Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2140324	04/28/2022
Name of Provider or Supplier	**Street Address, City, State**	
Arlington County Fire Department	1020 North Hudson St, Arlington, 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 off-site CLIA recertification survey was conducted for Arlington County Fire Department on April 28, 2022 by the Virginia Department of Health's Office of Licensure and Certification. The survey included an entrance interview on April 7, 2022 and virtual record review conducted on April 27, 2022. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiencies are as follows:
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records, lack of documentation, and interviews, the laboratory failed to maintain PT documents for six (6) of 6 PT events in the twenty-five (25) months reviewed (April 2020 to April 28, 2022). Findings include: 1. Review of the laboratory's 2020, 2021 and 2022 American Proficiency Institute (API) Chemistry Core PT documentation, a total of 6 events (2020 Events 2 & 3, 2021 Events 1-3, 2022 Event 1), revealed the following: API Chemistry Core 2020 Events 2 & 3-lack of attestation signature by testing personnel and laboratory director, lack of chemistry result documents, and lack of PT evaluation documents;

	API Chemistry Core 2021 Events 1-lack of attestation signature by testing personnel and laboratory director, lack of chemistry result documents, and lack of PT evaluation documents; API Chemistry Core 2021 Events 2-lack of attestation signature by laboratory director, lack of PT evaluation documents, and lack of corrective action documents; API Chemistry Core 2021 Events 3-lack of attestation signature by laboratory director, and lack of PT evaluation documents; API Chemistry Core 2022 Event 1-lack of attestation signature by laboratory director, lack of PT evaluation documents, and lack of corrective action documents. The inspector requested to review the PT documentation for the Chemistry Core events listed above. The laboratory provided no documentation for for review. 2. In an exit interview with two Technical Consultants and Testing Personnel on April 28, 2022 at approximately 2:45 PM, the findings were confirmed.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: A. Based on a review of the laboratory's policies and procedures, quality control (QC) documentation, and interviews, the laboratory failed to follow their established policy for the every six month review of the ePOC Blood Analysis System QC from April 2020 until April 2022. Findings include: 1. Review of the laboratory's procedure manual revealed a policy, "Quality Assurance Manual", which stated, "Quality control Reagents Performed Monthly-Hematocrit A and C and Level 1 and 3 will be run monthly and as needed for new lot verification. Results will be recorded on the devices as well as in paper log and reviewed by Technical Consultant and by Laboratory Director every 6 months." 2. A review of monthly QC paper logs from April 2020 to April 2022 revealed a lack of documentation of the review of the monthly QC from April 2020 until April 2022. The inspector requested to review the documentation of the every 6 month QC review by the Laboratory Director and Technical Consultant from April 2020 until April 2022. The laboratory provided no documentation for review. 3. A review of patient reports from April 2020 to April 2022 revealed no patient specimens were analyzed using the ePOC Blood Analysis System from April 2020 to April 2022. On April 28, 2022 at approximately 2:00 PM, the inspector inquired with the Testing Personnel (TP) if any patients were tested from April 2020 to April 2022. The TP stated no patients were tested from April 2020 to April 2022. 4. In an exit interview with two Technical Consultants and TP on April 28, 2022 at approximately 2:45 PM, the findings were confirmed. B. Based on a review of the laboratory's calibration verification records for the ePoc Blood Analysis System, policies and procedures, lack of documentation and interviews, the laboratory failed to follow their established policy for the every six (6) month calibration verification and Laboratory Director review for ten (10) of 10 analytes during the twenty-four (24) months reviewed. Findings include: 1. Review of the laboratory's calibration verification records (timeframe of April 2020 to April 2022) for Sodium (Na), Potassium (K), Ionized Calcium (iCa), Glucose (Glu), Creatinine (Creat), Lactate (Lac), Hematocrit (HCT), Hydrogen Ion Concentration (pH), Carbon Dioxide Partial Pressure (pCO2), and Oxygen Partial Pressure (pO2) reported on the ePOC readers revealed a lack of documentation of calibration verification and Laboratory

	Director's review of calibration verification for the ePOC readers (BC126, unit 111, unit 112). The inspector requested to review documentation of calibration verification performed and LD's review in the timeframe of April 2020 to April 2022 for Na, K, iCa, Glu, Creat, Lac, HCT, ph, pCO2 and pO2 on the ePOCs. In an email received on May 1, 2022, the technical consultant (TC) stated "I know we did calibration verification...will look in the machines for the dates...They are all recorded in the machines." The laboratory provided no documentation for review. 2. Review of the laboratory's policies and procedures revealed a policy, "Quality Assurance Manual", with a statement, "Calibration Verification: Performed every 6 months-All 5 levels of Calibration Verification will be performed every 6 months or after software updates. Correlation with random patient samples will also be performed on these intervals and reviewed by the laboratory director." 3. A review of patient reports from April 2020 to April 2022 revealed no patient specimens were analyzed using the ePOC Blood Analysis System from April 2020 to April 2022. On April 28, 2022 at approximately 2:00 PM, the inspector inquired with the Testing Personnel (TP) if any patients were tested from April 2020 to April 2022. The TP stated no patients were tested from April 2020 to April 2022. 4. In an exit interview with two Technical Consultants and TP on April 28, 2022 at approximately 2:45 PM, the findings were confirmed.
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 the review of the laboratory's "Quality Assurance Manual", policies and procedures, quality control (QC) records, calibration verification records, patient records, and interviews, the laboratory failed to follow their established Quality Assurance (QA) plan and identify and address analytic issues within the specialties of diagnostic chemistry, and hematology (Cross Reference D 2015, and 5401 A and B) from April 2020 to April 2022. Findings include: 1. Review of the laboratory's "Quality Assessment (QA)", policies and procedures, instrument validation /verification records, quality control (QC) records, calibration verification records, patient records revealed the following analytic issues: -lack of documentation of the laboratory director's attestation, original proficiency testing documents, evaluation of proficiency testing results and corrective actions for unsatisfactory results (see D2015); -lack of documentation of the laboratory following their established policy for the review of the ePOC system's monthly QC by the Laboratory Director (LD) and Technical Consultant from April 2020 until April 2022(see D5401 A.); -lack of documentation of the laboratory following their established policy for the every six month calibration verification and LD's review of the ePOC readers calibration verification from April 2020 until April 2022(see D5401 B). 2. Review of the "Quality Assurance Manual", revealed the following statements "Technical Consultant is responsible for the monitoring of daily laboratory QA/QC activities as follows: -Ensure that staff is analyzing QC samples, following SOPs, and implementing and documenting corrective actions. -Logs are reviewed at least monthly. -Ensure that instrument logs and QC documents are maintained and are completed with the correct information. -Ensure that instruments are calibrated and proper calibration records are maintained.... -Quarterly review of QA/QC plan and

	documentation of any changes made based on trends noticed." 3. Review of available documentation revealed a lack of documentation of the monthly log review, and quarterly review of the QA/QC plan from April 2020 to April 2022. On April 28, 2022 at approximately 2:00 PM, the inspector requested to review documentation of the monthly log review and quarterly QA/QC plan from April 2020 to April 2022. The laboratory provided no documentation for review. 4. In an exit interview with two Technical Consultants and Testing Personnel on April 28, 2022 at approximately 2:45 PM, the findings were confirmed.