

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2042954	(X3) Date Survey Completed 05/15/2025
Name of Provider or Supplier Just Us Kids Pediatrics	Street Address, City, State 105 Oakhill Boulevard, Newnan, 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 May 15, 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:
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, manufacturer instructions, and interview with the laboratory's technical consultant (TC), the laboratory failed to follow manufacturer's instructions of adhering to the stability of the Consult Liquid Urine Quality Controls (QC) to the expiration date on the label. Findings Included: 1. During a tour of the laboratory on 5/15/2025 at 11:51 AM one box of the urine QC material was observed available for testing. 2. Review of the manufacturer's package insert reveals the QC is stable to the date on the label if stored between 2 - 8 degrees celcius. The lot # UCL3030019 expired 3/15/25. There was not another lot # available to use. 3. During an interview in the laboratory on 5/15/2025 at 11:51 am, the laboratory's technical consultant (CMS 209) confirmed the finding that the QC was expired.</p>
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(b)(1) 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>

This STANDARD is not met as evidenced by:

Based on review of the WSLH proficiency testing (PT) evaluation reports and an interview with technical consultant (TC), the laboratory director (LD) failed to sign the attestation statements for 2024 events #1 and #3. Findings: 1. Review of the WSLH PT 2024 events #1 & #3 revealed the LD did not attest to the PT samples being handled and ran like patient samples. 2. Interview with the TC (CMS 209 form) in the break room area at 12:15 pm on 5/15/25 confirmed the finding above.