

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D2099541	(X3) Date Survey Completed 01/16/2020
Name of Provider or Supplier Families First Pediatrics - Riverton	Street Address, City, State 4651 W 13400 S, Riverton, 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
D5461	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(6)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Perform control material testing as specified in this paragraph before resuming patient testing when a complete change of reagents is introduced; major preventive maintenance is performed; or any critical part that may influence test performance is replaced. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on patient test records review, quality control records review, and interview with staff, the laboratory failed to ensure they performed two levels of quality control prior to testing patient samples following a complete change of Piccolo test reagents for 1 of 11 test cartridge lot number changes reviewed. The laboratory performed approximately 3 to 5 CMP tests per day using a serum specimen. Findings include: 1. Patient test records included documentation the laboratory used lot number 9251BB7 for patient 65460 on 10/02/2019. 2. Quality control records included documentation the laboratory performed quality control for lot number 9251BB7 on 10/04/2019. 3. In an interview conducted on 01/16/2019 at approximately 12:30 P.M. staff stated they were unaware they performed quality control after they testing patient samples.</p>
D5783	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The</p>

laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:

Based on quality control records review, lack of corrective actions, patient test records review, and interview with staff, the laboratory failed to document corrective actions taken when the high level of bilirubin quality control was out of range 4 of 11 test days reviewed. Findings include: 1. Quality control records included documentation the acceptable range for the high level of total bilirubin quality control was 30.0 mg/ml plus or minus 20% (6 mg/dl). 2. Quality control records included documentation the high level of total bilirubin control was out of range on , 05/15/2019 at 15.9 mg//dl, on 06/17/2019 at 14.9 mg/dl, on 07/29/2019 at 7.7 mg/dl; and on 9/11/2019 at 5.7 mg/dl. 3. The laboratory performs from 0 to 4 Piccolo CMP serum testing for total bilirubin tests per day. 4. In an interview with staff on 01/16/2019 at approximately 12:30 P.M. staff stated they failed to identify the control was out of range for acceptability and the laboratory failed to follow a corrective action plan for the out of range values and to reevaluate all patients tested between the last acceptable quality control run and 10/04/19 when the error was detected..