Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0994136	01/13/2026
Name of Provider or Supplier	**Street Address, City, State**	
Scranton Hematology Oncology	743 Jefferson Avenue Gsb Suite 205, Scranton, PA	

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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on lack of documentation, and interview with the Medical Technologist (MT), the laboratory failed to perform the twice annual verification of accuracy for Manual Reticulocyte (hematology) microscopic examinations for 1 of 1 year (2024). Findings Include: 1. On the day of survey, 01/13/2026 at 09:45 am, the laboratory could not provide documentation for 1 of 2 annual verification of accuracy for Manual Reticulocyte (hematology) microscopic testing performed for 1 of 1 year (2024). 2. The laboratory performed 41 manual reticuloctye (hematology) microscopic examinations in 2024. 3. The MT confirmed the findings above on 01/13/2026 at 10: 45 am. *** Repeat Deficiency***
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

	This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the Medical Technologist (MT), the laboratory failed to monitor and document room humidity to ensure operating conditions were met for 1 of 1 Virtual Diagnostics Envoy 500 Chemistry analyzer and 2 of 2 Abbott Cell Dyn Emerald hematology analyzers from 2/15/2024 to date of survey. Findings include: 1. Review of Abbott's operating conditions for Cell Dyn Emerald suggested less than 80% Relative Humidity and Virtual Diagnostics' operating conditions for the Envoy 500 has a suggested Relative humidity of 10 to 90%. 2. On the day of the survey, 01/13/2026 at 10:30 am, the laboratory failed to provide documentation for the monitoring of room humidity to ensure operating conditions were met for the following when chemistry and hematology testing was performed from 02/15/2024 to 01/13/2026: -1 of 1 Virtual Diagnostic Envoy 500 Chemistry Analyzer - 2 of 2 Abbott Cell Dyn Emerald Hematology Analyzers 3. The laboratory performed 10,343 chemistry and hematology tests in 2025 (CMS 116, estimated annual volume, dated 01/13/2026). 4. The MT confirmed the above findings on 1/13/2026 at 10:30am.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) (e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and This STANDARD is not met as evidenced by: Based on policy and proficiency testing (PT) result review, and interview with the Medical Technologist (MT), the laboratory director failed to ensure that all PT reports received were reviewed by the appropriate staff to evaluate and identify problems that required corrective action for 2 of 9 PT testing events performed in 2024 and 2025. Findings include: 1. Review of the laboratory's College of American Pathologists (CAP) PT testing reports revealed the LD failed to ensure the following PT testing events were reviewed and evaluated by the appropriate staff to identify problems that required corrective action when results for the following 2 of 9 PT testing events were ungraded by the PT agency from 2024 and 2025: - 2024 CAP 2024 Hematology Automated Differential 1st Event - 2025 CAP Blood Cell ID 1st Event 2. Further review of the laboratory's CAP and API PT results revealed the laboratory failed to perform corrective action for the following PT results when the laboratory received an unacceptable grade from the PT agency 2025: - 2025 CAP BCP-C Blood Cell ID; Score: 80%, BCP-24 - 2025 API Chemistry-Core-2nd Event: Score:80%, Carbon dioxide (CO2): CH-10 3. TS #3 confirmed the findings on 01/13/2026 at 11:00 am.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by:

	Based on review of the Laboratory Personnel Report (CMS-209), competency assessment (CA) records and interview with the Medical Technologist (MT), the Techinical Supervisor (TS) failed to evaluate the competency of 2 of 3 testing personnel (TP) that performed hematology and chemistry testing in 2024 and 2025. Findings include: 1. On the day of survey, 01/13/2026 at 9:30 am, review of the laboratory's CA records revealed the laboratory failed to provide complete CA records for 2 of 3 TP (TP#1 and #3, CMS 209, dated 01/13/2026) that performed hematology and chemistry testing in 2024 and 2025. 2. Upon further review of CA records, there was no documentation as to who performed CA for 2 of 3 TP (TP#1 and #3, CMS 209, dated 01/13/2026). 3. The MT confirmed the findings above on 01/13/2026 at 11: 00 am.