Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2140324	08/30/2018
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 CLIA initial survey was conducted at Virginia Hospital Center, Department of Pathology on August 30, 2018 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows: :
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the laboratory's policy and procedure manual, Individual Quality Control Plan (IQCP), quality control records, ePOC manufacturer's instructions, verification records of the ePOC Test System, temperature logs, patient test logs and interviews, the laboratory failed monitor and evaluate the analytic quality by: 1. failure to follow manufacturer's storage requirements for the BGEM Test Cards for sixty-one (61) of one hundred and seventeen (117) days (Cross Reference D5413), 2. failure to verify the performance specifications of the ePOC test system (serial numbers 19772, 20209 and 20208) in the environment where testing is performed (Cross Reference D5421), 3. failure to include on-site testing data for the ePOC test system in determining the frequency of quality control (Cross Reference D5445), 4. failure to document corrective actions taken when the ePOC BGEM Test Card storage temperatures were not within the manufacturer's storage requirements for sixty-one (61) of one hundred and seventeen (117) days (Cross Reference D5785), 5. failure to establish a written Quality Assessment policy (Cross Reference D5791).

D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, ePoc BGEM Test Card Specifications, temperature logs and an interview, the laboratory failed to follow manufacturer's storage requirements for the BGEM Test Cards for sixty-one (61) of one-hundred and seventeen (117) days reviewed from April 30, 2018 to August 29, 2018. Findings include: 1. Review of the laboratory's procedure manual revealed a procedure, "Point of Care Testing ePoc", which states: "Always store test cards at room temperature (15-30 C).". 2. Review of the BGEM Test Card Specifications revealed the item "12.2.1 Storage Stability" which states: "Test Cards must be stored in their Card Pouch at Room Temperature, 15-30 C (59-86 F) at all times." 3. Review of laboratory's ePOC storage case temperature logs revealed the temperature warmer than 30 degrees Celsius for the following number of days and dates: May 2018-14 days (5/1/18, 5/2/18, 5/3/18, 5/5/18, 5/8/18, 5/9/18, 5/17/18, 5/19/17, 5/23/18, 5/25 /18, 5/26/18, 5/27/18, 5/28/18, and 5/29/18); June 2018-12 days (6/1/18, 6/2/18, 6/6 /18, 6/8/18, 6/10/18, 6/14/18, 6/15/18, 6/20/18, 6/21/18,6/26/18, 6/27/18, and 6/28 /18); July 2018-17 days (7/2/18, 7/3/18, 7/4/18, 7/7/18, 7/10/18, 7/11/18, 7/12/18, 7/15 /18, 7/16/18, 7/18/18, 7/19/18, 7/21/18, 7/26/18, 7/27/18, 7/28/18, 7/29/18, and 7/30 /18); August 2018-18 days (8/1/18, 8/2/18, 8/5/18, 8/6/18, 8/7/18, 8/8/18, 8/9/18, 8/10 /18, 8/11/18, 8/12/18, 8/14/18, 8/15/18, 8/17/18, 8/20/18, 8/25/18, 8/26/18, 8/27/18 and 8/28/18); a total of 61 days. 4. An interview with Technical Consultant A and Technical Consultant B at approximately 10:45 AM confirmed that the laboratory failed to follow the manufacturer's storage requirements for the ePoc BGEM Test Cards for the dates and number of days listed above.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the laboratory's performance verification records, and an interview, the laboratory failed to verify the performance specifications of the ePOC test systems (serial numbers 19772, 20209 and 20208) in the environment in which testing is performed. Findings include: 1. Review of the laboratory's ePOC test

	system's (serial numbers 19772, 20209 and 20208, installed October 2017) performance verification documentation revealed the accuracy, precision, reportable range and normal range verifications were performed off-site at an affiliated hospital. 2. An interview with Technical Consultant A at approximately 11:30 AM, confirmed that the laboratory failed to perform the verification performance characteristics of the ePOC test system in the environment in which testing is performed.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: A. Based on the review of the laboratory's Individual Quality Control Plan (IQCP) documents, and interview, the laboratory failed to include on-site testing data for the ePOC test system in determining the frequency of quality control. Findings include: 1. Review of the laboratory's IQCP documents for the ePOC test system revealed no documentation of historical data available for external quality control materials assayed at the testing site. The inspector requested documentation of external quality control documentation from the testing site. No documentation was available for review. 2. An interview with Technical Consultant A at approximately 12:15 PM confirmed that the laboratory did not include on-site testing data for the ePOC test system when determining the frequency of quality control. B. Based on review of the laboratory's policy and procedure manual, Individual Quality Control Plan (IQCP), ePOC quality control (QC) records, patient test logs, and interview, the laboratory failed to follow their established quality control policy and document two (2) levels of quality control for the ePOC Test System while reporting two (2) patient test results from April 30, 2018 to August 30, 2018. Findings include: 1. Review of the laboratory's procedure manual revealed a policy, "Point of Care Testing: ePOC", which states controls HCT levels A and C and Metabolites levels 1 and 3 are run once a week for lot in use, with new shipment and new lot. 2. Review of the laboratory's IQCP revealed the laboratory is to "run external controls weekly as opposed to monthly due to extreme temperatures in the trucks." 3. Review of the ePOC QC records from April 30, 2018 to August 30, 2018 revealed QC performed as follows: 070/2/18 Level 1, 07/09/18 HCT A, 07/16/18 Level 2, 07/23/18 Level 3, 07/30/18 HCT A, 080/6/18 Level 3, 08/13/18 Level 3, 08/20/18 Level 3, 08/27/18 Level 3. At approximately 12:15 PM, the surveyor asked Technical Consult B to explain how QC was run on the ePOC. Technical Consultant B stated that they pick a different level each week and run on the instruments. 3. Review of the patient test logs revealed patient testing as follows: 05/05/18 Response ID AF181250C, 05/22/18 Response ID AF181420C. 4. An interview with Technical Consultant A at approximately 12:15 PM confirmed that the laboratory failed to perform and document weekly QC as established by their QC policy.
D5785	CORRECTIVE ACTIONS

	CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, ePoc BGEM Test Card Specifications, temperature logs and an interview, the laboratory failed to document corrective actions taken when the ePOC BGEM Test Card storage temperatures were not within the manufacturer's storage requirements for sixty-one (61) of one-hundred and seventeen (117) day reviewed from April 30, 2018 to August 29, 2018. (Cross Reference D5411.) Findings include: 1. Review of the laboratory's procedure manual revealed a procedure, "Point of Care Testing ePoc", which states: "Always store test cards at room temperature (15-30 C).". 2. Review of the BGEM Test Card Specifications revealed the line "12.2.1 Storage Stability" which states: "Test Cards must be stored in their Card Pouch at Room Temperature, 15-30 C (59-86 F) at all times." 3. Review of laboratory's ePOC instrument storage case temperature logs revealed the temperature warmer than 30 degrees Celsius for the following number of days and dates: May 2018-14 days (5/1/18, 5/2/18, 5/3/18, 5/5/18, 5/8/18, 5/9/18, 5/17 /18, 5/19/17, 5/23/18, 5/25/18, 5/26/18, 5/27/18, 5/28/18, and 5/29/18); June 2018-12 days (6/1/18, 6/2/18, 6/6/18, 6/8/18, 6/10/18, 6/14/18, 6/15/18, 6/20/18, 6/21/18,6/26 /18, 6/27/18, and 6/28/18); July 2018-17 days (7/2/18, 7/3/18, 7/4/18, 7/7/18, 7/10/18, 7/11/18, 7/12/18, 7/15/18, 7/16/18, 7/18/18, 7/19/18, 7/21/18, 7/26/18, 7/27/18, 7/28 /18, 7/29/18, and 7/30/18); August 2018-18 days (8/1/18, 8/2/18, 8/5/18, 8/6/18, 8/7 /18, 8/8/18, 8/9/18, 8/10/18, 8/11/18, 8/12/18, 8/14/18, 8/15/18, 8/17/18, 8/20/18, 8/25 /18, 8/26/18, 8/27/18 and 8/28/18); a total of 61 days. The inspector requested to review corrective action taken for the days in which the recorded temperatures were not within the manufacturer's storage requirements. There was no documentation for review. 4. An interview with Technical Consultant A at approximately 10:45 AM confirmed that the laboratory failed to perform and document corrective actions for the days in which the temperatures were not within the manufacturer's storage requirements.
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 review of the laboratory's policy and procedure manual and an interview, the laboratory failed to establish a written Quality Assessment policy. Findings include: 1. Review of the laboratory's policy and procedure manual revealed no policy for the quality assessment of the analytic system. 2. An interview with Technical Consultant A at approximately 11:00 AM confirmed the laboratory did not have a quality assessment policy.
D6020	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 the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, ePOC external quality control (QC) records, patient test logs and interview, the laboratory director failed to ensure that the quality control policies were followed prior to reporting two (2) patients (Response ID AF181250C and AF181420C) from April 30, 2018 to August 30, 2018. (Cross Reference D5445 B.)
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 Laboratory Personnel Report form (CMS-209), the laboratory personnel files and an interview with Technical Consultant A, the laboratory failed to maintain documentation of personnel education and experience qualification for one (1) of two (2) Technical Consultants. (Cross Reference D6034.)
D6034	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section. This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS-209), the laboratory personnel files and an interview, the laboratory failed to maintain documentation of personnel education qualifications and experience for one (1) of two (2) Technical Consultants. Findings include: 1. Review of the CMS 209 Laboratory Personnel Report revealed 2 Technical Consultants. 2. Review of the laboratory's personnel records revealed no education or experience documentation for Technical Consultant B. (See Personnel Code Sheet). The inspector requested to review the documentation. No records were available for review on the day of survey. 3. An interview with Technical Consultant A at

	approximately 10:45 AM confirmed that the laboratory failed to maintain documentation of the personnel education qualifications and experience of one (1) of two (2) Technical Consultants personnel listed on the CMS-209.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS-209), the laboratory personnel files and an interview with the Technical Consultant A, the laboratory failed to maintain documentation of personnel education qualifications for eleven (11) of nineteen (19) testing personnel. (Cross Reference D6065)
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS-209), the laboratory personnel files and an interview with Technical Consultant A, the laboratory failed to maintain documentation of personnel education qualifications for eleven (11) of nineteen (19) testing personnel. Findings include: 1. Review of the CMS 209 Laboratory Personnel Report revealed 19 testing personnel. 2. Review of the laboratory's personnel records revealed no education documentation for Testing Personnel B, C, D, E, F, H, I, L, M, Q, and R. (See Personnel Code Sheet.) The inspector requested to review the documentation. No records were available for review on the day of survey. 3. An interview with Technical Consultant A at approximately 10:45 AM confirmed that the laboratory failed to maintain documentation of the personnel education qualifications of eleven (11) of nineteen (19) testing personnel listed above.