Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0177186	05/07/2018
Name of Provider or Supplier	**Street Address, City, State**	
Alma Illery Medical Center	7227 Hamilton Ave, Pittsburgh, PA	

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
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of Beckman Coulter AU480 and Tosoh AIA 360 Analyzers calibration records and interview with General Supervisor (GS) #2, the laboratory failed to perform calibration verification (CV) on the Beckman Coulter AU480 and Tosoh AIA 360 Analyzer at least every 6 months from 2017 to the date of survey. Findings include: 1. On the day of survey, 05/07/2018, review of Beckman Coulter AU480 and Tosoh AIA 360 Analyzer CV, revealed that the laboratory has not

	performed CV at least every six months. No current calibration verification record were available at the time of inspection. 2. In 2017: 40, 359 Chemistry tests were performed on patients. 3. In 2018 (January 1st to May 7th) 15,664 Chemistry tests were performed on patients. 4. GS #2 confirmed the finding above on 05/07/2018 around 2:00 pm.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the review of Urine Microscopic Analysis Quality Control (QC) records and interview with the General Supervisor (GS) #2, the laboratory failed to document QC for Urine Microscopic Analysis each day of patient testing from 2017 to the date of survey. Findings Include: 1. On the date of survey 05/09/2018, review of Urine Microscopic QC records, revealed the laboratory has reference material available for Urine Microscopic analysis QC but not documented. 2. In 2017: 669 Urine Microscopic Analysis were performed on patients. 3. In 2018 (January 1st to May 7th) 288 Urine Microscopic tests were performed on patients 4. The GS#2 confirmed the findings above on 05/07/2018 around 02:45 pm.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of Quality Control (QC) records and interview with the General Supervisor (GS) #2, the laboratory failed to test the manual differential stain (Fisher Brand Hema-Quik II) for reactivity each day of patient testing from 2017 to the date of survey. Finding Include: 1. On the day of survey, 05/07/2018, review of QC records revealed, the laboratory did not document manual differential stain reactivity each day of patient in 2017 and 2018. GS #2 stated " it is performed but not documented". 2. In 2017 : 1,027 differentials were performed on patients. 3. In 2018 (January 1st to May 7th) 419 differentials were performed on patients. 4. The GS #2 confirmed the findings above on 05/07/2018 around 3:45 pm.
D5507	BACTERIOLOGY CFR(s): 493.1261(b)(c) (b) For antimicrobial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimicrobial agent(s) before, or

	concurrent with, initial use, using approved control organisms. (b)(1) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure. (b)(2) The laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results. (c) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of Antimicrobial Susceptibility test Quality Control (QC) Records, and interview with the General Supervisor (GS) #2, the laboratory failed to check QC for Antimicrobial Susceptibility QC each day of patient testing from 2017 to the date of survey (17 of 17 months). Findings Include: 1. On the day of survey, 05/07/2018, review of Antimicrobial Susceptibility test Quality Control (QC) Records, revealed that that the laboratory performed QC on a weekly bases in 2017 and 2018. 2. The Laboratory could not produce a Individual Quality Control Plan (IQCP), for performing Antimicrobial Susceptibility test Quality Control (QC) on a weekly bases. 3. In 2017: 256 Antimicrobial Susceptibility tests were performed. 4. In 2018 (January 1st to May 7th) 98 Antimicrobial Susceptibility tests were performed. 5. GS #2 confirmed the findings above on 05/07/2018 around 3:00 pm.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on surveyor review of Daily Temperature Logs and interview with General Supervisor (GS) #2, the laboratory failed to document all corrective actions (CA) taken when acceptable room temperature exceed acceptable limits in 2017 (12 of 12 months). Findings include: 1. On the day of survey, 05/07/2018, review of the chemistry and hematology laboratory Daily Temperature Logs, revealed that the acceptable temperature ranges were exceeded on days of patient testing and documentation of corrective actions were not available. 2. Daily Temperature Log-Hematology and Chemistry Room Temperature: Acceptable Range (73-84 degrees Fahrenheit) January 2017: 9 of 20 days exceeded rooms temperatures without a CA documented. February 2017: 5 of 14 days exceeded rooms temperatures without a CA documented. March 2017: 6 of 23 days exceeded rooms temperatures without a CA documented. April 2017: 3 of 13 days exceeded rooms temperatures without a CA documented. May 2017: 2 of 21 days exceeded rooms temperatures without a CA documented. June 2017: 4 of 21 days exceeded rooms temperatures without a CA documented. July 2017: 7 of 17 days exceeded rooms temperatures without a CA documented. August 2017: 3 of 17 days exceeded rooms temperatures without a CA documented. September 2017: 2 of 18 days exceeded rooms temperatures without a

	CA documented. October 2017 : 3 of 19 days exceeded rooms temperatures without a CA documented. November 2017: 7 of 14 days exceeded rooms temperatures without a CA documented. December 2017:3 of 18 days exceeded rooms temperatures without a CA documented. 3. GS #2 confirmed on 05/07/2018 around 1:30 pm that the laboratory did not document corrective action taken for temperatures that exceed acceptable limits.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must 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 review of the Laboratories Procedure Manual and interview with General Supervisor (GS) #2, the laboratory director (LD) failed to ensure that all the procedure manuals have been signed and approved from September 2016 to the date of survey. Findings include: 1. On the day of survey, 05/07/2018, review of the Laboratories Procedure Manual, revealed that the current LD did not sign and approve the current manual in use for patient testing since their start date of 09/14/2016. 2. GS #2 confirmed the findings above on 05/07/2018 around 12:45 pm.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on, the review of personnel records and interview with the General Supervisor (GS) #2, the Technical Supervisor failed to evaluate the competency of all testing personnel who perform, Bacteriology, Chemistry, Hematology, Parasitology, Mycology, and Urinalysis testing from 2017 to the date of survey. Findings: 1. On the date of survey 05/07/2018, review of personnel documents, revealed that 5 of 5 testing personnel who perform Bacteriology, Chemistry, Hematology, Parasitology, Mycology, and Urinalysis patient tests, were not assessed for competency in 2017 and 2018. 2. The regulatory responsibilities delegated to 2 of 2 GS's in 2017 and 2018 were not assessed for competency. 3. In 2017 the laboratory performed testing on 44,828 patient specimen. 4. GS #2 confirmed the findings above on 05/07/2018 around 12:15 pm