Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2009488	(X3) Date Survey Completed 02/11/2021
Name of Provider or Supplier Accu Lab, Llc - Kidney-Hypertension-Clinic, Pc	**Street Address, City, State** 605 Old Norcross Road, Lawrenceville, GA	
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 Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on February 11, 2021. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on maintenance document review and staff interview, the laboratory failed to ensure protection from physical, chemical, and biohazardous materials as required. Findings include: 1. Maintenance document review revealed the lack of weekly eyewash maintenance logs available at the time of survey for 2018 (October through December), 2019, 2020, and 2021 thus far. 2. An interview with Staff #2 (CMS 209) in the billing area on 2/11/2021 at approximately 4:30 p.m. confirmed the lack of the aforementioned eyewash maintenance documents.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on proficiency test (PT) document review and staff interview the laboratory failed to evaluate and verify corrective action activities as required. Findings include:

	1. American Proficiency Institute (API) PT document review revealed the lack of corrective action for the following PT scores: Core Chemistry -- 2020 First Event: ALT (Alanine Aminotransferase) score of eighty percent (80%); 2020 Second Event: Creatine score of 80%. 2. An interview in the billing area on 2/11/2021 with Staff #2 (CMS 209) at approximately 4:30 p.m. confirmed the lack of corrective action for the aforementioned PT scores.
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 Hematology calibration document review and staff interview, the laboratory failed to perform instrument calibration with required frequency. Findings include: 1. Medonic hematology analyzer calibration document review revealed no calibration documentation was available at the time of survey between 1/8/2019 and 12/12/2019 to meet the frequency requirement of every six months. 2. An interview with Staff #2 (CMS 209) on 2/11/2021 in the billing area at approximately 4:00 p.m. confirmed the lack of required aforementioned documents.