Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2020233	09/19/2018
Name of Provider or Supplier	**Street Address, City, State**	
Carter Clinic, Pa	4009 Barrett Drive Suite 100, Raleigh, NC	

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
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) 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. This STANDARD is not met as evidenced by: Based on review of manufacturer's operator manual, review of analyzer maintenance records and technical supervisor (TS) interview 9/19/18, the laboratory failed to document monthly maintenance of the Diatron Pictus 700 chemistry analyzer. Review of Diatron Pictus 700 operator's manual revealed section 7.4. "Monthly maintenance recommendations....7.4.1 Washer volume calibration....Following ....Maintenance >Washer Volume Calibration....It is possible the testing and calibration of the washer volume...screen will show the pump steps settings and new pump steps required for system delivery in all four wash steps....Target is that all deliveries are between 500 and 700 microliters. It is recommended the use of the test at least once a week. 7.4.2 Other tasks...Perform a full photometer calibration....Empty an clean washing solution reservoir.....Perform an intensive washer cleaning." Review of Diatron Pictus 700 maintenance records revealed no documentation of monthly maintenance from time of last survey until time of current survey 9/19/18, at period of approximately 26 months. Interview with TS at approximately 1:00 p.m. confirmed the laboratory failed to document monthly maintenance. the TS stated she had not confirmed the laboratory was using the correct maintenance form for the Diatron Pictus 700 analyzer and the analyzer will not let you proceed with patient testing unless the required maintenance is performed first.
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 manufacturer's package insert, review of laboratory procedures, review of laboratory calibration and calibration verification records and technical supervisor (TS) inerview 9/19/18, the laboratory failed to perform calibration verification at least once every 6 months as required for Ethyl Alcohol (ETOH). Review of Thermo Scientific-Dri Ethyl Alcohol reagent package insert revealed "Quality Control and Calibration.....Both negative and 100 mg/dl alcohol calibrators should be used to calibrate the assay." Review of laboratory procedure and laboratory calibration records for ETOH testing revealed the laboratory performs a weekly 2 point calibration of ETOH using a 0 mg/dl (negative) and a 100 mg/dl calibrator as required per package insert. Review of laboratory procedure "Calibration Verification" revealed "....CLIA/COLA regulations specify the lab must also perform calibration verification at least every six months, using a least three levels of materials that are within the reportable range of the test.....To perform calibrations verification:....2. Run at least three levels of materials, in the same manner and test mode that patient specimens are tested...." Review of laboratory calibration verification records for ETOH revealed the laboratory failed to perform a 3 point calibration verification at least once every 6 months from time of last survey until current survey 9/19/18, a period of approximately 26 months. Interview with TS at approximately 11:00 a.m. confirmed the laboratory had not performed a 3 point calibration verification of ETOH. She stated she did not think it was required because it was a positive or negative result and one of the calibrators used is at the cut off level, 100 mg/dl, so she assumed the calibration verification requirement was met.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The

	laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of laboratory procedure, review of quality control records and technical supervisor (TS) interview 9/19/18, the laboratory failed to document corrective actions for quality control failures on the Diatron Pictus 700 chemistry analyzer as required. Review of laboratory procedure "Required Quality Control" revealed "Troubleshooting QC Failure: When quality control results are not within acceptable limits.....3. If no problems found with control or reagents (#2) repeat control run. If control results are within acceptable limits, document corrective action on Troubleshooting Log .....4. Failure of repeat control run: When repeat of controls fail to test within acceptable limits, recalibrate and repeat control run. If control test within acceptable limits, document corrective actions and proceed with patient testing. 5. When above corrective actions fail, contact Technical Support for additional troubleshooting recommendations. Record all corrective actions on instrument Troubleshooting Log." Review of quality control records revealed the laboratory had multiple quality control failures with no documentation of the corrective actions performed. For example: 1. 12/5/17, Methadone quality control, level CL2, was repeated 9 times. 2. 12/5/17, Opiate quality control, level CL2, was repeated 4 times. 3. 12/28/17, Opiate quality control, levels CL1 and CL2, were repeated 4 times. 4. 4 /10/18, Buprenorphine quality control, level CL1, was repeated 7 times. 5. 4/19/18, Buprenorphone quality control, level CL1, was repeated 8 times. 6. 8/31/18, Amphetamine and Benzodiazepine quality control, levels CL1 and CL2, were repeated 10 times. Review of laboratory records revealed the laboratory did not have a "Troubleshooting Log" for the Diatron Pictus 700 chemistry analyzer in use from time of last survey until time of survey 9/19/18, a period of approximately 26 months. Interview with TS at approximately 1:00 p.m. confirmed the laboratory did not have a "Troubleshooting Log" for the Diatron Pictus 700 chemistry analyzer, and had not documented corrective actions for quality control failures as required.
D6098	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8) The laboratory director must ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of a random patient test report (accession #142632), and interview with the TS (technical supervisor) 9/19/18, the laboratory director failed to ensure that the laboratory's test reports included all pertinent information required for interpretation. The laboratory's "Test Reports" policy states "Test Reports Required Information: ... Required FDA Statement: All Urine Drug Screen patient reports must have the following statement of each report: Qualitative results are 'Presumptive' performed by laboratory developed enzyme immunoassay. Clinical consideration and professional judgement should be exercised and further confirmation testing by GC or LC Mass Spectrometry may be required. 'The performance characteristics of this test were determined by The ... Laboratory. It has not been cleared or approved by the U.S. Food and Drug Administration'. ... All Urine Confirmation patient reports (Mass Spec Reports) must have the following statement of each report: 'The performance characteristics of this

	test were determined by The ... Laboratory. It has not been cleared or approved by the U.S. Food and Drug Administration'. ..." Review of a random patient test report (accession #142632) revealed the test report did not include the required statements indicated in the laboratory's policy. During interview at approximately 3:20 p.m., the TS confirmed the statements were not included on the patient test report. She stated it was supposed to be there and she was unsure when the test report changed.