Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0657394	08/16/2018
Name of Provider or Supplier	**Street Address, City, State**	
Lancaster Cancer Center Ltd	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
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: Based on surveyor observation of the laboratory, review of laboratory room temperature records and interview with the Technical Consultant (TC), the laboratory failed to monitor and document the room temperature where the Beckman Coulter Access 2 ISE solutions (13 of 13 Bottles) are stored from 2017 to the date of survey. Findings include: 1. On the day of survey, 08/16/2018, while on the tour of the laboratory, it was discovered that the room where the Beckman Coulter Access and its solutions are stored, the room temperature is not monitored. 2. Review of the ISE solution labels, revealed they need to be kept between the temperature of 2 degrees to 25 degrees Celsius. 3. The Cabinet in the room stored: - 4 of 4 bottles of ISE Mild Standard Solution, Lot# M802042 - 6 of 6 bottles of ISE Buffer Solution, Lot# M803095 - 3 of 3 bottles of ISE Reference Solution, Lot #M707082 4. The TC confirmed the findings above on 08/16/2018 around 11:00 am.
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 Beckman Coulter AU480 Analyzers calibration verification (CV) records and interview with Technical Consultant (TC), the laboratory failed to perform CV on the Beckman Coulter AU480 Analyzer at least every 6 months. Findings include: 1. On the day of survey, 08/16/2018, review of Beckman Coulter AU480 Analyzer CV records, revealed that the laboratory performed CV on 12/27 /2017 and again on 07/22/2018, which is outside of the six-month time schedule (should have been performed no later than 06/27/2018). 2. The TC confirmed the finding above on 08/16/2018 around 10:30 am.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of American Association of Bioanalysts (AAB) proficiency testing (PT) records and interview with Technical Consultant (TC), the Laboratory Director failed to ensure that all proficiency testing reports received and identified problems that require corrective action in 2017. Findings include: 1. On the day of survey, 08/16 /2018, the laboratory failed to document corrective actions for AAB Endocrinology, Event #2 PT results in 2017 for both Free TY and TSH, with a result of 80%. 2. The TC confirmed the findings above on 08/16/2018 around 10:00 am.