

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 51D0910926	<b>(X3) Date Survey Completed</b> 11/03/2021
<b>Name of Provider or Supplier</b> Minnie Hamilton Health Care Center Inc	<b>Street Address, City, State</b> 186 Hospital Hill, Grantsville, WV	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced, on site, recertification survey was conducted at Minnie Hamilton Health Care Center Inc. on November 3, 2021, by the West Virginia Office of Laboratory Services. The laboratory was surveyed to assess compliance with the Federal Clinical Laboratory Improvement Amendment (CLIA) regulations under 42 CFR 493. Specific deficiencies are explained below.
<b>D2087</b>	<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 received an unsatisfactory performance score for 3 of 23 analytes in the 3rd Chemistry Core proficiency testing event 2020. Findings: 1. Review of American Proficiency Institute (API) records identified the following scores: 2020 Chemistry Core 3rd event pCO2= 60% pH= 60% pO2= 60% 2. An interview with the general supervisor, 11/2/21 at approximately 10:30 AM, confirmed the findings.</p>
<b>D2127</b>	<p>HEMATOLOGY CFR(s): 493.851(d)</p> <p>Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to return results within the</p>

	<p>specified time frame for 1 of 3 Hematology proficiency testing (PT) events in 2020. Findings: 1. Review of College of American Pathologist (CAP) PT records identified the following: FH9-A 2020 Hematology Auto Differentials 0% Unsatisfactory score for event, results not returned 2. An interview with the general supervisor, 11/2/21 at approximately 10:30 AM, confirmed the findings.</p>
<p><b>D2173</b></p>	<p><b>COMPATIBILITY TESTING</b> CFR(s): 493.863(a)</p> <p>Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to achieve an overall testing score of 100% for Compatibility Testing in 1 of 3 proficiency testing (PT) events in 2020. Findings: 1. Review of College of American Pathologist (CAP) PT records identified the following: J-C 2020 Compatibility Testing= 80% 2. An interview with the general supervisor, 11/2/21 at approximately 10:20 AM, confirmed the findings.</p>
<p><b>D3025</b></p>	<p><b>REQUIREMENTS FOR TRANSFUSION SERVICES</b> CFR(s): 493.1103(d)</p> <p>Investigation of transfusion reactions. The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities.</p> <p>This STANDARD is not met as evidenced by: Based on record review, policies and procedures (P&amp;P), lack of documentation, and interview the facility failed to establish the specific criteria and parameters to promptly identify a blood or blood product transfusion reaction. Findings: 1. Review of laboratory blood bank records identified no transfusion reactions documented for 2020 or 2021. 2. Review of laboratory blood bank P&amp;P identified "Suspected Transfusion Reaction Workup" which states "Detection of the reaction is the responsibility of persons performing the transfusion." 3. Review of nursing P&amp;P identified "Blood Transfusion" which states to monitor the patient for "adverse effects of blood transfusion since IV products have a more rapid effect. This would include but not limited to: circulatory overload, hemolytic reaction." 4. No facility P&amp;P that outlines the specific signs and symptoms of a transfusion reaction or patient monitoring parameters before, during, and after a transfusion could be located. 5. An interview with the general supervisor and the nursing supervisor, 11/3/21 at approximately 1:10 PM, confirmed the findings.</p>
<p><b>D3035</b></p>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)(ii)</p> <p>In addition, the laboratory must retain 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).</p>

This STANDARD is not met as evidenced by:  
Based on record review and interview the laboratory failed to retain the required transfusion records for 1 of 1 incident of emergency release of blood and blood products reviewed for 2021. Findings: 1. Review of emergency release blood bank forms identified patient 67976 as receiving 2 units of uncrossmatched, O Negative packed red blood cells on 6/2/21. The emergency release forms were complete and signed by the attending physician. No transfusion forms could be located for either unit. 2. An interview with the general supervisor, 11/3/21 at approximately 9:30 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, lack of documentation, and interview, the laboratory failed to (f) document quality control (QC) performed for 1 of 7 days of patient testing reviewed (5/26/21 thru 6/10/21). Findings: 1. Review of Transfusion Service Testing Record identified 7 days of patient testing- 5/26/21, 5/28/21, 5/31/21, 6/2/21, 6/4/21, 6/7/21, 6/10/21. No documentation of which method testing personnel utilized for patient testing (manual gel method or automated Vision method) could be located. 2. Review of specified days of patient testing identified QC for the automated Vision method 7 of 7 days. 2. The general supervisor stated on 11/3/21 at approximately 10:00 AM that manual gel patient testing was performed 6/2/21. No documentation of that quality control could be located. 3. An interview with the general supervisor, 11/3/21 at approximately 10:45 AM, confirmed the findings.

**D5791**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1289(a)(c)

(a) 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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:  
Based on review of policies and procedures (P&P), blood bank transfusion records, and interview the laboratory failed to establish written P&P to monitor, assess, and when indicated, correct problems identified in transfusion medicine. Specifically: a) Ensuring all blood bank documentation is accurate and complete for transfusions of

blood and blood products b) Ensuring the facility has established P&P that define necessary vital signs to be obtained before, during, and after transfusion and the specific parameters for those vital signs to identify possible transfusion reactions c) Ensuring the retention of blood and blood product transfusion records d) Ensuring documentation of quality control for each method utilized for patient testing Findings: (a) Review of blood bank transfusion forms and emergency release forms identified that patient 67976 received multiple units of blood and blood products on 6/2/21: i) 2 units of O Negative packed red cells and 3 units of O Positive packed red cells -2 of 2 transfusion forms for the 0 Negative units could not be located -3 of 3 transfusion forms for O Positive units were not complete as they had no documentation if units were released crossmatched or uncrossmatched as established in the laboratory P&P ii) 2 units of fresh frozen plasma (FFP); documentation of the unit numbers were found to be inaccurate, incomplete, and sometimes illegible: -Unit 1 was inaccurately and incompletely recorded as ending in 9553000J with expiration date of 10/30/21 in the Transfusion Service Testing Record, 953000J with expiration date of 10/30/21 in Blood Bank Log, and 95300J with no expiration date documented on the transfusion form. -Unit 2 product number was inaccurately and illegibly recorded in Transfusion Service Testing Record and transfusion form. The Transfusion Service Testing Record had no expiration date documented. iii) No documentation of the transfusion of either unit of FFP for patient 67976 could be located in the EHR. (b) No facility P&P could be located that included vital signs to be monitored for specific changes to identify potential transfusion reactions. Refer to D3025. (c) Transfusion records for patient blood and blood product transfusions were not retained. Refer to D3035. (d) Quality control not documented accurately. Refer to D5559. An exit interview with the general supervisor, 11/3/21 at approximately 1:10 PM, confirmed the findings.