

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D2125887	(X3) Date Survey Completed 02/14/2018
Name of Provider or Supplier Afc Urgent Care	Street Address, City, State 389 Bridgeport Ave, Shelton, 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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory director (LD) failed to attest that proficiency testing (PT) samples were performed in the same manner as patient specimens. Findings include: 1. Record review of the 2017 American Proficiency Institute Hematology/Coagulation Event 3 attestation page on 2/14/18 revealed the attestation page had the name of the LD printed in the signature section. 2. Staff interview with the lead laboratory tech and the center adminin on 2/14/18 at 12:30 PM confirmed the PT testing personnel printed the name of the LD in the LD attestation section and the LD did not sign the attestation page.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to ensure moderate complexity testing personnel (MCTP)received the appropriate training and have demonstrated they can perform all testing operations reliably to provide and report accurate results. Findings include: 1. Record review of the Laboratory's, 'Laboratory</p>

Director: Duties and Responsibilities' policy on 2/14/18 revealed, "The laboratory director's duties include the following: a. Responsible for the employment of personnel who are qualified and competent to perform their assigned duties and annual evaluation and documentation of the performance of testing personnel. b. Responsible for the orientation and training of new employees. c. Responsible for assuring compliance with all applicable regulations. d. Ensure that the testing personnel are performing the test methods as required for accurate and reliable results. e. Ensure that prior to testing patient specimens, testing personnel receive the appropriate training for the type and complexity of testing to be performed. Testing personnel must demonstrate that they can perform reliably and provide and report accurate results." 2. Record review of the laboratory's Procedure Manual, 'Section II Personnel' policy on 2/14/18 revealed the following: a. "Employees will be evaluated on their knowledge of the training manual with a written examination. The examination will take place at the commencement of employment, at 6 months, and annually thereafter. b. Testing personnel will receive formal training on the operation of each laboratory instrument and procedure on commencement of employment. c. The laboratory director will evaluate testing personnel performance prior to the start of patient sample testing, at or before 6 months of commencement of employment and annually thereafter. An evaluation form for this purpose will cover compliance with standard operating procedures, competency in test performance and instrument maintenance and function checks and participation in proficiency testing when applicable. d. Annually, all laboratory employees will review the sections of the laboratory policy and procedure manual as they pertain to their duties. This review will be documented. " 3. Record review of the laboratory's 2017 and 2018 training records on 2/14/18 revealed the following: a. The laboratory did not have documentation for 4 of 4 MCTP's written examination as written in the above procedure. b. 2 of 4 MCTP did not have any training records before performing complete blood count (CBC) testing. c. 1 of 4 MCTP did not have completed training records before performing CBC's. d. 4 of 4 MCTP were not evaluated to assess their competency to perform CBC's prior to testing patient samples. 4. Record review of the laboratory's Procedure Manual, 'Laboratory Staff Attestation 2017' sheet on 2/14/18 revealed 1 of 4 testing personnel failed to sign indicating they have read the manual prior to testing patient samples. 5. Staff interview with the lead laboratory tech and the center admin on 2/14/18 at 11:30 AM confirmed the above findings. 6. The laboratory performs approximately 3,600 moderate complexity test per year in the specialty of hematology.

D5211

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(a)

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:
Based on record review and staff interview the laboratory failed to review Proficiency Testing (PT) reports when results are received. Findings include: 1. Record review of the Laboratory's, 'Laboratory Director: Duties and Responsibilities' policy on 2/14/18 revealed, "The laboratory director's duties include the following: Review and sign the proficiency test reports and ensure the appropriate staff also reviews the reports to evaluate the laboratory performance and identify problems requiring corrective action." 2. Record review of the laboratory's Procedure Manual, 'Section VII Quality Assurance' policy on 2/14/18 revealed, "The laboratory director will sign the graded

results." 3. Record review of American Proficiency Institute (API) PT, 2017 Hematology/Coagulation 3rd Event, comparative evaluation report on 2/14/18 revealed the laboratory director failed to document review of the results. 4. Staff interview with the lead laboratory tech and the center admin on 2/14/18 at 10:30 AM confirmed the above findings. 5. The laboratory performs approximately 3,600 moderate complexity tests annually in the specialty of hematology.

