

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D2053177	<b>(X3) Date Survey Completed</b>  05/25/2023
<b>Name of Provider or Supplier</b>  K & S Clinical Diagnostics	<b>Street Address, City, State</b>  1995 North Park Pl, Se, Suite 205, Atlanta, GA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on May 25, 2023. 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:
<b>D2000</b>	<p><b>ENROLLMENT AND TESTING OF SAMPLES</b> CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on CAP (College of American Pathology ) Proficiency Test (PT) document review and staff interviews, the laboratory failed to enroll in a CMS approved PT program in the first and second quarters of 2023. Findings: 1. Review of (CAP) Proficiency Testing (PT) documents revealed the laboratory failed to enroll in PT testing during the first and second quarter of 2023 resulting in FAILURE to participate in both events. 2. An interview with the Technical Supervisor(TS) (TP #4 CMS 209) in the review room at approximately 12:20 PM on 05/25/2023, confirmed no enrollment in a CMS approved PT program in 2023.</p>
<b>D6021</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(5)</p>

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on documents review and interview with the Technical Supervisor (TS), the Lab Director(LD) failed to ensure that ALL Quality Assurance (QA) guidelines were followed to identify and fix problems in the laboratory in 2023 as required by Clinical Laboratory Improvement Amendments (CLIA). Findings: 1. Monthly QA document review revealed the Lab Director and the Technical Supervisor (TS), did NOT realize that the laboratory's CAP Proficiency Testing (PT) enrollment fees were not paid in 2023. 2. An interview with the laboratory's (TS) (TP# 4 CMS 209 in the review room on 05/25/2023 at approximately 12:35 PM, confirmed the Lab Director failed to ensure proper oversight of the laboratory as it concerns PT enrollment in 2023.