Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0977679	06/06/2018
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 June 6, 2018 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:
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of policies and procedures, a facility tour, patient test logs, and an interview, the laboratory director (LD) failed to document approval and review of the laboratory's modifications of the written procedure for patient Rh blood typing. Findings include: 1. Review of the laboratory's policy and procedure manual revealed a procedure for Rh Blood Slide Test Typing that was approved by the LD on 6/2/14. The procedure stated in step number nine (9) and ten (10) "If no agglutination occurs initially, incubate the test for five minutes at 18-24 degrees Celsius. After incubation, immediately observe for agglutination. If the slide is smooth after that time, no agglutination, the result is negative and the patient is Rh negative. Record all results into the daily log and patient's chart". 2. During a tour of the facility, the inspector made an inquiry of where and what timing device is used when the testing personnel perform the incubation step for negative results of the Rho Blood Slide Test Typing. The primary testing personnel stated, "We do not perform the five minute incubation step. I was not trained to do that step." 3. Review of the laboratory's patient log documentation from July 2016 to the date of the survey on 6/6/18, a total of twenty-four (24) months, revealed no evidence of the laboratory performing the additional incubation step per the written protocol for negative results. The inspector requested to review documentation of the incubation step. No documentation was available for

	review. 4. In an interview with the primary testing personnel at approximately 4:30 PM on 6/6/18, it was confirmed that the laboratory failed to follow the established policy for Rh Blood Slide Test Typing and that the LD failed to document approval and review of the laboratory's modifications of the written procedure for patient Rh blood typing during the twenty-four (24) months reviewed.
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, patient test logs, quality assurance (QA) records, and an interview, the laboratory failed to ensure that the quality assurance (QA) policies were maintained during the twenty-four (24) 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 Policies section that stated: "All personnel who perform tests have documented training for the tests and understand the protocol and procedures for the tests". The QA plan included a Compliance Monitor section that stated "Explanation of any "no" responses to the QA plan or corrective actions should be attached to the quarterly QA form on a separate sheet of paper". 2. Review of the policies and procedures revealed a procedural protocol for Rh Blood Slide Test Typing that included an incubation step outlined for an initial negative Rh blood typing test. Review of the patient test logs from July 2016 to the date of the survey on 6/6/18, revealed no documentation of the incubation results for twenty-four (24) of twenty-four (24) months reviewed. (Cross Reference D 5407.) 3. Review of the laboratory's available quarterly QA documentation from July 2016 to June 2018 revealed no documentation of corrective actions for the procedure modification of the Rh Blood Slide Test Typing as outlined above. 4. In an interview with the primary testing personnel at approximately 4:30 PM, it was confirmed that the laboratory failed to ensure that the QA policies were documented and maintained during the twenty-four (24) months reviewed.
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: 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 quality assurance (QA) policies were maintained during the twenty-four (24) 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 Policies section that stated "All personnel who perform tests have documented training for the tests and have read the protocol and procedures for the tests. Personnel evaluations are performed as necessary." 2. Review of the testing personnel records revealed no annual competency assessments for five (5) of five (5) testing personnel in calendar years 2016 and 2017. (Cross Reference D 6046.) 3. Review of the laboratory's available quarterly QA documentation from July 2016 through the date of the survey on 6/6/18 revealed no documentation of corrective actions for the missing personnel competency check lists. 4. In an interview with the primary testing personnel at approximately 4:30 PM on 6/6 /18, it was confirmed that the laboratory director failed to ensure QA policies which include competency assessments were maintained during the twenty-four (24) months reviewed.
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: Based on a review of Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, and an interview, the laboratory failed to document annual competency assessments for immunohematology blood grouping (Rh) testing for five (5) of five (5) testing personnel in 2016 and 2017. Findings include: 1. Review of the CMS 209 form revealed five (5) testing personnel and that the Laboratory Director (LD) serves as the Technical Consultant (TC). 2. Review of the laboratory personnel files revealed no immunohematology blood grouping (Rh) patient testing competency assessments in calendar years 2016 and 2017 for: Testing personnel A, Testing personnel B, Testing personnel C, Testing personnel D, Testing personnel E. The inspector requested to review the competency documentation. The documentation was not available for review. (See Personnel Code Sheet.) 3. In an interview with the primary testing personnel at approximately 4:30 PM on 6/6/18, it was confirmed that the TC failed to document the immunohematology competency assessments for the five (5) testing personnel outlined above in two (2) out of two (2) years reviewed.