

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0161435	(X3) Date Survey Completed 03/05/2025
Name of Provider or Supplier Shaker Pediatrics Pc	Street Address, City, State 10 Century Hill Drive Suite 5, Latham, NY	
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
D2014	<p>TESTING OF PROFICIENCY TESTING SAMPLES</p> <p>(b)(6) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of College of American Pathologists (CAP) proficiency testing (PT) reports as well as interview with the Testing Personnel (TP), the laboratory failed to complete the attestation statement provided by the PT program, signed by the analyst and Laboratory Director (LD), documenting that PT samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the PT event. FINDINGS: 1. There was no documentation of TP and LD signature and date of signature on the CAP PT attestation statements for the third event of 2022 as well as the first, second, and third events of 2023 and 2024. 2. The TP confirmed the findings on March 5, 2025, at approximately 3:00 P.M.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p>

	<p>This STANDARD is not met as evidenced by: Based on review of competency assessment records, Standard Operating Procedures (SOPs), as well as interview with the TP, the laboratory failed to perform and document TP training and competency assessment. FINDINGS: 1. There was no documentation of S.M. TP training and competency assessment for 2022, 2023, 2024, and 2025. 2. This is contrary to instructions included in the current, approved SOPs. 3. The TP confirmed the findings on March 5, 2025, at approximately 11:30 A.M.</p>
<p>D5413</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on direct observations, review of SOPs, manufacturer's package inserts, lack of room temperature and humidity records, as well as interview with the TP, the laboratory failed to monitor and document ambient room temperature and humidity in the area where waived and non-waived test materials were stored, patient specimens processed, and testing performed. FINDINGS: 1. There was no documentation of ambient room temperature and humidity for the area where waived and non-waived test materials were stored, patient specimens processed, and testing performed. 2. No thermometer/humidistat was present in the area for monitoring ambient temperatures. 3. The current, approved SOPs did not include instructions for performing such activity. 4. The TP confirmed the findings on March 5, 2025, at approximately 2:30 P. M.</p>
<p>D6030</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)</p> <p>(e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;</p> <p>This STANDARD is not met as evidenced by: Based on review of personnel competency performance records, SOPs, as well as interview with TP, the LD failed to comply with current, approved policies to assure TP competency. Refer to D5209.</p>