

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0657394	(X3) Date Survey Completed 11/13/2024
Name of Provider or Supplier Lancaster Cancer Center Ltd	Street Address, City, State 703 Lampeter Rd, Lancaster, 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
D5205	<p>COMPLAINT INVESTIGATIONS CFR(s): 493.1233</p> <p>The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation, review of laboratory procedures, and interview with the Technical Consultant (TC), the laboratory failed to establish and maintain a policy to ensure all complaints and problems reported to the laboratory are documented and investigated when needed from 02/23/2023 to the day of survey. Findings include: 1. On the day of survey, 11/13/2024 at 1:00 pm, the laboratory could not provide a policy to ensure all complaints and problems reported to the laboratory were documented and investigated as needed from 02/23/2023 to 11/13/2024. 2. The TC confirmed the finding above on 11/30/2024 at 01:00 pm.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the Technical Consultant (TC), the laboratory failed to ensure the verification of accuracy for Reticulocyte Hemoglobin (Ret-He) examinations were performed at least twice annually in 2023. Findings include: 1. The laboratory's Reticulocyte Hemoglobin Comparison policy states" Every 6 months we perform a comparison with the local hospital (Lancaster</p>

General Hospital - LGH) to compare our reticulocyte hemoglobin's (RET-He). The Ret-He is first run on the Sysmex XN-450, and then the specimen is sent to LGH for comparison on the Sysmex XN-10." 2. On the day of survey, 11/13/2024, the laboratory failed to provide documentation that the verification of accuracy of Ret-He examinations performed on the Sysmex XN-10 was performed at least twice annually in 2023. 3. The TC confirmed the findings above on 11/13/2024 at 10:45 am.

D5311

SPECIMEN SUBMISSION, HANDLING, AND REFERRAL
CFR(s): 493.1242(a)

The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:
Based on review of laboratory procedures, lack of documentation, and interview with the Technical Consultant (TC), the laboratory failed to establish a complete written procedure to ensure the reference laboratory's instructions for specimen referral were followed from 02/23/2023 to the date of the survey. Findings include: 1. The laboratory's Send out Policy states "When our physicians order testing that we do not perform in house, the samples are collected by the lab personnel and sent to the hospital via courier. There are 2 pickup times, 10:45 am and 03:00 pm". 2. On the date of the survey, 11/13/2024, review of the laboratory's procedures revealed the laboratory failed to include the following in the Send Out policy to ensure the reference laboratory's instructions for specimen referral were followed from 02/23/2023 to 11/13/2024: - Specimen storage and preservation - Specimen processing 3. The laboratory failed to provide a current service manual for 1 of 1 reference laboratory (Lancaster General Hospital) that patient specimens are referred to. 4. The TC confirmed the above findings on 11/13/2024 at 11:30 am.

D5405

PROCEDURE MANUAL
CFR(s): 493.1251(c)

Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's procedures, operator manuals, and interview with the Technical Consultant (TC), the laboratory failed to have a complete written procedure manual for chemistry testing performed that met the requirements of 493.1251 from 02/23/2023 to the date of the survey. Findings include: 1. On the day of the survey, 11/13/2024 at 11:30 am, review of the procedure manuals for chemistry testing revealed the operators manuals were used to perform testing on 1 of 1 Beckman Coulter AU680 chemistry analyzer from 02/23/2023 to 11/13/2024: 2. Review of the operators manual revealed that the test system instructions used failed to include the following requirements of 493.1251 that are specific to the laboratory: -

Step by step performance of the procedure including test calculations and interpretation of results - Preparation of slides, solution, calibrators, controls, reagents, stains, and other material used in testing. - Control procedures - Calibration and calibration verification procedures. - Corrective action to take when calibrations or control results fail to meet the laboratory criteria for acceptability. - Limitations in the test methodology, including interfering substances. -The reportable range for test results for the test system as established or verified in 493.1253. - Reference intervals (normal values). - Imminently life-threatening test results, or panic or alert values. - The laboratory 's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. - Description of the course of action to take if a test system becomes inoperable. 3.The operators manuals were not approved for use by the current laboratory director prior to the start of patient testing. 4. The TC confirmed the findings on 11/13/2024 at 01:00 pm.

D5413

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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:
 A. Based on review of the laboratory's temperature records and interview with the Technical Consultant (TC), the laboratory failed to monitor and document refrigerator and freezer temperatures to ensure operating conditions were met for the proper storage of hematology, chemistry and immunology reagents from 02/23/2023 to 11/13/2024. Findings Include: 1. On the date of the survey, 11/13/2024 at 11:00 am, review of the laboratory's temperature control logs revealed the laboratory failed to monitor and document freezer (acceptable range: 0--20 degrees Celsius) and refrigerator temperatures (acceptable ranges 2-8 degrees Celsius) on weekends and holidays to ensure the proper storage of reagents for the Sysmex XN-450, Beckman Coulter AU480, and the Beckman Coulter Access II analyzers from 02/23/2023 to 11/13/2024: 2. Observation of the laboratory by the surveyor, on 11/13/2024 at 12:30 pm, revealed the following reagents were stored in the refrigerator and freezer:
 Refrigerator: Chemistry Reagents: Immunology reagents - 1 of 1 box Chem calibrators 1 - 3 of 3 boxes Ferritin calibrators - 1 of 1 box Chem calibrators 2 - 5 of 5 boxes CEA - 0.5 of 1 box Transferrin - 2 of 2 boxes BR Monitor - 0.5 of 1 box Iron - 5 of 5 boxes TSH - 0.5 of 1 box Phosphorus - 2 of 2 boxes Ferritin Reagent - 1.5 of 2 boxes Glucose - 2 of 2 boxes Free T4 - 2 of 2 boxes Magnesium - 2 of 2 boxes Vitamin D - 1.5 of 2 boxes Uric Acid - 2 of 2 boxes Urea Nitrogen - 2 of 2 boxes Total Protein - 1 of 1 box Bilirubin - 1 of 1 box Lactate Dehydrogenase -Hematology reagents: 2 of 2 boxesXN-1 Check - 1 of 1 box Serum Protein calibrators - 2 of 2 boxes Creatine - 1 of 1 box Bicarbonate - 1 of 1 box Calcium - 2 of 2 boxes ALT - 1 of 1 box AST - 1 of 1box Gamma glutamyl transferase Freezer: -1 of 1 box Audit Micro control Gene Chem Plex - 1 of 1 box Bilirubin - 2 of 2 box Access Vitamin D calibrator - 1 of 1 box Free T4 calibrator - 1 of 1 box Bio Rad 1 Liquichek Immunoassay - 1of 1 box Bio Rad 2 Liquichek Immunoassay - 2 of 2 boxes Bio Rad

