Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0228956	02/07/2024
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 7, 2024 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 and includes the Condition under 42 CFR part 493 CLIA Regulation: D6033 -42 CFR. 493.1409 Technical Consultant Moderate Complexity.
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on tour observation, review of procedures, lack of documentation, and interviews, the laboratory failed to follow their protocol for laboratory eye wash safety /maintenance for twenty-one (21) of 21 months reviewed (May 2022 to the time of the survey on February 7, 2024). Findings include: 1. During a tour of the laboratory on 2 /7/24 at 10:00 AM, the inspector noted no eye wash in view. 2. Review of the laboratory's procedures revealed a protocol titled "General Laboratory Safety Program" with subheading "Eye Wash Safety and Maintenance" that stated: "The eyewash station must be properly labeled and capable of flushing both eyes for a minimum of 15 minutes with cool or tepid water. All testing personnel must know the location of the eyewash station and trained in its use and maintenance. A saline solution bottle is not an appropriate method and cannot be used in place of an eyewash station being installed." 3. The inspector inquired regarding the observed lack of eye wash in the laboratory with records of eye wash maintenance documentation per the protocol outlined above. The primary testing personnel stated on 2/7/24 at 11:00 AM: "We have bottled saline eye wash that is stored in the next

	room". The inspector was guided to an adjacent room and noted one four (4) ounce bottle of Bausch + Lomb Eye Relief Wash (Lot Number 6319814 ingredients- Purified Water, Boric Acid, and Sodium Chloride) stored inside an upper cabinet. The inspector noted that the eye irrigating solution had an expiration date of February 2020 (4 years expired). 4. An interview with the primary testing personnel and office manager on 2/7/24 at 12:30 PM confirmed the above findings
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services (CMS) CLIA Laboratory Certification form, Food and Drug Administration's Emergency Use Authorizations extension, manufacturer's instructions for use, tour, package insert instructions, patient/quality control (QC) logs, lack of documentation, procedures, CMS Laboratory Personnel Report form, laboratory personnel files, and interviews, the Technical Consultant failed to: 1. ensure acceptable real-time PCR QC for SARS-CoV-2, Influenza A, Influenza B, and Respiratory Syncytial Virus testing was verified /documented for twenty-three of twenty-five Cepheid reagent cartridge lot numbers during the timeframe of May 2022 through December 2023. Cross Reference D6042. 2. to document Abbott Emerald hematology competency assessments for nine of ten testing personnel in calendar year 2023 per established procedure. Cross Reference D6046.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services CLIA Laboratory Certification form (CMS 116), Food and Drug Administration's (FDA) Emergency Use Authorizations (EUA) extension, manufacturer's instructions for use (IFU), tour, package insert instructions, patient/quality control (QC) logs, lack of documentation, procedures review, and interview, the Technical Consultant (TC) failed to ensure that the laboratory documented acceptable negative and positive QC for SARS-CoV-2 (COVID), Influenza A (FLU A), Influenza B (FLU B), and Respiratory Syncytial Virus (RSV) real-time RT PCR testing for twenty-three (23) of twenty-five (25) Cepheid reagent cartridge lot numbers while four hundred eighty-five (485) patient panels were reported from May 2022 to December 31, 2023. Findings include: 1. Review of the laboratory's CMS 116 form revealed that the laboratory director (LD) identified COVID, FLU A, FLU B, and RSV patient testing utilizing RT PCR reagent cartridges by Cepheid for the GeneXpert Xpress System for the timeframe of May