D5403

PROCEDURE MANUAL
CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:
Based on surveyor observation, record review and staff interview the laboratory failed to have a complete procedure manual available to testing personnel for the specialty of hematology and collection requirements for the Quantiferon TB Gold test. Findings include: 1. Surveyor observation of the blood collection tube storage area on 2/14/18 at 11:00 AM revealed 15 prepackaged tube sets for Quantiferon TB Gold test collection. The packages did not contain collection instructions. 2. Record review of the laboratory's procedure manual on 2/14/18 revealed the following: a) The procedure manual did not contain the patient normal ranges for complete blood counts. b) The procedure manual did not contain collection instructions for the Quantiferon TB Gold test. 3. Staff interview with the lead laboratory tech and the center adminin on 2/14/18 at 11:30 AM confirmed the above findings. 4. The laboratory performs approximately 3,600 moderate complexity tests per year in the specialty of hematology.

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 and staff interview the laboratory director failed to fulfill his /her responsibilities of operating a moderate complexity laboratory. Refer to D6016, D6018, D6020, D6029 and D6031.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(i)

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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory director (LD) failed to attest that proficiency testing (PT) samples were performed in the same manner as patient specimens. Refer to D2009.

D6018

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(iii)

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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

Based on record review and staff interview the laboratory director (LD) failed to review Proficiency Testing (PT) reports when results are received. Refer to D5211.

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 record review and staff interview, the laboratory director (LD) failed to actively maintain a quality control (QC) program to assure the quality of laboratory services provided. Findings include: 1. Record review of the Laboratory's, 'Laboratory Director: Duties and Responsibilities' policy on 2/14/18 revealed, "The laboratory director's duties include the following: a. Ensure that quality control and quality

management plans are established and maintained to assure the quality of laboratory testing and identify problems as they occur. b. Review all maintenance, calibration and quality control records on a regular basis." 2. Record review of the laboratory's, 'Internal Quality Control' policy on 2/14/18 revealed, "QC data is reviewed regularly by the supervisor and monthly for review by the laboratory consultant and LD." 3. Record review of the laboratory's CMS 209 form on 2/14/18 revealed the LD functions as the LD, Clinical Consultant, and the Technical Consultant. 4. Record review on 2/14/18 of the laboratory's quality control data for the Medonics M hematology instrument placed into service on August 31, 2017 revealed the quality control data from 8/31/17 through 2/14/18 was not reviewed by the laboratory director. 5. Staff interview with the lead laboratory tech and the center admin on 2/14/18 at 11:30 AM confirmed the above findings. 6. The laboratory performs approximately 3,600 moderate complexity test per year in the specialty of hematology.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:
Based on record review and staff interview the laboratory director failed to ensure moderate complexity testing personnel (MCTP) received the appropriate training and have demonstrated they can perform all testing operations reliably to provide and report accurate results. Refer to D5209.

D6031

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(13)

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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:
Based on surveyor observation, record review and staff interview the laboratory director failed to have a complete procedure manual available to testing personnel for the specialty of hematology and collection requirements for the Quantiferon TB Gold test. Refer to D5403.

D6070

TESTING PERSONNEL RESPONSIBILITIES
CFR(s): 493.1425(b)(1)

Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, testing personnel (TP) failed to follow established laboratory procedures as written in the procedure manual. Findings include: 1. Record review of the laboratory's Procedure Manual, 'Laboratory Reports' section on 2/14/18 revealed, "Panic Values are verbally reported (in addition to the written report) to the ordering health care provider. This will be documented in the comprehensive remedial action log and initialed by the person delivering the result." 2. Record review of the laboratory's Procedure Manual, 'Alert Values' section on 2/14/18 revealed, "All alert value incidents are noted in "remedial action" log." 3. Staff interview with the lead laboratory tech (LT) and the center adminin on 2/14/18 at 1:00 PM revealed the laboratory does not have a comprehensive remedial action log. LT stated panic values are brought to the ordering health care provider's attention but are not documented.

D6072

TESTING PERSONNEL RESPONSIBILITIES

CFR(s): 493.1425(b)(3)

Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.

This STANDARD is not met as evidenced by:

Based on record review and staff interview laboratory testing personnel (TP) failed to follow quality control policies as written in the procedure manual. Findings include: 1. Record review of the laboratory's Procedure Manual, '3.1.5.3 Internal Quality Control Policy', Section 7. unacceptable control results on 2/14/18 revealed , "All preventative maintenance, service or repair performed by the operator or technical support representative must be documented in the Remedial Action Log." 2. Record review on 2/14/18 of the laboratory's quality control data from 8/1/17 through 2/14/18 revealed the laboratory does not have a Remedial Action Log. 3. Staff interview with the lead laboratory tech and the center adminin on 2/14/18 at 1:00 PM confirmed the above findings.