

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2053177	(X3) Date Survey Completed 07/03/2025
Name of Provider or Supplier K & S Clinical Diagnostics	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on July 03, 2025. 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:
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES 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 Proficiency Test (PT) document review and staff interview, the laboratory failed to enroll in a CMS approved PT program OR peer review program in the second quarters of 2024 and first quarter of 2025. Findings: 1. Review of Proficiency Testing (PT) documents revealed the laboratory failed to enroll in a CMS approved PT testing program OR peer review program for Alcohol Testing in the second quarter of 2024 and 1st quarter of 2025. Alcohol testing was performed in April, May and June of 2024. 2. (PT) peer review documentation was available only in the 3rd quarter of 2024 (12/16/2024 with a lab in Michigan). 3. An interview with the Technical Supervisor(TS) (TP #3 CMS 209) in the lab review room at approximately 11:30 PM on 07/03/2025, confirmed no enrollment in a CMS approved PT OR peer review program in the second quarter of 2024 and 1st quarter of 2025.</p>

D6082

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(1)

(e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

This STANDARD is not met as evidenced by:

Based on documents review and interview with general supervisor (GS), the laboratory director failed to ensure that all phases of testing (preanalytic, analytic, post analytic and proficiency testing (PT) guidelines were followed to identify and fix problems in the laboratory from June 2023 through the date of survey July 03, 2025 as required by Clinical Laboratory Improvement Amendments (CLIA). Findings: 1. (QA) documents review revealed the lab director who is also the technical supervisor (TS) had a monthly QA checklist during the months of testing but failed to realize proficiency testing (PT) records were missing for 3rd quarter 2023, 1st and 2nd quarters 2024, 1st and 2nd quarter of 2025. 2. An interview with the laboratory's (GS) (TP# 3 CMS 209) in the lab review room on 07/03/2025 at approximately 12:20 PM, confirmed the lab director failed to ensure proper oversight of the laboratory from June 2023 thru the date of survey 07/03/2025.