Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 39D0177186	**(X3) Date Survey Completed** 10/18/2022
Name of Provider or Supplier Alma Illery Medical Center	**Street Address, City, State** 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 the Beckman Coulter AU480 and Tosoh AIA 360 analyzers calibration records and interview with technical supervisor # 2 (TS), the laboratory failed to perform calibration verification (CV) for 27 of 27 analytes on the Beckman Coulter AU480 analyzer and for 1 of 1 analytes on the Tosoh AIA 360 analyzer at least every 6 months from 08/13/2020 to the date of survey. Findings include: 1. On the day of the survey, 10/18/2022 at 12:15 pm, the laboratory could not provide

	documentation of CV performed at least every 6 months on the Beckman Coulter AU480 and Tosoh AIA 360 analyzers for the following analytes from 08/13/2020 to the date of survey: A. 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 -Carbon dioxide (CO2) -Creatinine Kinase (CK) -Creatinine -Gamma-glutamyl transferase (GGT) -Glucose - Cholesterol, HDL -Iron, total -Lactate dehydorgenase (LDH) -Magnesium -Phosphorus -Protein, total -Triglycerides -Uric acid -Glycohemoglobin A1c B. Tosoh AIA 360 -Prostate-specific antigen (PSA) 2. The laboratory performed 42,478 chemistry examinations in 2021 (annual volume listed on CMS 116 form). 3. TS #2 confirmed the findings above on 10/18/2022 around 2:30 pm.
D5505	BACTERIOLOGY CFR(s): 493.1261(a)(3) (a) The laboratory must check the following for positive and negative reactivity using control organisms: (a)(3) When each batch (prepared in-house), lot number (commercially prepared), and shipment of antisera is prepared or opened, and once every 6 months thereafter. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the Technical Supervisor (TS)#2, the laboratory failed to document the quality control (QC) for the Streptex latex Agglutination test kit for the identification of streptococcus bacteria from 08/17/2020 to 10/18/2022. Findings include: 1. On the day of the survey, 10/18/2022 at 11:00am. The laboratory could not provide QC records for positive and negative reactivity for each lot number and each shipment of the Streptex latex agglutination test kits used for the identification of streptococcus serotyping from 08/17/2020 to 10/18/2022. 2. The TS#2 confirmed the above finding on 10/18/2022 at 02:30pm.
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 Quality Assurance (QA) documentation and interview with testing personnel #2 (TP), the Laboratory Director (LD) failed to ensure a QA program was maintained and documented to ensure the quality of services provided by the laboratory from 08/17/2020 to the date of survey. Findings include: 1. On the date of survey, 10/18/2022 at 12:30 pm, the laboratory could not provide documentation for the periodic QA evaluation performed to assess the laboratory's pre-analytical, analytical, and post-analytical processes from 08/17/2020 to 10/18/2022. 2. The laboratory performed 54,270 non waived tests in 2021 (annual volume listed on CMS 116 form). 3. TP #2 confirmed the findings above on 10/18/2022 around 02:30 pm. * Repeat Deficiency
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES

	CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of the laboratory competency assessment records and interview with technical supervisor #2 (TS), the TS failed to evaluate and document the annual competency assessment for 4 of 4 testing personnel (TP) who performed testing in microbiology, immunology, chemistry, and hematology from 08/17/2020 to the date of survey. Findings include: 1. On the day of survey 10/18/2022 at 09:17 am, the TS could not provide annual competency assessment records for 4 of 4 TP (CMS 209 personnel #2, #3, #4, and #5) who performed the following examinations from 01/01 /2021 to 12/31/2021: -Chemistry (Beckman AU480 and Tosoh AIA-360) -Hematology (Beckman AcT 5diff AL) -Urinalysis (Clinitek Status) -Manual differentials -Urinalysis microscopics -SSA for Urine Protein -Urine Cultures -Antimicrobial Sensitivities -Throat screens (Group A) -Vaginal/Rectal screen (Group B) -Sickle Cell Screen -Sedimentation Rate (ESR) -Rapid plasma reagin (RPR) -Rheumatoid Factor (RF) -Mononucleosis Screen -Serum, human chorionic gonadotropin (hCG) -Urine, human chorionic gonadotropin (hCG) 2. Further review of competency assessment records revealed that the TS evaluated 4 of 4 TP (CMS 209 personnel #2, #3, #4, and #5) for their testing performance for only the following analyzers/testing performed in 2020 and 2022: -Microbiology Antibiotic Susceptibility -API 20E -AU480 Chemistry analyzer -AcT 5diff-AL analyzer -Tosoh AIA-360 analyzer 3.The laboratory performed 54,270 non waived examinations in 2021 (annual volume listed in CMS 226 form). 4. TS #2 confirmed the findings above on 10/18/2022 around 02:30 pm.