

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D0994136	<b>(X3) Date Survey Completed</b>  10/29/2019
<b>Name of Provider or Supplier</b>  Scranton Hematology Oncology	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory procedure manuals and interview with technical supervisor (TS), the laboratory failed to establish a complete procedure to assess the competency of 4 of 4 TP who performed manual differential examinations, complete blood count (CBC) and complete metabolic panel (CMP) tests and 1 of 1 clinical consultant competency in 2018 and 2019. Findings include: 1. On the day of survey, 10/29/2019, the laboratory failed to provide a complete written policy to assess the competency of 4 of 4 TP for each type of testing (manual differential examinations, CBC and CMP) and 1 of 1 clinical consultant competency from 2018 and 2019. 2. The TS confirmed the findings above on 10/29/2019 around 08:55 am.</p>
<b>D5429</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on, the review of records, observation of laboratory thermometers and interview with the technical supervisor (TS), the laboratory failed perform the maintenance/ calibration of 1 of 1 laboratory refrigerator and 1 of 1 freezer from 2017</p>

	<p>to the date of survey. Findings Include: 1. On the date of survey, 10/29/2019, while on tour of the laboratory, the surveyor observed 1 of 1 Fisher Scientific Traceable thermometer (refrigerator), S/N#150803434 was due for maintenance / calibration on 10/26/2017 and 1 of 1 Acu-Rite thermometer (Freezer) did not state the last maintenance or calibration date. 2. The laboratory could not provide documentation of last calibrations/ maintenance for both thermometers that house reagents for the Evoy 500 chemistry analyzer and the Abbot Cell Dyn- Emerald hematology analyzer. 3. The TS confirmed the findings above on 10/29/2019 around 11:00 am.</p>
<p><b>D5775</b></p>	<p><b>COMPARISON OF TEST RESULTS</b> CFR(s): 493.1281(a)(c)</p> <p>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Envoy 500 chemistry analyzer records and interview with the technical supervisor (TS), the laboratory failed to evaluate the relationship between 2 of 2 Abbott Cell Dyn Emerald hematology analyzers in 2018. Findings Include: 1. On the day of survey, 10/29/2019, the TS could not provide documentation of comparison studies performed on 2 of 2 Abbott Cell Dyn Emerald hematology analyzers in 2018 2. The TS confirmed the finding above on 10/29/2019 around 10:50 am.</p>
<p><b>D6094</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on, the review of laboratory quality assurance procedure, quality assurance records and interview with technical supervisor (TS), the laboratory failed to ensure that quality assessment programs are documented to assure the quality of laboratory from December 2017 to the date of survey. Findings Include: 1. The Quality Assurance procedure states "revise your quality assurance program on the result of the monthly evaluations.." 2. On the day of survey, 10/29/2019, the laboratory could not provide documentation of monthly quality assessment activities performed form December 2017 to September 2019. 3. The TS confirmed the findings above, on 10/29 /19 around 9:15 am. *** Repeat Deficiency***</p>
<p><b>D6125</b></p>	<p><b>TECHNICAL SUPERVISOR RESPONSIBILITIES</b> CFR(s): 493.1451(b)(8)(v)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.</p>

This STANDARD is not met as evidenced by:

Based on review of the competency assessment records, proficiency testing (PT) records and interview with the Technical Supervisor (TS), the TS failed to assess 1 of 4 TP for test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples, who performed manual differential, Complete blood count (CBC) and complete metabolic panel (CMP) tests in 2018 and 2019. Findings include: 1. On the day of survey, 10/29/2019, review of PT records and TP competency assessment records revealed, the assessment of external proficiency testing samples was not performed for 1 of 4 TP who performed manual differential, CBC and CMP tests in 2018 and 2019. 2. The following personnel were not assessed for test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples: - In 2018 Hematology, TP#1 - In 2018 Chemistry, TP#2 - In 2019 Hematology, TP#1 - In 2019 Chemistry, TP#3 3. The TS confirmed the finding above on 10/29/2019 around 9:50 am. .