Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D2127836	01/25/2018
Name of Provider or Supplier	**Street Address, City, State**	
Acm Global Laboratories	129 Glover Ave, Norwalk, 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	The AFC Urgent Care Laboratory was surveyed pursuant to 42CFR Part 493 of the Clinical Laboratory Improvement Amendment of 1988 (CLIA). This was an initial survey performed on January 25, 2018.
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: Based on record review and staff interview testing personnel (TP) were not following laboratory policies and procedures in the sub-specialty of toxicology. Findings include: 1. Record review of the laboratory's standard operating procedure for "initial testing procedure" (document # 1484.03 - section 9) on 1/25/18 revealed new lot of assayed quality control (QC) and calibrators are to be run in parallel with the current lot and documented on the new reagent lot log. 2. Record review of the laboratory's QC and calibrator lot to lot verification sheets on 1/25/18 revealed the TP were not following the above procedure for verifying and documenting new lot of QC and calibrator materials before placing them in use, specifically: a) Fentanyl QC lot# E30476 placed into service on 1/18/18 b) Ethyl glucuronide (ETG) QC lot# 72426703 used for alcohol testing placed into service on 1/16/18. c) pH 4.5 and 9 calibrators lot# 3T448UL-K1 4.5 placed into service on 1/12/18. 3. Staff interview with the technical supervisor on 1/25/18 at 1:30 PM confirmed TP did not follow the laboratory's lot to lot verification procedure for the above QC and calibrator materials before placing them into service. 4. The laboratory performs an estimated volume of 92,076 toxicology tests annually.

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 record review and staff interview, the laboratory failed to establish a procedure for verifying unassayed quality controls (QC) for new lots and shipments in the sub-specialty of toxicology. Findings include: 1. Record review of the laboratory's unassayed QC lot to lot verification "initial testing procedure" (document #1484.03) on 1/25/18 revealed: a. Procedure was unavailable for verifying new lot and shipments of unassayed QC currently in use. b. Procedure for the establishment of statistical parameters for unassayed QC were not available. 2. Staff interview with the technical supervisor on 1/25/18 at 1:15 PM confirmed the above findings. 3. The laboratory performs an estimated volume 92,076 tests annually in the sub-specialty of toxicology.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (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

	acceptable statistical parameters for unassayed quality control (QC) materials before placing them into use. Findings include: 1. Record review of the QC package inserts on 1/25/18 revealed the laboratory is using unassayed QC materials in the sub-specialty of toxicology. 2. Record review of the laboratory's QC log on 1/25/18 revealed unassayed QC materials were placed in use before establishing statistical parameters. 3. Staff interview with the technical supervisor (TS) on 1/25/18 at 1:00 PM confirmed: a. TS was unaware unassayed QC materials were being used by the laboratory. b. Statistical parameters were not established by the laboratory prior to placing them into use. c. Laboratory's procedure manual is not updated to reflect the above requirement.
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 assess and evaluate the competency of the testing personnel (TP) to demonstrate they could perform all testing operations reliably and accurately. Findings include: 1. Record review of the laboratory equipment maintenance log and patient test records on 1/25 /18 revealed the following: a. 1 of 2 TP worked at the laboratory for a period of 5 weeks in December to January 2017-'18 and conducted instrument maintenance for Beckman Olympus AU 680 analyzer. b. 1 of 2 TP worked during the above period tested and reported patient samples. 2. Record review of the CMS-209 form for the 'laboratory personnel report' on 1/25/18 revealed 1 of 2 TP was not listed. 3. Staff interview with the technical supervisor on 1/25/18 at 11:30 AM confirmed the following: a. 1 of 2 TP worked in the laboratory for 4-5 weeks when the primary TP left. b. Training and competency assessment records were not available for 1 of 2 TP. c. 1 of 2 TP worked in the laboratory and was not listed on the CMS-209 form. 4. The laboratory performs an estimated volume of 92,076 tests annually in the specialty of chemistry.