Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 11D2009488	**(X3) Date Survey Completed** 02/21/2023
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 proficiency testing review was completed on February 21, 2023. At the time of the review, the laboratory was not in compliance with the Clinical Laboratory Improvement Amendments of 1988, 42 CFR 493.1 through 42 CFR 493.1780. The following condition deficiencies were cited: D2016 - 42 CFR 493.803 Condition: Successful participation [proficiency testing] D6000 - 42 CFR 493.1403 Condition: Moderate Complex Laboratory Director
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of the CMS CASPER 155 report and review of American Proficiency Institute (API) reports, the laboratory failed to achieve satisfactory

	proficiency testing (PT) performance for Total Bilirubin (T BIL) in three out of four testing events (2021 event 3 and 2022 events 2 and 3), resulting in the non-initial unsuccessful participation for T BIL. Findings include: Refer to D 2096
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of the CMS CASPER Report 155 and review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) reports, the laboratory failed to achieve satisfactory participation in three out of four testing events (3rd event of 2021, 2nd and 3rd events of 2022), resulting in the non-initial unsuccessful participation for Total Bilirubin (T BIL). Findings include: 1. A review of CASPER report 155 revealed the laboratory failed T Bil on the following: 2021 Event 3 TBIL Score 0% 2022 Event 2 TBIL Score 60% 2022 Event 3 TBIL Score 20% 2. A review of the laboratory's proficiency testing reports from API confirmed the laboratory failed TBIL with the aforementioned scores.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of the CMS CASPER 155 report and review of American Proficiency Institute (API) reports, the laboratory director failed to provide overall management and direction for proficiency testing performance. The laboratory director failed to ensure proficiency testing samples were tested as required. Refer to D6016
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on review of the CMS CASPER Report 155 and the American Proficiency Institute (API) 2021 event 3 and 2022 events 2 & 3 PT evaluation reports, the laboratory director failed to ensure successful proficiency testing performance in Total

	Bilirubin (T BIL) in three out of four testing events (2021 event 3 and 2022 events 2 and 3), resulting in the non-initial unsuccessful participation for T BIL.