Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0977679	02/05/2020
Name of Provider or Supplier	**Street Address, City, State**	
A Tidewater Womens Health Clinic	891 Norfolk Square, Norfolk, 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 A Tidewater Women's Health Clinic on February 5, 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:
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a review of policies and procedures, personnel records, patient test logs, quality assurance (QA) records, Centers for Medicare and Medicaid Services Laboratory Personnel Report form, lack of documentation, and interviews on the date of the survey 2/5/20, the laboratory director (LD) failed to: 1. ensure that the laboratory's QA policies were maintained during the twenty (20) months reviewed (See D6021 *REPEAT DEFICIENCY); 2. document annual competency assessments for immunohematology blood grouping (Rh) testing for two (2) of 2 testing personnel (TP) in calendar years 2018 and 2019 (See D6046 * REPEAT DEFICIENCY).
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and

	maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: **REPEAT DEFICIENCY** Based on a review of policies and procedures, personnel records, patient test logs, quality assurance (QA) records, and an interview, the laboratory director (LD) failed to ensure that the QA policies were maintained during the twenty (20) months reviewed. Findings include: 1. Review of the laboratory's policy and procedure manual revealed a written and approved QA policy that included a quarterly check list and monitors for compliance to be performed by the LD. The QA plan and check list included a Personnel Section that stated "All personnel who perform testing have documented training for the tests and have read the protocol and procedures for the tests. Personnel evaluations are performed annually." 2. Review of the testing personnel records revealed no annual competency assessments for two (2) of 2 testing personnel in calendar years 2018 and 2019. (See D6046.) 3. Review of the laboratory's available quarterly QA documentation from June 2018 through the date of the survey on 2/5/20 revealed no documentation of corrective actions for the missing personnel competency check lists. 4. In an exit interview with the laboratory manager at approximately 1:30 PM on 2/5/20, the above findings were confirmed
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: **REPEAT DEFICIENCY** Based on a review of Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, lack of documentation, and interviews, the technical consultant failed to document annual competency assessments for immunohematology blood grouping (Rh) testing for two (2) of 2 testing personnel (TP) in calendar years 2018 and 2019. Findings include: 1. Review of the CMS 209 form revealed that the Laboratory Director (LD) served as the Technical Consultant (TC) and identified TP A and TP B as qualified to perform Rh immunohematology patient testing for the twenty (20) months reviewed (timeframe June 2018 to 2/5/20). See attached Personnel Code Sheet. 2. Review of the laboratory personnel files revealed no competency assessments for patient Rh immunohematology testing in calendar years 2018 and 2019 for TP A and TP B. The inspector requested to review the competency documentation. The documentation was not available for review. The laboratory manager stated at approximately 1:00 PM on 2/5/20: "We have competency assessments that were completed on 1/2/20 for you to review, but I do not have the records for 2018 and 2019". 3. In an exit interview with the laboratory manager at approximately 1:30 PM on 1/2/20 the above findings were confirmed.