Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 49D0229237	**(X3) Date Survey Completed** 05/08/2019
Name of Provider or Supplier Pediatrics Of Kempsville Pc	**Street Address, City, State** 1212 Lake James Dr - Suite C, Virginia Beach, 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 Pediatrics of Kempsville PC on May 8, 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:
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 non-graded hematology PT analyte results on four (4) of six (6) events reviewed from calendar year 2017 to the date of the survey on May 8, 2019. Findings include: 1. Review of the laboratory's American Proficiency Institute (API) PT documentation, a total of six (6) events, revealed no evaluation or verification of accuracy for the non-graded responses due to no consensus for: 2018 1st Event- White Blood Count (WBC) QBC 09 not graded; 2018 2nd Event- White Blood Count (WBC) QBC 02 not graded; Platelet Count (PLT) QBC 04 and 05 not graded; 2018 3rd Event- White Blood Count (WBC) QBC 11 and 15 not graded; 2019 1st Event- White Blood Count (WBC) QBC 02 and 05 not graded; Platelet Count (PLT) QBC 04 not graded. The inspector requested to review evaluation documentation for the non graded challenges outlined above. No additional documentation was available for review. 2. In an exit interview with the lead testing personnel at approximately 3:00 PM, the above findings were confirmed.

D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on a laboratory tour, review of Drucker Diagnostic's manufacturer's user guide and operations manual for QBC hematology analyzer, daily temperature and instrument maintenance logs, and interviews, the laboratory failed to follow the manufacturer's instructions to monitor room temperature to ensure proper functioning of the hematology analyzer and failed to document two (2) required maintenance procedures for the twenty-two (22) months reviewed (June 2017 to April 2019). Cross Reference D5413 (a repeat deficiency) and D5429.
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 a tour, review of manufacturer's user guide for QBC hematology analyzer, daily temperature logs, and interviews, the laboratory failed to follow manufacturer's instructions to monitor room temperature for acceptable range to ensure proper functioning of the hematology analyzer. **REPEAT DEFICIENCY Findings include: 1. During a tour at approximately 1 PM, the inspector noted a certified thermometer and temperature logs in use for monitoring the laboratory's reagent refrigerator. The inspector inquired if the laboratory monitored the room temperature and the testing personnel stated "No, we do not record the room temperature of the lab area". 2. Review of the Drucker Diagnostic QBC manufacturer's users manual revealed a quality control (QC) policy guideline that stated: "The QBC System operates optimally at an ambient room temperature (68 to 90 degrees Fahrenheit or 20 to 32 degrees Celsius). End users must record the ambient temperature of the laboratory. Record the temperatures on a temperature chart. Sample temperature charts are located in Section 12 of our CLIA Compliance User's Manual". 3. Review of the available daily temperature logs from June 2017 up to the date of survey revealed no documentation of the laboratory room temperature. The inspector requested to review the laboratory room temperature logs. No documentation was available for review. 4. In an exit interview with the lead testing personnel at approximately 3:00 PM, the above findings were confirmed.

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: A. Based on a review of manufacturer's user guide, centrifuge service manual, hematology instrument maintenance logs, and an interview, the laboratory failed to document required semi-annual centrifuge revolutions per minute (RPM)calibration during the twenty-two (22) months reviewed (June 2017 to April 2019). Findings include: 1. Review of the laboratory's Drucker Diagnostic's QBC Autoread Plus manufacturer's user's guide maintenance section revealed the following statement: QBC Centrifuge Unit RPM Check- "The rotor of the QBC centrifuge is designed to spin at 12,000 +/- 80 rpm. At least every 6 months or after any adjustments or repairs, check the rotor speed with a non-contact strobe calibrated tachometer to assure that the speed is sufficient to meet the required speed for the QBC procedure". 2. Review of the manufacturer's QBC analyzer's centrifuge service manual revealed QBC Check logs that listed the required task as "perform RPM check every six months". 3. Review of the laboratory's available recorded instrument maintenance logs from 6/13 /17 to 4/30/19 revealed no documentation that the laboratory performed the RPM maintenance check procedure outlined above. 4. In an exit interview with the lead testing personnel at approximately 3:00 PM the above findings were confirmed. B. Based on a review of manufacturer's user guide, hematology instrument maintenance logs, and an interview, the laboratory failed to document every three (3) month required centrifuge timer check maintenance during the twenty-two (22) months reviewed (June 2017 to April 2019). 1. Review of the laboratory's Drucker Diagnostic's QBC Autoread Plus manufacturer's user's guide revealed the following statement: QBC Centrifuge Timer Check- "The electronic timer of the centrifuge is designed to be accurate to 300 +/- 15 seconds. Check the timer for accuracy against a quartz timer or calibrated stopwatch at least every 3 months."QBC Centrifuge Timer Check- "The electronic timer of the centrifuge is designed to be accurate to 300 +/- 15 seconds. Check the timer for accuracy against a quartz timer or calibrated stopwatch at least every 3 months." 2. Review of the laboratory's available recorded instrument maintenance logs from 6/13/17 to 4/30/19 revealed no documentation that the laboratory performed the centrifuge timer maintenance check procedure as outlined above. 3. In an exit interview with the lead testing personnel at approximately 3:00 PM the above findings were confirmed.