

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0994136	(X3) Date Survey Completed 02/15/2024
Name of Provider or Supplier Scranton Hematology Oncology	Street Address, City, State 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	<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> <p>This STANDARD is not met as evidenced by: Based on review of College of American Pathologist (CAP), American Proficiency Institute (API) proficiency testing (PT) records, and interview with the technical supervisor #1 (TS#1), the laboratory failed to provide 2 of 6 CAP and 4 of 6 API PT attestation statements signed by the laboratory director in 2022 and 2023. Findings Include: 1. On the day of survey, 02/15/2024, review of CAP and API PT records revealed the following PT attestation statements were not signed by the laboratory director in 2022 and 2023: Hematology - 2022 CAP Hematology Automated Differential- FH1-A and FH1-C Chemistry - 2022 API Chemistry Core Events #1, #2 and #3 - 2023 API Chemistry Core Event # 1 2. TS #1 confirmed the findings above on 02/15/2024 at 12:55 pm. *Repeat Deficiency</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish</p>

and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:

Based on lack of documentation and interview with the technical supervisor #1 (TS#1), the laboratory failed to establish a procedure to assess the competency of their testing personnel (TP), general supervisor (GS), and technical supervisor (TS) for their responsibilities in 2022 and 2023. Findings include: 1. On the day of survey, 2/15/2024 at 01:24 pm, the laboratory failed to provide a procedure to assess the competency of TS, GS, and testing personnel (CMS 209 personnel 1, 2, and 3) for their responsibilities in 2022 and 2023. 2. The laboratory failed to provide competency assessment records for the following 1 of 1 GS, and 1 of 1 TS (personnel #1 on CMS 209) for their supervisory responsibilities from 03/08/2022 to the date of survey. 3. TS #1 confirmed the findings above on 02/15/2024 around 01:24 pm.
*Repeat Deficiency

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 technical supervisor #1 (TS#1), the laboratory failed to perform the twice annual verification of accuracy for Manual Reticulocyte (hematology) microscopic examinations from 3/08/2022 through the date of survey. Findings Include: 1. On the day of survey, 02/15/24 at 01:45 pm, the laboratory could not provide documentation of twice annual verification of accuracy for Manual Reticulocyte (hematology) microscopic testing from 03/08/2022 to 02/15/2024. 2. TS #1 confirmed the findings above on 2/15/2024 at 1:45pm.

D5305

TEST REQUEST
CFR(s): 493.1241(c)

The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.

This STANDARD is not met as evidenced by:

Based on lack of documentation and interview with the technical supervisor #1

(TS#1), the laboratory failed to provide test requisitions for hematology and chemistry tests performed from 03/08/2022 through day of survey. Findings Included: 1. On the day of survey 02/15/2024 at 03:06 pm, the laboratory failed to provide patient test requisitions with the required information for hematology and chemistry testing performed from 3/08/2022 through day of survey. 2. TS #1 confirmed the above finding on 02/15/2024 at 3:06 pm.

D5439

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on review of the Envoy 500 chemistry analyzer calibration verification (CV) records and interview with technical supervisor #1 (TS#1), the laboratory failed to perform CV for 18 of 18 analytes on the Envoy 500 analyzer at least every 6 months from 08/30/2022 to 07/25/2023. Findings include: 1. On the day of the survey, 02/15/2024 at 01:59 pm, the laboratory failed to provide documentation of CV on the Envoy 500 analyzer for the following analytes at least every 6 months: Envoy 500 - Albumin -Alkaline Phosphatase (ALP) -Alanine aminotransferase (ALT) -Aspartate aminotransferase (AST) -Blood urea nitrogen (BUN) -Bilirubin, Direct -Bilirubin, Total -Calcium -Chloride -Sodium -Potassium -Carbon dioxide (CO2) -Creatinine - Glucose -Lactate dehydrogenase (LDH) -Magnesium -Protein, total -Uric acid 2. The laboratory performed CV on 8/30/2022 and 7/25/2023. 3. The laboratory performed 26,723 chemistry examinations in 2023 (annual volume listed on CMS 116 form). 4. TS #1 confirmed the findings above on 02/15/2024 at 01:59 pm.

D5447

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(i)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different

concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of manual reticulocyte quality control documentation, review of patients results and interview with technical supervisor #1 (TS #1), the laboratory failed to perform quality control at least once a day before reporting manual reticulocyte results from 3/08/2022 to the day of survey. Findings include: 1. On the day of survey 02/15/2024 at 02:17 pm, review of the laboratory's Reticulocyte Count policy stated, "on every day that a reticulocyte count is ordered on a patient, choose two levels of Retic-chex control." 2. Review of the patient Reticulocyte log revealed the laboratory failed to include two control materials of different concentrations before resulting patient results from 03/08/2022 to 02/15/2024. 3. TS #1 confirmed the above findings on 02/15/2024 at 02:17 pm.

D5775

COMPARISON OF TEST RESULTS

CFR(s): 493.1281(a)(c)

(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.

This STANDARD is not met as evidenced by:

Based on lack of documentation and interview with technical supervisor #1 (TS#1), the laboratory failed to evaluate twice a year the relationship between test results using different methodologies and instrumentation in hematology from 03/08/2022 to the date of the survey. Findings include: 1. On the date of the survey, 02/15/2024 at 01:54 pm, the laboratory failed to provide documentation of the biannual comparison studies for the following 2 of 2 tests performed from 03/08/2022 to 02/15/2024: - Cell Dyn Emerald Serial Number 10040 (CBC with Auto Differential) v. Cell Dyn Emerald Serial Number 10042 (CBC with Auto Differential) - Manual white blood cell differentials vs. automated white blood cell differentials (Cell Dyn Emerald) 2. TS #1 confirmed the above findings on 02/15/2024 at 01:54 pm.

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 documentation, review of the laboratory's quality assurance (QA) procedure, and interview with technical supervisor #1 (TS #1), 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 03/08/2022 to the date of survey. Findings include: 1. Review of the laboratory's Quality Assurance policy states, "the laboratory director oversees the implementation of the QA plan and helps identify and correct problems as they occur. The QA plan is periodically reviewed to

minimize the possibility of recurrence of problems. When problems are identified, areas for improvement to the QA plan may be implemented. Quality Assurance includes the following components: *Personnel Training and Qualifications, *Proficiency Testing, *Procedure Manual, *Specimen Collection and Handling Specifications, *Patient Test Management/Record Keeping, *Quality Control Program, * Instrument Maintenance Program, * Laboratory Safety. As necessary, revise your Quality Assurance based on the results of the monthly evaluations." 2. On the date of survey, 02/15/2024 at 02:30 pm, the laboratory failed to provide documentation for the periodic QA evaluation performed to assess the laboratory's pre-analytical, analytical, and post-analytical processes from 03/08/2022 to 02/15/2024. 3. TS #1 confirmed the findings above on 02/15/2024 at 02:30 pm.