Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0994136	03/08/2022
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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (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. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with Testing Personnel (TP) #2, the laboratory failed to provide 6 of 6 American Proficiency Institute (API) and 2 of 3 College of American Pathologist(CAP) proficiency testing (PT) attestation statements for chemistry and hematology in 2020 and 2021. Findings Include: 1. On the day of survey, 03/08/2022 at 09:33 am, the laboratory did not provide the following API an CAP PT attestation statements in 2020 and 2021 a. API Chemistry Core: - 2020 Event #1, Event #2, Event #3. - 2021 Event #1, Event #3. b. CAP Hematology: - 2021 Event B. 2. The following API and CAP PT attestation statements were not signed by the Testing personnel and the laboratory director/designee in 2021. a. API Chemistry Core: - 2021 Event #2. b. CAP Hematology: - 2021 Event C 3. TP#2 confirmed the findings above on 03/08/2022 around 11:20 a.m.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235

	As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of laboratory competency assessment records, review of the laboratory procedure manual, and interview with the Testing Personnel (TP)#2, the laboratory failed to follow their competency assessment procedure and assess the competency assessment of 1 of 1 Technical Supervisors (TS), 1 of 1 General Supervisor (GS) for their supervisory responsibilities and 4 of 4 Testing Personnel (TP) for manual differentials from 03/08/2020 to 03/08/2022. Findings Include: 1. On the day of survey 03/08/2022 at 10:14 a.m, The TP#2 could not provide competency assessment records for 1 of 1 TS and 1 of 1 GS for their supervisory responsibilities in 2020 and 2021. 2 The laboratory could not provide competency assessment records with the six components required by CLIA for 4 of 4 TP who performed manual differentials in 2020 and 2021. 2. The TP#2 confirmed the findings above on 03/08 /2022 at 11:20 a.m. * Repeated deficiency.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based a review of proficiency testing records and interview with the testing personnel (TP)#2, the Laboratory failed to review and evaluate the results obtained on proficiency testing for 1 of 3 American Proficiency Institute (API) and 3 of 6 College of American Pathologist (CAP) for Chemistry and Hematology in 2020 and 2021. Findings: 1. On the day of survey, 03/08/2022 at 09:50 a.m., the records reviewed revealed that the laboratory could not provide records of the evaluation and review of the following: a. API Chemistry: 2020 event#1 b. CAP Hematology: 2020 Event A, Event C, and 2021 Event C 2. The TP#2 confirmed the findings above on 03/08/2022 around 11:20 a.m.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on lack of Quality Assurance (QA) documentation and interview with the testing personnel (TP)#2, the Laboratory Director (LD) failed to ensure a QA program, was established, and maintained to ensure the quality of services provided by the laboratory from 03/08/2020 to 03/08/2022. Findings include: 1. On the day of survey 3/08/2022 at 11:05 a.m, the laboratory could not provide QA records. 2. The

	laboratory performed 48,526 non waived tests in the last year according to CMS-116 submitted by the laboratory. 3. The TP#2 confirmed there were no QA record on 03/08 /2022 at 11:20 a.m. * Repeated Deficiency