

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2213617	(X3) Date Survey Completed 09/09/2022
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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by:</p> <p>===== Based on review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records, the Centers for Medicare and Medicaid Services Form 209 Laboratory Personnel Report (CMS-209) and interview with the laboratory technical consultant, determined that PT samples were not tested by all testing personnel listed on the CMS-209 in 2020, 2021, and 2022. The findings include: 1. Review of the laboratory's API Proficiency Testing Attestation records revealed only one of three testing personnel's signature as testing PT samples (2020 Event 2 and 3; 2021 Event 1, 2 and 3; 2022 Event 1 and 2). 2. Review of the CMS-209 revealed three personnel who perform patient testing. 3. Interview with the technical consultant on September 9, 2022 at 11:30 am confirmed that PT samples were not tested by all testing personnel listed on the CMS-209 for 7 events in 2020, 2021, and 2022. =====</p>