

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D1039229	(X3) Date Survey Completed 01/31/2024
Name of Provider or Supplier Wellmont Health System	Street Address, City, State 1519 Main Street, Sneedville, TN	
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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's College of American Pathologists (CAP) proficiency testing (PT) records and an interview with the lab technical specialist, the laboratory director/designee failed to sign 19 of 29 attestation statements reviewed for 2023. The findings include: 1. A review of the laboratory's 2023 CAP PT records for Chemistry, Hematology, and Microbiology revealed the laboratory director/designee failed to sign 19 of the 29 attestation statements reviewed. 2. In an interview with the lab technical specialist on 01.31.2024 at 2:45 p.m. confirmed the laboratory director /designee failed to sign 19 of the 29 PT attestation statements reviewed for 2023.</p>
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p>

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's College of American Pathologists (CAP) proficiency testing (PT) records and an interview with the lab technical specialist, the laboratory failed to retain the PT attestation statement for two years for one of 29 PT events reviewed from 2023. The findings include: 1. A review of the laboratory's CAP PT records revealed the laboratory did not retain the attestation statement for blood oximetry 2023 event two. 2. In an interview with the lab technical specialist on 01.31.2024 at 2:45 p.m. confirmed the laboratory failed to retain the PT attestation statement for at least two years for one of 29 PT events reviewed from 2023.