	Street Address, City, State 237 West Harrison Street, Osborne, KS	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on review of "Proficiency Test handling and Result Submission" procedure, the lack of secondary review documentation, lack of corrective action (CA) documentation addressing the failure to document review when a clerical error occurred, and interview with general supervisor (GS) #1, the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the general laboratory systems. Findings: 1. Review of "Proficiency Test handling and Result Submission" procedure signed by the laboratory director (LD) on December 10, 2019, revealed on page 3, item 5. e. " All laboratory personnel will perform a secondary review before electronic submission." The secondary review will be a comparison of the actual instrument printout or log sheet to the results on the electronic submission page." 2. Review of American Proficiency Institute (API) CA Checklist for 2024 Chemistry Core 3rd Event revealed the following: a. Checklist question-Were the results transcribed onto the result forms correctly? Lab entered "No." b. Checklist question-Were the results transcribed from the results forms to the website correctly? Lab entered "No." c. Corrective Action entry: "Consider eliminating the use of API result form. Going to weekly review of manual results to audit the process. Triple check manual entry of API." d. Document was signed by GS #1 and the LD on December 3, 2024. e. Review of submission documents for this event revealed no documentation of review prior to submission of results to API. f. Additional review of "Proficiency Test handling and Result Submission" procedure showed no changes to policy made to include the</p>

"Triple check manual entry of API" stated as CA signed by LD on December 3, 2024 for 2024 Chemistry Core 3rd Event. 2. Interview with the GS #1 on March 26, 2025, at 1:45 p.m. confirmed, the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the general laboratory systems. .

D5401

PROCEDURE MANUAL
CFR(s): 493.1251(a)

(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:
Based on a review of the laboratory procedure "Platelet Storage and Transfusion" and interview with GS #1, the laboratory failed to follow written procedures to determine ABO compatibility prior to platelet transfusion. 1. Review of the procedure " Platelet Storage and Transfusion" under Ordering Platelets, it stated "Platelets must be ABO compatible." The procedure is signed by the LD March 15, 2025. 2. Review of the retired procedure by the same name, includes the ABO compatibility provision and was signed by the LD on September 17, 2020. 3. Review of blood bank test logs for March 11, 2025, revealed a patient received four platelet packs: a. One A positive platelet pack b. One B positive platelet pack c. Two O positive platelet pack d. No documentation of the patient's ABO blood type determination. 4. Interview with GS #1 on March 26, 2025, at 11 a.m. confirmed, the laboratory failed to follow written procedures to determine ABO compatibility prior to platelet transfusion.