3 Liquichek Immunoassay - 1 of 1 box Bio Rad 1 Specialty Liquehek - 1of 1 box Bio Rad 2 Specialty Liquehek - 1 of 1 box Bio Rad 3 Specialty Liquehek - 1of 1 box LTA 3. The TC confirmed the above findings on 11/13/2024 at 11:00 am. B. Based on lack of documentation and interview with the Technical Consultant (TC), the laboratory failed to define and document criteria for water quality conditions to ensure accurate and reliable test system operation of the laboratory's deionized water (DI) system from 02/23/2023 to the date of the survey. Findings include: 1. On the day of the survey, 11/13/2024 at 12:30 pm, the laboratory failed to provide a procedure and documentation for the maintenance performed to ensure accurate and reliable test system operation of 1 of 1 ELGA DI water system used from 02/23/2023 to 11/13 /2024. 2. The TC confirmed the findings above on 11/13/2024 at 01:00 pm.

D5435

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(b)(2)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:
Based on observation of the laboratory, lack of documentation, and interview with the Technical Consultant (TC), the laboratory failed to establish and maintain a function check protocol that ensures each piece of equipment used in the laboratory provides accurate and reliable test results from 02/23/2023 to the day of the survey. Findings Include: 1. On the day of survey, 11/13/2024, the laboratory failed to provide documentation for the function check protocol established by the laboratory to ensure 1 of 1 Quest centrifuge used for specimen processing of chemistry testing provides accurate and reliable test results from 02/23/2023 to the day of the survey. 2. The laboratory failed to provide documentation of the function checks performed for 1 of 1 Quest centrifuge, observed by the surveyor during a tour of the laboratory, in use from 02/23/2023 to 11/13/2024. 3. The TC confirmed the findings above on 11/13 /2024 at 12:30 pm. .

D5813

TEST REPORT
CFR(s): 493.1291(g)

The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values.

This STANDARD is not met as evidenced by:
Based on review of patient test reports and interview with the Technical Consultant (TC), the laboratory failed to document the date, time, and person to whom critical test results were reported to from 02/23/2023 to 11/13/2024. Findings include: 1. On the day of survey, 11/13/2024 at 11:00 am, review of 1 of 1 patient test reports revealed the laboratory failed to document the date, time, and person to whom the

critical values were reported to from 02/23/2023 to 11/13/2024. 2. The laboratory failed to provide a procedure for how the laboratory ensures authorized personnel are notified in a timely manner for critical values. 3. The TC confirmed the findings on 11/13/2024 at 11:00 am.

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1299(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:
Based on record review, lack of documentation, and interview with the Technical Consultant (TC), the laboratory failed to establish and follow written policies and procedure for an ongoing mechanism to monitor, assess, and correct problems identified for postanalytical systems specified in 493.1291(a)(1) from 02/23/2023 to the date of the survey. Findings include: 1. On the date of survey, 11/13/2024, at 10:30 am, the laboratory failed to provide a procedure or documentation of the ongoing mechanism used to periodically verify the accuracy of the following from 02/23/2023 to 11/13/2024: - Calculated date for examinations performed on 1 of 1 Sysmex XN-10 (hematology), and 1 of 1 Beckman AU (chemistry) - Results sent to laboratory interfaced system (LabDaq) - Patient-specific data 2. The TC confirmed the above finding at 10:30 am on 11/13/2024.

D6020

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on record review, lack of documentation, and interview with the technical consultant (TC), the Laboratory Director (LD) failed to ensure a quality control (QC) program was established and maintained to assure the quality of laboratory services provided for chemistry and hematology examinations performed from 02/23/2023 to 11/13/2024. Findings include: 1. On the day of survey, 11/13/2024 at 12:00 pm, review of the laboratory's QC records revealed the LD failed to ensure a QC program was established and maintained to assure the quality of laboratory services provided for chemistry and hematology examinations performed on the following analyzers from 02/23/2023 to 11/13/2024: - 1 of 1 Sysmex XN450 (hematology) - 1 of Beckman AU4680 (chemistry) - 1 of 1 Beckman Access (chemistry/immunology) 2. During an interview, the TC stated. "The laboratory uses the stated manufacture values for the acceptable ranges of QC for hematology and chemistry, and the monthly QC values are submitted to Sysmex and Beckman for statistical analysis for shifts and trends." 3. The laboratory failed to provide documentation for the verification performed by the laboratory to ensure the acceptable ranges of QC

correlate with the established values when implementing a new lot of QC from 02/23/2023 to 11/13/2024. 4. The laboratory failed to provide documentation of the monthly QC reports submitted and analyzed by Sysmex and Beckman from 02/23/2023 to 11/13/2024. 5. The TC confirmed above findings on 11/13/2024 at 1:10 pm