

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2213617	(X3) Date Survey Completed 06/08/2026
Name of Provider or Supplier Sofha Pediatrics Of Kingsport	Street Address, City, State 2002 Brookside Drive Suite 200, Kingsport, TN	
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
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> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's proficiency testing (PT) records and staff interview, the laboratory director/designee failed to sign one of four PT attestation statements reviewed from 2025 and 2026. The findings include: 1. A review of the laboratory's American Proficiency Testing (API) PT records revealed that the laboratory director/designee failed to sign the attestation statement for 2026 Event One. 2. An interview on 06.08.2026 at 11:40 a.m. with the technical consultants (TC1 and TC2) confirmed the above survey findings.</p>
D6032	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14)</p> <p>(e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's Centers for Medicare & Medicaid Services Laboratory Personnel Report (FORM CMS-209), personnel records, and staff</p>

interviews, the laboratory director failed to define the duties and responsibilities of one of two technical consultants. The findings include: 1. A review of the FORM CMS-209 revealed two technical consultants (TC1 and TC2) listed. 2. A review of the laboratory's personnel records revealed no job description or list of duties and responsibilities defined for TC2. 3. An interview on 06.08.2026 at 11:40 a.m. with TC1 and TC2 confirmed the above survey findings.