

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D2295608	(X3) Date Survey Completed 03/31/2025
Name of Provider or Supplier Families First Pediatrics - Stanbury Park	Street Address, City, State 5136 North Cambridge Way, Stansbury Park, UT	
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
D6000	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: _ Based on record review and interview with laboratory staff, the laboratory director failed to provide management and direction to the laboratory by failure to ensure the verification of laboratory procedures are performed to determine the accuracy, precision, and other pertinent performance characteristics of methods. (See D6013) _</p>
D6013	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii)</p> <p>(e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and</p> <p>This STANDARD is not met as evidenced by: _ Based on lack of documentation for new instrument verification of performance specifications and interview with the laboratory manager, the laboratory director failed to ensure verification procedures were adequate for approximately 2100 tests performed annually on the Piccolo Xpress Chemistry Analyzer since the laboratory's effective date of 12/13/2023. Findings include: 1. The laboratory record review failed to include the signature and date the director approved the accuracy, precision, reportable range and normal range evaluations performed for the Piccolo Xpress chemistry analyzer before reporting of patient test results. 2. In an interview conducted on 03/31/2024 at approximately 12:22 PM, the laboratory manager</p>

confirmed the laboratory failed to perform verification of performance specification for the Piccolo Xpress Chemistry Analyzer before reporting patient test results.