Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0228956	02/19/2020
Name of Provider or Supplier	**Street Address, City, State**	
Tidewater Family Practice Pc	4660a Haygood Road, 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 Tidewater Family Practice on February 18-19, 2020 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:
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 review of policies and procedures, manufacturer's operations manual, instrument maintenance records, quality control, patient test reports, lack of documentation, and interviews, the laboratory failed to: 1. document performance of required hematology analyzer maintenance twice annually in calendar year 2019 (see D5429); 2. document two levels of acceptable chemistry QC on 12/6/18 and 12/11/18 with fifteen (15) patients reported (see D5447 **REPEAT DEFICIENCY).
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 a review of policies and procedures, manufacturer's operations manual, instrument maintenance records, lack of documentation, and an interview, the laboratory failed to document performance of required Abbott Emerald hematology analyzer maintenance twice in calendar year 2019. Findings include: 1. Review of the laboratory's procedure manual revealed a maintenance log that detailed Lubricating Syringe Pistons semi annually. 2. Review of the Abbott Emerald Operations Manual revealed manufacturer's instructions to "perform Lubricating Syringe Pistons maintenance procedure twice annually". 3. Review of the laboratory's Emerald hematology maintenance logs from April 2018 through January 2020, revealed that the semiannual piston syringe lubrication maintenance was recorded as performed once in calendar year 2019 (on 08/01/19). The inspector requested to review additional documentation of the piston syringe maintenance in calendar year 2019. No other records were available. The primary testing personnel stated on 2/19/20 at approximately 11:00 AM: "I do not have any other documentation about the maintenance. It appears that it was missed." 4. In an exit interview with the technical consultant and primary testing personnel on 2/19/20 at approximately 1:30 PM the above findings were confirmed.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the policies and procedures, Quality Control (QC) records, patient test reports and interviews, the laboratory failed to document two levels of acceptable Total Cholesterol QC on 12/06/18 and 12/11/18 with fifteen (15) patients reported . **REPEAT DEFICIENCY Findings include: 1. Review of the laboratory's policies and procedures revealed a QC policy that stated that QC is verified each day of patient testing. 2. Review of the laboratory's Total Cholesterol QC records (Abbott Architect analyzer) and LabDaq Laboratory Information System (LIS) patient logs for December 2018 revealed that the laboratory failed to document two levels of acceptable QC for the following dates and patient identification numbers tested: 12/06 /18 -54838, 54844, 54845, 54846, 54847, 54850, 12/11/18- 54885, 54886, 54887, 54888, 54889, 54890, 54891, 54892, 54893, for a total of two (2) days with 15 patients reported. The technical consultant (TC) stated on 2/18/20 at approximately 4: 30 PM, that the QC issue had been discussed in a quality assurance review but that it had not been noted that patients had been reported prior to corrective action on the dates outlined above. 3. An exit interview with the TC and primary testing personnel on 2/19/20 at approximately 1:30 PM, the above findings were confirmed.