

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D0661823	(X3) Date Survey Completed 12/01/2021
Name of Provider or Supplier Grafton City Hospital	Street Address, City, State 1 Hospital Plaza, Grafton, WV	
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
D0000	An announced, on site, recertification survey was conducted at Grafton City Hospital on November 30 and December 1, 2021, by the West Virginia Office of Laboratory Services. The laboratory was surveyed to assess compliance with the Federal Clinical Laboratory Improvement Amendments (CLIA) regulations under 42 CFR 493. Specific deficiencies are explained below.
D2087	<p>ROUTINE CHEMISTRY CFR(s): 493.841(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to achieve a satisfactory performance score for the analytes PO2 and Total Bilirubin in one of three proficiency testing (PT) events in 2021. Findings: 1. Review of America Proficiency Institute (API) PT records revealed the following unsatisfactory scores for the Chemistry Core 3rd event 2021: PO2= 60% Total Bilirubin= 60% 2. An interview with the general supervisor, 11/30/21 at approximately 11:30 AM, confirmed the unsatisfactory analyte performance for PO2 and Total Bilirubin.</p>
D5555	<p>IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f)</p> <p>(c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.</p>

This STANDARD is not met as evidenced by:
 Based on record review and interview the laboratory failed to (c) maintain the required storage temperature of red blood cell products for 65 of 164 hours during temporary storage. Findings: 1. Review of P&P identified a required storage temperature of 2-6 degrees Celsius for red blood cell products. 2. Review of the Emergency Blood Bank Temperature log for incident I22-2021 (4/30/21 at 1600 thru 5/7/21 at 1200) identified storage temperatures taken for the temporary storage of packed red blood cells and reagents documented at hour intervals. 3. Review of the temperatures documented identified out of range temperatures (greater than 6 degrees Celsius) for 65 of the 164 hours that the storage temperature was monitored (4/30/21 at 1600 thru 5/3/21 at 0800). 4. Review of the blood product tracking logs identified 19 units of packed red blood cells that were potentially affected by the out of range storage temperatures. 5. An interview with the general supervisor, 12/1/21 at approximately 11:30 AM, confirmed the findings.

D5559

IMMUNOHEMATOLOGY
 CFR(s): 493.1271(e)(f)

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

This STANDARD is not met as evidenced by:
 Based on record review and interview, the laboratory failed to (f) perform and document quality control (QC) for Immunohematology for 4 of 93 days of patient testing. Findings: 1. Review of the Transfusion Service Testing Record (1/1/21 thru date of survey) identified 93 days of patient testing. 2. Review of QC records (1/01/21 thru date of survey) identified 4 days of patient testing that no Immunohematology QC was documented as performed. 3. An interview with the general supervisor, 12/1/21 at approximately 9:15 AM, confirmed the findings.

D5785

CORRECTIVE ACTIONS
 CFR(s): 493.1282(b)(3)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.

This STANDARD is not met as evidenced by:
 Based on policies and procedures (P&P), record review, lack of documentation, and interview the laboratory failed to take action and document corrective actions taken when (b)(3) the storage temperature of the packed red blood cell products were out of

range for 65 of 164 hours during temporary storage. Findings: 1. Review of P&P identified a required storage temperature of 2-6 degrees Celsius for red blood cell products. 2. Review of the Emergency Blood Bank Temperature log for incident I22-2021 (4/30/21 at 1600 thru 5/7/21 at 1200) identified out of range temperatures (greater than 6 degrees Celsius) for 65 of the 164 hours that the storage temperature was monitored (4/30/21 at 1600 thru 5/3/21 at 0800). 3. No documentation of corrective action taken when the storage temperatures were out of range could be located. 4. Review of the blood product tracking logs identified 19 units of packed red blood cells that were potentially affected by the out of range storage temperatures. 5. An interview with the general supervisor. 12/1/21 at approximately 11:30 AM, confirmed the findings.