Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 49D0230376	**(X3) Date Survey Completed** 04/17/2019
Name of Provider or Supplier Pediatric Center, Pc	**Street Address, City, State** 901 Enterprise Pkwy - Suite 200, Hampton, VA	
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**
D0000	An announced CLIA recertification survey was conducted at Pediatric Center, PC on April 17, 2019 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on a review of Casper Report 155, proficiency testing (PT) records and interviews, the laboratory failed to enroll in a hematology PT module for Complete Blood Count (CBC) in calendar year 2017. **REPEAT DEFICIENCY Findings include: 1. During a pre-survey review of the laboratory's CLIA Casper Report 155 revealed one (1) hematology event was reported for CBC testing (Cell ID, Hematocrit, Hemoglobin, White Blood Cell, Platelet) in calendar year 2017. The inspector noted scores were available for 2017 Event 2. No scores were reported for inclusion for 2017 Event 1 or 2017 Event 3. 2. Review of the laboratory's retained 2017 PT results revealed American Proficiency Institute (API) scores for Event 2. The inspector called API customer support to inquire about 2017's Event 1 and 3 at approximately 1:30 PM. The API technical specialist stated, "Our records indicate that the laboratory did not enroll for 2017. The notes in our system indicate that the lab called us and

	requested that we send only Event 2 because they were enrolling with American Academy of Family Physicians (AAFP) for 2017". The inspector inquired regarding the laboratory's protocol for PT enrollment in an interview at approximately 3:00 PM, the primary testing personnel stated, "We tried to enroll with AAFP in 2017 but we never received the samples. I did call AAFP and they told us we would receive the samples but we never did. I called API to order the 2nd event when I noticed we had not run PT. The lab director told us to go back to API for 2018'. 3. In an exit interview with the primary testing personnel, at approximately 4:00 PM, the above findings were confirmed.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records and interviews, the laboratory failed to evaluate hematology PT scores of zero (0%) due to non participation on one (1) of four (4) events in the twenty-four (24) months reviewed. Findings include: 1. Review of the laboratory's 2017 and 2018 American Proficiency Institute (API) hematology PT documentation, a total of 4 events, revealed no evaluation or verification of accuracy for: 2018 Event 3: Hematology Score 0% (Cell ID 0%, Hematocrit 0%, Hemoglobin 0%, WBC 0%, Platelets 0%). The inspector requested to review evaluation documentation for the event listed above. No additional documentation was available for review. The primary testing personnel stated, "We sent our results in late because our instrument was down and we failed to report that to API. We ran the samples late and I looked at the results to see if we got the correct results but I did not document it and the lab director did not evaluate it either". 2. In an interview with the primary testing personnel, at approximately 4:00 PM, the above findings were confirmed.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) 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. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a review of procedures and interviews, the laboratory did not have a written policy of the reference (normal) ranges or a protocol for panic (critical) values for Complete Blood Count (CBC) patient results analyzed on the Drucker QBC hematology instrument. Findings include: 1. Review of the laboratory procedure manual revealed a QBC CBC procedure that did not include established reference or critical value ranges. No documentation or notation of the established panic values were revealed elsewhere in the quality assurance procedure manual. 2. During a laboratory tour at approximately 2:00 PM, the inspector asked the primary testing personnel to outline the laboratory's protocol for CBC critical values reported on the QBC analyzer. The testing personnel stated, "Critical values are not included in our policies but I can meet with the Lab Director and add that to our procedure manual." 3. In an interview with the primary testing personnel, at approximately 4:00 PM, the above findings were confirmed.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of policies and procedures, hematology quality control (QC) records, and an interview, the laboratory failed to follow their policy for monthly hematology QC statistics review in order to monitor, assess and correct problems with QBC Complete Blood Count (CBC) analyzer for twenty-four (24) of 24 months reviewed. Findings include: 1. Review of the laboratory's procedure manual revealed a quality assurance (QA) plan to monitor, assess and correct problems with the QBC Hematology analyzer. The policy stated, "Daily controls should be plotted on the QC log. QBC controls should be recorded for each parameter as indicated by the package insert sheet. Monthly standard deviations will be reviewed". 2. Review of the laboratory's QC records revealed no monthly statistical results (review timeframe: March 2017 to March 2019). The inspector requested to review the monthly statistical QC review. No records were available. 3. In an interview with the primary testing personnel, at approximately 4:00 PM, the above findings were confirmed.
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 a review of proficiency testing (PT) records and an interview, the laboratory director (LD) failed to document review of Complete Blood Count performance on hematology PT testing for one (1) of four (4) events during the twenty-four (24) months reviewed. Findings include: 1. Review of the laboratory's American Proficiency Institute (API) hematology PT records (a total of four events) revealed the following: 2018 Event 3 - No documentation of review of results scored for Cell ID 0%, Hematocrit 0%, Hemoglobin 0%, WBC 0%, and Platelets 0%. 2. In an interview with the primary testing personnel, at approximately 4:00 PM, the above findings were confirmed.
D6049	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: Based on a review of Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, and an interview, the technical consultant (TC) failed to document annual competency assessments that included review of intermediate test results or worksheets, quality control (QC) records, and preventative maintenance records for primary testing personnel A in 2017 and 2018. Findings include: 1. Review of the CMS 209 revealed that the lab director (LD) performs the duties of TC and there were two (2) testing personnel. 2. Review of the 2017 and 2018 laboratory personnel files revealed TP A's QBC Complete Blood Count (CBC) and Microbiology competency assessments lacked the competency procedures of review of intermediate test results or worksheets, QC records, and preventative maintenance records. The inspector requested to review additional competency documentation. The primary testing personnel stated, "our competency check sheet only includes direct observation of patient testing". (See Personnel Code Sheet.) 3. In an interview with the primary testing personnel, at approximately 4:00 PM, the above findings were confirmed.
D6052	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(vi) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills. This STANDARD is not met as evidenced by: Based on a review of Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, and an interview, the technical consultant (TC) failed to document annual competency assessments that included evaluation of problem solving skills for primary testing personnel A in 2017 and 2018. Findings include: 1. Review of the CMS 209 revealed that the lab director (LD) performs the duties of TC and there were two (2) testing personnel. 2. Review of

	the 2017 and 2018 laboratory personnel files revealed TP A's QBC Complete Blood Count (CBC) and Microbiology competency assessments lacked the competency procedures of problem solving skills. The inspector requested to review additional competency documentation. The primary testing personnel stated, "our competency check sheet only includes direct observation of patient testing". (See Personnel Code Sheet.) 3. In an interview with the primary testing personnel, at approximately 4:00 PM, the above findings were confirmed.