

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2053177	(X3) Date Survey Completed 07/01/2021
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 1, 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:
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on the review of College of American Pathology (CAP) Proficiency Testing (PT) records and interviews with the Technical Supervisor(TS), the laboratory director failed to review and attest that PT samples were tested in the same manner as patient specimens in 2019, 2020 and 2021. Findings include: 1. Review of (CAP) PT records revealed the laboratory failed to provide or retain signed attestation forms by the laboratory director for all events in 2019, 2020 and 2021. 2. All Proficiency Testing (PT) documents were signed by the Technical Supervisor (TS) without a delegation letter from the laboratory director at the time of survey. 3. An interview with the (TS) and on 07/01/2021 at approximately 12:30 pm in the review room confirmed that (CAP) PT documents were not reviewed and signed by the laboratory director in 2019, 2020 and 2021.</p>
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p>

This STANDARD is not met as evidenced by:
Based on College of American Pathology (CAP) Proficiency Testing (PT) documents review and an interview with the Technical Supervisor (TS), the laboratory failed to document corrective action for unsuccessful (CAP) proficiency test (PT) results as required by Clinical Laboratory Improvement Amendments. Findings include: 1. Review of (CAP) PT documents revealed the laboratory failed to document corrective action for failed PT results (63 %, 2020 Event #1) for the following analytes; Benzoyllecgonine 150, Norbuprenorphine and Delta-9-THC-COOH. 2. No corrective action for (84%, 2020 Event #2) for the following analytes; Oxazepam and Temazepam. 3. An interview with the (TS) on 07/01/2021, in the review room at approximately 12:25 p.m., confirmed that there was no corrective action performed and documented for the aforementioned (CAP) PT results.