Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0977679	06/08/2022
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 8, 2022 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:
D2159	ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on an review of proficiency testing (PT) records, lack of documentation, and an interview, the laboratory failed to submit immunohematology ABO and RHo (D) Typing PT results for two (2) of seven (7) events reviewed receiving unsatisfactory scores (review timeframe February 2020 to 6/8/22). Findings include: 1. Review of the laboratory's American Proficiency Institute (API) ABO and RHo (D) Typing PT Modules (2020 Events 1-3, 2021 Events 1-3, 2022 Event 1) revealed unsatisfactory scores for the following events: API 2020 Event 1: ABO/Rh Group = 0 % and D (Rho) Typing = 0%; API report noted "failed to participate; results not reported to API for five of five challenge samples resulting in score of zero"; API 2021 Event 1: ABO/Rh Group = 0% and D (Rho) Typing = 0%, API report noted "failed to participate; results not reported to API for five of five challenge samples resulting in score of zero". 2. The inspector inquired regarding corrective action for the two events outlined above. The lead testing personnel stated on 6/8/22 at approximately 11:30 AM, "We did not submit and received the zero scores from API in both 2020 and 2021. We had a situation for one of the events that the results were not transmitted to API when they were entered and the other one we never submitted because we got all negatives and were not sure the test was working". The inspector requested to review

	the self grading for the the two events. No documentation was available for review. 3. An exit interview with the lead testing personnel on 6/8/22 at approximately 12:00 PM confirmed the above findings.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report Form (CMS 209), microscopy proficiency testing (PT) records, and an interview, the laboratory failed to verify the accuracy of vaginal Wet Prep Potassium Hydroxide (KOH) testing twice annually in calendar year 2020. Findings include: 1. Review of the laboratory's CMS 209 personnel form revealed that one (1) testing personnel was identified as performed patient vaginal Wet Prep KOH microscopy examination during the twenty-seven months reviewed (March 2020 to 6/8 /22). See Testing Personnel Code Sheet. 2. Review of the laboratory's American Proficiency Institute (API) microscopy PT documentation (2020 Events 1-2, 2021 Events 1-2, 2022 Event 1) a total of five (5) events, revealed the laboratory utilizes PT to verify personnel microscopy accuracy. The inspector noted that one of the two 2020 API microscopy reports revealed unsatisfactory scores: 2020 Event 2 - Microscopy Module scored 0 %; two (2) of 2 challenge samples both scored as 0% (API noted "failure to participate"). The inspector inquired regarding the unsatisfactory scores outlined above. No additional accuracy checks were available for review for calendar year 2020. 3. An exit interview with the lead testing personnel on 6/8/22 at approximately 12:00 PM confirmed the above findings.
D6017	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(ii) 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)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records, Centers for Medicare and Medicaid Services Laboratory Personnel Report Form (CMS 209), lack of documentation, and interviews, the laboratory director failed to ensure: 1. Immunohematology (ABO and RHo D Typing module) results for two of seven PT events were submitted timely for scoring by American Proficiency Institute (API) during the twenty-seven months reviewed - Cross Reference D2159; 2. Vaginal Wet Prep Potassium Hydroxide (KOH) test results were submitted to API within the grading deadline for one of two PT events in calendar year 2020 - Cross Reference D5217.
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) results and an interview, the laboratory director (LD) failed to document review of the laboratory's performance in immunohematology PT for two (2) of seven (7) events reviewed. Findings include: 1. Review of the laboratory's American Proficiency Institute (API) ABO and RHo (D) Typing PT records revealed no documentation of self grading for unsatisfactory scores 0% on the following 2 events: 2020 Event 1 - RH-01, RH-02, RH-03, RH-04, RH-05 all scored as 0% 2021 Event 1 - RH-01, RH-02, RH-03, RH-04, RH-05 all scored as 0% The inspector noted that the reports outlined above included LD comments regarding a failure to submit the PT events but failed to include a review of the ten challenge samples to self evaluate the laboratory's performance. 2. An exit interview with the lead testing personnel on 6/8/22 at approximately 12:00 PM confirmed the above findings.