

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 51D1082418	<b>(X3) Date Survey Completed</b> 11/06/2024
<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>D5807</b>	<p>TEST REPORT CFR(s): 493.1291(d)</p> <p>Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.</p> <p>This STANDARD is not met as evidenced by: Based on review of 50 September 2024 and October 2024 patient final test reports obtained from the Orchard laboratory information system (LIS) and interview with testing personnel (TP1), the laboratory failed to ensure the reference intervals for 6 of 20 complete blood count (CBC) parameters analyzed were included on patient test reports from September 2024 (date LIS and DxH 500 put into use) thru date of survey. Findings: 1. Review of 19 patient CBC test reports from the LIS (September 2024) revealed no stated reference intervals for 6 of 20 parameters listed on a final report: neutrophil %, eosinophil %, basophil %, # neutrophil, # eosinophil, # basophil. 2. Review of 31 patient CBC reports from the LIS (October 2024) revealed no stated reference intervals for 6 of 20 parameters listed on a final report: neutrophil %, eosinophil %, basophil %, # neutrophil, # eosinophil, # basophil. 3. During an interview on 11/6/24 at 9:30 AM, TP1 stated the DxH 500 and Orchard LIS were put into use September 3, 2024. TP1 stated Orchard had been contacted about the lack of reference intervals on the final patient test report but the issue has not been resolved. 4. An exit interview with TP1, 11/6/24 at 12:00 PM, confirmed the lack of reference intervals for the 6 CBC parameters on patient final test reports from the Orchard LIS.</p>
<b>D6064</b>	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(a)</p> <p>Each individual performing moderate complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required.</p>

This STANDARD is not met as evidenced by:

Based on review of primary source verification (West Virginia state licensure primary source verification portal) and interview with testing personnel (TP1), one of two laboratory testing personnel (TP2) failed to possess a current West Virginia laboratory license as required by the West Virginia 64 CSR 57 Clinical Laboratory Practitioner and Licensure Certification rule. Findings: 1. On site, the state surveyor identified 6 of 20 days in September 2024 that patient complete blood count (CBC) results were released without QC being performed and acceptable: 9/9, 9/10, 9/11, 9/12, 9/13, 9/16. Refer to D6025. 2. During an interview with TP1, 11/6/24 at 11:05 AM, TP1 stated that an individual (TP2) from a different facility performed all CBC testing between 9/9 and 9/16. The laboratory was unable to provide a valid state laboratory license for TP2. 3. A review of the WV state licensure primary source verification portal confirmed TP2 did not have a current laboratory testing license (POCT 13059, expired 10/1/2022).