

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 51D1082418	<b>(X3) Date Survey Completed</b> 05/12/2022
<b>Name of Provider or Supplier</b> Manchin Clinic South Llc	<b>Street Address, City, State</b> 181 Middletown Loop, Whitehall, 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, routine recertification survey was conducted at Manchin Clinic South on May 12, 2022, 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>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 submit the proficiency testing (PT) results for 1 of 3 American Proficiency Institute (API) 2021 events before the deadline. Findings: 1. Review of API records identified an unsatisfactory performance of 0% for the 2nd Hematology testing event of 2021. 2. Review of API records revealed a self evaluation of results by the laboratory. 3. An interview with the technical consultant, on 5/12/22 at approximately 9:45 AM, confirmed the PT results had not been submitted in time.</p>
<b>D5781</b>	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)</p>

(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on record review, written policies and procedures (P&P), lack of documentation, and interview the laboratory failed to document corrective actions taken when (b)(1)(i) patient results were released with ACT2 Diff Hematology analyzer flags for 25 of 47 patient results reviewed. Findings: 1. Review of 47 random patient printouts from the ACT2 Diff Hematology analyzer identified 25 records with 1,2,3, or M histogram error flags on released results. 2. Review of P&P revealed the process to handle 1,2,3, or M histogram error flags: rerun the patient specimen and if flags still present to notify physician for decision of further testing. 3. No documentation of reruns or physician notification as corrective actions could be located for the 25 patient specimens with 1,2,3, or M histogram error flags. 4. An interview with the technical consultant and testing personnel (TP1), on 5/12/22 at approximately 1:10 PM, confirmed the findings.