

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D2122410	<b>(X3) Date Survey Completed</b>  03/13/2025
<b>Name of Provider or Supplier</b>  Kidzcare Pediatrics	<b>Street Address, City, State</b>  4233 Us 411 Ste B, Madisonville, TN	
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>D2009</b>	<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> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records and staff interview, the testing personnel and/or the laboratory director/designee failed to sign four of six attestation statements from 2023 and 2024. The findings include: 1. A review of the laboratory's 2023 and 2024 API proficiency testing attestation statements revealed the following: - The testing personnel and laboratory director/designee failed to sign the Hematology 2023 third event and 2024 first event. - The laboratory director/designee failed to sign the Hematology 2024 second and third events. 2. An interview with the laboratory lead on 03.13.2025 at 11:15 a.m. confirmed the above survey findings.</p>
<b>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory procedure manual, review of calibration records, and staff interview, the laboratory failed to follow its</p>

written procedure for calibration frequency in 2024. The findings include: 1. Observation of the laboratory on 03.13.2025 at 9:00 a.m. revealed a Horiba Micros 60 hematology analyzer (Serial Number: 809CS97970) used for patient Complete Blood Count (CBC) testing. 2. A review of the laboratory's Complete Blood Count procedure revealed, "Calibration is performed and documented with every lot number of reagent, at least every six months, and whenever major maintenance is done." 3. A review of laboratory calibration records revealed the laboratory failed to perform calibration every six months in 2024. 4. An interview with the laboratory lead on 03.13.2025 at 11:15 a.m. confirmed the above survey findings.