Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D2079387	06/26/2019
Name of Provider or Supplier	**Street Address, City, State**	
Afc Urgent Care Stamford	3000 Summer Street, Stamford, 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
D0000	A CLIA paper desk review of proficiency testing was conducted on 6/26/19 for the AFC Urgent Care laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of the Proficiency Testing (PT) data report, (Report 155) report and graded results from, American Proficiency Institute (API), the laboratory failed to successfully participate in White blood cell Differential PT. See D2130.
D2127	HEMATOLOGY

	CFR(s): 493.851(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on an off-site desk review of the laboratory's 2019 American Proficiency Institute (API) proficiency testing (PT) records and phone interview, the laboratory failed to submit their testing results to API within the specific time frame resulting in an unsatisfactory score for the automated White Blood Cell (WBC) Differential PT survey. Findings include: 1. Desk review of the laboratory's API PT final testing results for the automated WBC Differential on 6/26/19 revealed the laboratory achieved a score of zero (0) for the first event of 2019. 2. Desk review of the laboratory's plan of correction for the above PT survey on 6/26/19 revealed "authorized staff to run testing was on vacation" with no plan of correction to prevent recurrence. 3. Phone interview with the laboratory administrator on 6/27/19 at 11:45 AM confirmed the laboratory failed to achieve satisfactory performance for the PT event listed above due to not submitting their testing results on time.
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on American Proficiency Institute (API) proficiency performance review for calendar year 2018 the laboratory failed to ensure that remedial action was taken and documented in response to unacceptable analyte scores resulting in a second unsuccessful ocurrence in the specialty of hematology. Findings include: 1. Record review of the hematology/coagulation 2018 American Proficiency Institute (API) PT comparative evaluation forms on 6/26/19 revealed the following unacceptable PT results: a. Sample HSY-08 Event 2 for 2018 Lymphocyte% "result submitted was 98.9, clerical error should of been 38.9". b. Sample HSY-07 through HSY-10 Event 2 for 2018 Neutrophils/Granulocytes% "results were incorrectly submitted as whole numbers instead of Granulocyte % - clerical error". 2. Record review of the laboratory's plan of correction for the above 2018 unacceptable PT results on 6/26/19 revealed the following: a. Sample HSY-08 - "Review of results show typo. Results within range 9/20/18". b. Sample HSY-07 through HSY-10 -"Review of results show whole number result input, incorrect. % should have been noted. % results within ranges". c. Remedial action or plan to prevent occurrence was not documented. d. The PT was signed and dated as reviewed by the laboratory director on 9/20/18. 3. Record review of the laboratory's PT section F. Corrective Action section policy on 6/18/19 revealed problems due to clerical errors failed to state a plan to prevent recurrence. 4. Staff phone interview with the practice administrator (PA) on 6/26/19 at 11:45 AM

	confirmed the laboratory did not document remedial action or a plan to prevent recurrence. PA stated the unacceptable score was due to a clerical error.
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on a review of the Proficiency Testing (PT) data report, Casper Report 155, graded results from the proficiency testing organization American Proficiency Institute (API), and phone interview, the laboratory failed to successfully participate for the automated White Blood Cell (WBC) Differential. The laboratory has unsatisfactory scores for the 1st event and 2nd event of 2017, the 2nd event for 2018 and the 1st event for 2019 for the analytes listed above. Findings include: 1. Desk review of the laboratory's 2017,2018 and 2019 API PT records on 6/26/19 revealed automated WBC Differential scores of less than eighty percent were obtained for the following Hematology PT events: 2017 API Event 1 for automated WBC Differential the score was 60% and was unsatisfactory. 2017 API Event 2 for automated WBC Differential the score was 67% and was unsatisfactory. 2018 API Event 2 for automated WBC Differential the score was 60% and was unsatisfactory. 2019 API Event 1 for automated WBC Differential the score was 0% and was unsatisfactory. Resulting in a subsequent unsuccessful performance for the above. 2. Phone interview with the laboratory administrator on 6/26/19, confirmed that the laboratory was unsuccessful in the PT events listed above.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on record review of the laboratory's Proficiency Testing (PT) data reports, PT plan of corrections, Casper Report 155D and staff interview, the laboratory director failed to ensure that effective remedial action was instituted in response to unsatisfactory PT scores resulting in a second unsuccessful performance for the auotmated White Blood Cell Differential in the specialty of Hematology. Refer to D2016.