Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0228956	05/04/2022
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 May 4, 2022 by the Virginia Department of Health's Office of Licensure and Certification. The inspector noted that the laboratory performs SARS-CoV-2 (COVID-19) testing and is in compliance with the applicable COVID-19 reporting requirements. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
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), proficiency testing (PT) / accuracy verification records, lack of documentation, and an interview, the laboratory failed to verify the accuracy of Potassium Hydroxide (KOH) Wet Prep microscopy testing twice annually during the twenty-five (25) months reviewed (March 2020 to the date of the survey, May 4, 2022). Findings include: 1. Review of the laboratory's CMS 209 personnel form revealed that one (1) testing personnel (TP A) was identified by the lab director (LD) as responsible for performing patient KOH microscopy examinations during the review timeframe of March 2020 to 05/04/22. (See Testing Personnel Code Sheet.) 2. Review of the laboratory's American Proficiency Institute (API) PT documentation, a total of seven (7) events, revealed no KOH Wet Prep microscopy module results. The inspector requested to review twice annual accuracy verification for KOH Wet Prep in calendar years 2020 and 2021. No documentation was available for review. The technical consultant (TC) stated at approximately 12:30 PM, "I was not aware that the procedure was not being evaluated twice annually for accuracy but we will correct this as soon as possible. I plan to notify API to add it to our enrollment." 3. An exit

	interview with the LD, TC, office manager, and lead testing personnel on 05/04/22 at approximately 1 PM confirmed the above findings.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a tour, review of procedure manual, lack of documentation, and interviews, the laboratory did not have a written policy for Potassium Hydroxide (KOH) Wet Prep procedure while conducting the patient microscopy testing during the twenty-five (25) months reviewed (March 2020 to the date of the survey, May 4, 2022). Findings include: 1. During a laboratory tour, on 05/04/22 at approximately 10:30 AM, the inspector noted an Accuscope 3004 microscope and KOH reagents in use for KOH Wet Prep microscopy examination. 2. Review of the laboratory procedure manual revealed no KOH Wet Prep procedure. The laboratory inspector requested to review a laboratory director (LD) approved microscopy procedure. No document was available for review. The technical consultant (TC) stated at approximately 12:30 PM, "I was not aware that the procedure was not in the manual. I will get with the director and add it as soon as possible". 3. An exit interview with the LD, TC, office manager, and lead testing personnel on 05/04/22 at approximately 1 PM confirmed the above findings.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. 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), laboratory testing personnel (TP) files, procedures, lack of documentation, and interviews, the technical consultant (TC)

	failed to document Potassium Hydroxide (KOH) Wet Prep competency evaluation for TP A in calendar years 2020 and 2021. (See Testing Personnel Code Sheet.) Findings include: 1. Review of the laboratory's CMS 209 personnel form revealed that one (1) testing personnel (TP A) was identified by the lab director (LD) as responsible for performing patient KOH microscopy examinations during the review timeframe of March 2020 to 05/04/22. 2. Review of the available laboratory personnel files revealed no annual KOH Wet Prep competency evaluations for TP A. The inspector requested to review the competency assessments for calendar year 2020 and 2021. No documentation was available for review. 3. Review of the laboratory procedure manual revealed quality assurance protocols that outlined annual competency assessments to be completed annually by the LD or the LD's designated TC for all testing personnel. 4. An exit interview with the LD, TC, office manager, and lead testing personnel on 05/04/22 at approximately 1 PM confirmed the above findings.