	2022 to the date of the inspection, 2/7/24. 2. Review of the FDA's EUA extension (dated 07/18/23) for Cepheid GeneXpert Xpress SARS-CoV-2/Flu/RSV Plus testing revealed IFU External Controls Instructions as: "Testing with the Xpert Xpress SARS-CoV-2/Flu/RSV Plus test is intended for use by trained operators who are proficient in performing tests using either GeneXpert Dx, GeneXpert Infinity and/or GeneXpert Xpress systems. External controls should be used in accordance with local, state, and federal accrediting organizations as applicable and following package instructions". 3. During a tour of the laboratory on 02/7/24 at 10:00 AM the inspector noted one (1) Cepheid GeneXpert Xpress analyzer (Serial Number 1100085555) in use for real-time RT-PCR testing with SARS-CoV-2/Flu/RSV Plus Cartridges. 4. Review of the laboratory's procedures revealed the Cepheid GeneXpert Xpress SARS-CoV-2/Flu /RSV Plus package insert that stated: "External controls are to be tested at the frequency noted below: a. Each time a new lot of Xpert Xpress CoV-2/Flu/RSV plus kits is received; b. Each time a new shipment of Xpert Xpress CoV-2/Flu/RSV plus kits is received even if it is the same lot previously received; c. Each time a new operator is performing the test (i.e., operator who has not performed the test recently); d. When problems (storage, operator, instrument, or other) are suspected or identified; e. If otherwise more frequently required by your institution's standard Quality Control (QC) procedures." 5. Review of the Cepheid analyzer's onboard patient and QC logs from 5/5/22 to 2/7/24 revealed acceptable SARS CoV-2 Positive QC (Target RNA detected), SARS CoV-2 Negative QC (Target RNA not detected), FLU A Positive QC (Target RNA detected), FLU A Negative QC (Target RNA not detected), FLU B Positive QC (Target RNA detected), FLU B Negative QC (Target RNA not detected), RSV Positive QC (Target RNA detected), RSV Negative QC (Target RNA not detected) results for two lot numbers: 09616 on 09/02/22 and 47203 on 02/02/24. The inspector noted there were no positive/negative target RNA controls verified/assayed for the following lot numbers utilized for reporting patient results: 05/05/22 to 12/31 /22: 21222, 09324, 08307, 06717, 07912, 07824, 05924 while reporting one hundred ninety one (191) patient panels; 01/02/23 to 12/31/23: 42304, 16707, 29509, 16404, 29302, 16204, 15908, 26809, 24916, 15501, 26809, 22506, 14206, 21210, 13513, 21222 while reporting two hundred ninety-four (294) patient panels; A total of 23 lot numbers were utilized for reporting 485 patient panels while not following manufacturer's QC guidelines. 6. The inspector requested to review additional QC records for the timeframe outlined above. No additional documentation was available for review. The inspector requested to review an approved Individualized Quality Control Plan (IQCP). No documentation was available for review. 7. Review of the laboratory's procedures revealed the following protocol: Technical Consultant Duties included statement: "The Technical Consultant is responsible for technical and scientific oversight including establishing a quality control program appropriate for the testing performed." 8. An interview with the primary TP and office manager on 2/7 /24 at 12:30 PM confirmed the above findings.
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, procedures, lack of

	documentation, and interviews, the technical consultant (TC) failed to document an evaluation of Abbott Emerald hematology competency assessments for nine (9) of ten (10) testing personnel (TP) in calendar year 2023 per established procedure. Findings include: 1. Review of the CMS 209 personnel form revealed that the laboratory director (LD) identified Personnel A as qualified/responsible to perform the duties of TC and 10 TP (TP # 1-10) as qualified/responsible for moderate complexity hematology testing utilizing Abbott Emerald instrument. (See Personnel Code Sheet.) 2. Review of the available personnel records revealed: Competency assessments for TP #1 were completed by the TC (Personnel A) in calendar years 2022 and 2023; Competency assessments for TP #2 - #10 were completed by TP #1. The inspector noted that TP #1 did not meet the qualification requirement to perform TC duties. 3. Review of the laboratory's procedures revealed the following two protocols: Technical Consultant Competency Form the LD outlined and identified Personnel A as TC and included statement: "The Technical Consultant is responsible for evaluating the competency of all testing personnel on an ongoing basis and evaluates and documents testing personnel's performance at six months and twelve months during the first year of employment and yearly thereafter." Staff Orientation -Training and Competency stated: "The Technical Consultant (TC) for moderate complexity testing is responsible for performing and documenting competency assessments. Peer testing personnel who do not meet the regulatory qualifications of a TC cannot be designated to perform competency assessments." The inspector inquired regarding the delegation of competency assessments for TP #2 - #10 to TP #1. The TC stated on 2/7/24 at approximately 11:30 AM, "I do come on site periodically but did not perform the competency assessments as noted. I did perform the assessment for the primary tech in the previous year. I can work with the staff to be directly involved going forward in the hematology competency assessments of all the TP." 4. An interview with the primary TP (TP #1) and office manager on 2/7/24 at 12:30 PM confirmed the above findings.