

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D2288168	(X3) Date Survey Completed 07/22/2024
Name of Provider or Supplier Families First Pediatrics - West Jordan	Street Address, City, State 5459 West 7800 South Ste 100, West Jordan, 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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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: (1) Water quality. (2) Temperature. (3) Humidity. (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 document review, direct observation, and interview with Testing Personnel 2 (TP2), room temperature and humidity of the laboratory was not monitored and documented since the laboratory's effective date of 08/22/2023. The laboratory performed approximately 1800 chemistry tests annually on the Piccolo Xpress Chemistry Analyzer. Findings include: 1. Document review of the Piccolo Xpress Chemistry Analyzer Operator's Manual revealed the chemistry analyzer required an operating environment between 15C to 32C and relative humidity noncondensing between 8 to 80%. 2. Direct observation of the laboratory on 08/22/2023 at 3:25 PM failed to locate a thermometer, hygrometer, and an ambient laboratory conditions log. 3. In an interview on 08/22/2023 at 3:30 PM, TP2 confirmed room temperature and humidity were not monitored and documented for the Piccolo Xpress Chemistry Analyzer.</p>
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it</p>

can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on record review and interview with Testing Personnel 2 (TP2), the laboratory failed to ensure verification of performance specifications of the Piccolo Xpress Chemistry Analyzer before reporting patient test results. The laboratory performs approximately 1800 chemistry tests annually. Findings include: 1. Record review on 7/22/2024 failed to produce the verification of performance specifications for the Piccolo Xpress chemistry analyzer. 2. Interview with TP2 on 7/22/2024 at approximately 3:15 PM, confirmed the laboratory failed to perform verification of performance specification for the Piccolo Xpress Chemistry Analyzer before reporting patient test results.

D5805

TEST REPORT

CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on record review and interview with Testing Personnel 2 (TP2), the laboratory failed to list the correct address of the laboratory's location since the laboratory's effective date of 08/22/2023. The laboratory performs approximately 1800 chemistry tests annually. Findings include: 1. The patient visit report packet that includes laboratory results stated the address of the laboratory as 1320 W SO JORDAN PKWY, SOUTH JORDAN, UT 84095-8847. 2. At the time of the survey, the location of the laboratory was at 5459 W 7800 S, WEST JORDAN, UT 84084-6023. 3. Interview with the TP2 on 08/22/2023 at 3:25 PM confirmed the patient visit report packet that includes laboratory results did not reflect the actual testing site of where testing was performed since the laboratory's effective date of 02/22/2023.