Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0177186	07/17/2024
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
D0000	A recertification survey was conducted on 07/17/2024. The laboratory was found to be out of compliance with the following condition: 493.1441 Condition: Laboratories performing high complexity testing; laboratory director
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on record review and interview with Technical Supervisor (TS) #2, the laboratory director (LD) failed to be present for a reasonable period of each working day in each laboratory for which he is director from 10/18/2022 to the day of survey as required by PA State regulations. Findings include: 1. The PA State regulation 5.22 (g) states: "A director shall be present for a reasonable period of each working day in each laboratory for which he is director." 2. The Laboratory Director's position responsibilities signed by the LD on 09/20/2019 states, "The Laboratory Director must be accessible to the laboratory to provide on-site, telephone or electronic consultation as needed. If the laboratory director delegates his responsibilities, he remains responsible for ensuring that all duties are properly performed." 3. On the day of survey, 07/17/2024 at 8:19 am, an interview with TS #2 (CMS 209 personnel #2) revealed that the Laboratory Director visited the laboratory every few months from 10 /18/2022 to 07/17/2024. 4. TS #2 confirmed the findings above on 07/17/2024 at 10: 55 am.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory

	must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on observation of the laboratory, lack of documentation, and interview with technical supervisor (TS) #2 the laboratory failed to perform and document the maintenance/ function checks for 1 of 1 centrifuge and 1 of 1 microscope used to perform microscopic urinalysis examinations from 10/18/2022 to the day of survey. Findings Include: 1. The laboratory's Quality Assessment policy states, "Records of all maintenance and service must be maintained including but not limited to: routine maintenance, as needed maintenance, startup and shutdown logs, and preventative maintenance conducted by authorized service technicians. This applies to analyzers, microscopes, centrifuges, diH2O systems, etc." 2. On the day of survey, 07/17/2024, the laboratory failed to provide the maintenance/function check records for the following instrumentation: - 1 of 1 microscope used to perform microscopic urinalysis examinations, due 6/22/2024. - 1 of 1 Hamilton Bell centrifuge due 11/21/2023. 3. The above findings were confirmed by TS #2 on 07/17/2024 at 10:55 am.
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 the Beckman Coulter AU480 and TOSOH AIA 360 analyzer calibration verification (CV) records and interview with technical supervisor (TS) #2, the laboratory failed to perform CV for 23 of 27 analytes on the Beckman Coulter AU480 analyzer and 1 of 1 analyte on the TOSOH AIA 360 analyzer at least once every 6 months from 10/14/2022 to 07/17/2024. Findings include: 1. On the day of the survey, 07/17/2024 at 9:28 am, review of the laboratory's CV records revealed the laboratory failed to perform CV at least once every 6 months on the Beckman Coulter AU480 and TOSOH AIA 360 analyzers for the following analytes from 10/14/2022 to 07/17/2024: Beckman Coulter AU480 -Albumin -Alkaline Phosphatase (ALP) -

	Alanine aminotransferase (ALT) -Amylase -Aspatartate aminotransferase (AST) -Blood urea nitrogen (BUN) -Bilirubin, Direct -Bilirubin, Total -Calcium -Chloride -Sodium -Potassium -Cholesterol, Total -Creatinine Kinase (CK) -Glucose -Lactate dehydorgenase (LDH) -Gamma-glutamyl transferase (GGT) -Cholesterol, HDL -Iron, Total -Phosphorus -Triglycerides -Protein, total -Uric acid TOSOH AIA 360 -Prostate specific antigen (PSA) 2. The laboratory performed 51,116 chemistry examinations in 2023 (CMS 116 estimated annual volume). 3. TS #2 confirmed the findings above on 07/17/2024 at 10:55 am. *REPEAT DEFICIENCY
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 observation of the laboratory, review of records, and interview with Technical supervisor (TS) #2, the laboratory director failed to provide overall management and direction of the laboratory in accordance with 493.1445 from 10/18/2022 to 07/17/2024. Refer to D6094, D6103
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on lack of documentation, review of the laboratory's Quality Assessment (QA) policy and interview with technical supervisor (TS) #2, the Laboratory Director (LD) failed to ensure a QA program was established and maintained to ensure the quality of services provided by the laboratory from 1/23/2023 to the date of survey. Findings include: 1. The laboratory's QA policy states, "Conduct bimonthly Quality Assessments to review current policies and their effectiveness. Any changes to policy needed to address problems during the previous 2 months will be made during this QA, if not already done. The effectiveness of previous corrective actions will also be evaluated and changes made if necessary." 2. On the date of survey, 07/17/2024 the laboratory failed to provide documentation for the periodic QA evaluation performed to assess the laboratory's pre-analytical, analytical, and post-analytical processes from 1/23/2023 to 07/17/2024. 3. TS #2 confirmed the findings above on 07/17/2024 around 10:55 am. *REPEAT DEFICIENCY
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and

	proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with technical supervisor (TS) #2, the Laboratory Director (LD) failed to ensure established policies were followed to maintain competency for 1 of 2 technical supervisor (TS), 1 of 2 technical consultant (TC) and 1 of 1 general supervisor (GS) for their supervisory responsibilities performed and 4 of 4 testing personnel (TP) who conducted preanalytical, analytical and postanalytical phases of testing in microbiology, immunology, chemistry and hematology in 2023. Findings include: 1. The laboratory's Competency policy states, "Staff who perform laboratory testing will have competency assessment at 6 months, 12 months and yearly thereafter. General Supervisor, Technical Consultant, Technical Supervisor or Clinical Consultant will be assessed annually for their supervisor competence in addition to laboratory competence if performing any lab testing. The Competency Assessment will be documented on the Competency form by the Director or the Director's designee." 2. On the day of survey, 07/17/2024, the laboratory failed to provide documentation of the annual competency assessments for the following personnel in 2023: - CMS 209 personnel #2 for their supervisory responsibilities performed as TS, TC and GS. - CMS 209 personnel #2, #3, #4, #5 who performed testing in microbiology, immunology, chemistry and hematology. 3. TS #2 confirmed the findings above on 07/17/2024 at 10:55 am.