

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 43D0406826	(X3) Date Survey Completed 03/18/2025
Name of Provider or Supplier Horizon Health Elk Point	Street Address, City, State 204 East Main Street, Elk Point, SD	
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	A recertification survey for compliance with 42 CFR Part 493, Requirements for Laboratories, was conducted on 3/18/25. The Horizon Health Elk Point laboratory was found not in compliance with the following requirement: D2015.
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(b)(7) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to maintain a copy of the required documentation related to the processing of three of four proficiency testing (PT) events reviewed (2023 Hematology/Coagulation 3rd event; 2024 Hematology/Coagulation 2nd event; 2024 Hematology/Coagulation 3rd event). That documentation would ensure the results submitted for evaluation had been the results obtained by the laboratory processing the PT samples. Findings include: 1.Review on 3/18/25 of the laboratory's 2023 and 2024 American Proficiency Institute (API) PT event records revealed: *The laboratory had subscribed to PT events through API. *PT specimens were processed, and the results submitted electronically via the company's website upon completion of testing. *The laboratory had the ability to print a copy of the final PT results that were submitted for evaluation. *The laboratory had not retained copies of the final electronically submitted results for evaluation for the following events: -2023 API Hematology/Coagulation 3rd event -2024 API Hematology/Coagulation 2nd event -2024 API Hematology/Coagulation 3rd event Review of the laboratory's PT policy, last revised on 9/6/24 revealed. "If results are entered electronically to the PT provider's website, print a copy of the results entry. Inspect it for errors before submitting the results. Keep this copy with the worksheets. All records, including attestation sheets, are to be made available for inspection by the surveyor." Interview on 3/18/25 at 10:15 a.m. with nurse manager A revealed: *PT</p>

results were submitted electronically after they had been processed. *The laboratory had the ability to print a copy of all final PT results submitted for evaluation. *The laboratory had not printed copies of the final submitted PT results but instead had been printing only a preview of the results.