

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0311228	(X3) Date Survey Completed 04/15/2026
Name of Provider or Supplier Knoxville Pediatric Associates, Pc	Street Address, City, State 245 Joule Street, Alcoa, 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
D6079	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's Aspen Web 116 database specialties, the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (Form CMS-116), lack of documentation, and staff interview, the laboratory director failed to ensure compliance with 493.51(c) which requires laboratories to notify the state agency of deletions or changes in test methodologies included in a specialty or subspecialty, or both, within six months of the change, when the laboratory stopped performing testing in the sub-specialty of bacteriology in November 2024 and failed to notify the state agency of the change. The findings include: 1. A review of the Aspen Web 116 database revealed the laboratory's CLIA certification included the sub-specialty of bacteriology. 2. A review of the Form CMS-116 submitted for the survey on 04.15.2026 did not include bacteriology as a specialty. 3. Documentation of state agency notification for the deletion of bacteriology was not available on the date of the survey (04.15.2026). 4. An interview on 04.15.2026 at 8:30 a.m. with the nurse manager confirmed that the laboratory ceased testing for bacteriology in November 2024 and failed to notify the state agency of the changes.</p>