Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D2066341	03/09/2018
Name of Provider or Supplier	**Street Address, City, State**	
Afc Urgent Care	161 Boston Ave, Bridgeport, CT	

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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on record review and staff interview the laboratory failed to enroll in proficiency testing (PT) for the specialty of chemistry. Findings include: 1. Record review of the laboratory patient logs on 3/9/18 revealed 2 patients were tested using the troponin I OneStep RapiCard Insta-test system one on 11/10/17 (64618) and 1/31 /18 (66481). 2. Review of the CLIA application test menu on 3/28/18 revealed no evidence that the laboratory performed the above test using the OneStep RapiCard Insta test system. 3. During telephone interview on 3/28/18 with laboratory manager at 1:00 PM he/she stated the laboratory was not enrolled in PT for Troponin in 2016, 2017 and 2018.
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 record review and staff interview, the laboratory failed to follow the manufacture's instructions for the Troponin I OneStep Rapid Insta test(refer to D5411);failed to establish performance specifications for the not FDA approved Troponin I OneStep Rapid Insta test prior to patient testing (refer to D5423); failed to establish control procedures to monitor the accuracy and precision of the Troponin I OneStep Rapid Insta test process (refer to D5441).
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to follow the manufacturer's instructions for the Troponin I OneStep Rapid Insta test in the specialty of chemistry. Findings include: 1. Record review of the laboratory's patient logs from 07-17-17 through 03-19-18 on 3/9/18 revealed 2 patients were tested for troponin, one on 11/10/17 (64618) and one on 1/31/18 (66481). 2. Record review of the package insert for the OneStep Troponin I RapiCard Serum/WB Insta Card on 3/9 /18 revealed controls cTnI positive and cTnI negative are required but not provided. 3. During telephone interview on 3/28/18 with laboratory manager at 1:00 PM he/she confirmed quality control was not performed on 11/10/17 or 1/31/18 for the troponin test.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to establish performance specifications for the OneStep Troponin I RapiCard Serum/WB Insta test prior to patient testing for high complexity testing in the specialty of chemistry. Findings include: 1. Record review of the laboratory's patient logs on 3/9/18 for the

	period of 07/17/17 through 03/09/18 revealed the laboratory performed patient testing for 2 patients, one on 11/10/17 (64618) and one on 1/31/18 (66481), using the Troponin I OneStep RapiCard Insta test system. 2. Record review of the manufacture package insert for the above test on 3/9/18 revealed that it was not CLIA waived nor FDA approved. 3. Review of the FDA website on 3/9/18 for the above test revealed the test system/manufacture was not listed in the FDA CLIA database. 4. During telephone interview on 3/28/18 with laboratory manager at 1:00 PM confirmed performance specifications were not established for the above troponin I OneStep RapiCard Insta test system and patient testing was performed on 11/10/17 (64618) and 1/31/18 (66481).
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to establish control procedures to monitor the accuracy and precision of the Troponin I OneStep Rapid Insta test. Findings include: 1. Record review of the laboratory's patient logs on 3/9/18 for the period of 07/17/17 through 03/09/18 revealed the laboratory performed patient testing for 2 patients, one on 11/10/17 (64618) and one on 1/31/18 (66481), using the Troponin I OneStep RapiCard Insta test system. 2. During telephone interview on 3/28 /18 with laboratory manager at 1:00 PM confirmed the laboratory did not establish control procedures or perform QC for the troponin OneStep RapiCard test system.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on record review and staff interview, the laboratory director (LD) failed to qualify as LD for high complexity testing in the specialty of chemistry. Refer to D6078
D6078	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1443 The laboratory director must be qualified to manage and direct the laboratory

	personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2) Be a doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and (b)(2)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and-- (b)(3)(i) Be certified and continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory director (LD) failed to meet LD requirements to operate and perform high complexity testing. Findings include: 1. Record review of the laboratory director's (LD) qualifications on 3/9/18 revealed the LD failed to have at least 2 years of experience directing or supervising high complexity testing. 2. During telephone interview on 3/21/18 with laboratory director (LD) at 1:00 PM confirmed the OneStep Troponin I RapidCard Serum/WB Insta test system was used for the above dates. LD also stated he/she thought the test was CLIA wiaved.