

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 46D0969151	<b>(X3) Date Survey Completed</b> 01/14/2020
<b>Name of Provider or Supplier</b> Wasatch Pediatrics - Draper Office	<b>Street Address, City, State</b> 114 E 12450 S Ste 100, Draper, UT	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5461</b>	<p><b>CONTROL PROCEDURES</b> 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 testing records review, quality control records review, and interview with staff, the laboratory failed to perform control materials before resuming patient testing when a complete change of reagents is introduced for 1 of 11 new lot numbers of Piccolo Hepatic function test cartridges placed into use. The laboratory performed approximately 2 Hepatic function cartridge tests per day to report total and direct bilirubin tests. Findings include: 1. Patient test records reviewed included documentation patient #824 was tested on 06/18/2018 using lot number 8112AA3 for testing. 2. The quality control records review included documentation the laboratory performed quality control for lot number 8112AA3 on 06/19/2018. 3. In an interview with staff on 01/14/2020 staff confirmed the quality control was performed after the patient was tested and results were reported for the new lot number.</p>
<b>D5791</b>	<p><b>ANALYTIC SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p>

This STANDARD is not met as evidenced by:  
Based on Individual Quality Control Plan (IQCP) review, lack of documentation, and interview with staff, the laboratory failed to follow their IQCP to monitor Piccolo test records, in conjunction with the laboratory IQCP, to determine the reduced frequency of quality control performance was adequate for 1 of 2 years of total and direct bilirubin testing reviewed (2019). Findings include: 1. The laboratory IQCP failed to include documentation the director reviewed the IQCP in 2019. 2. In an interview with staff on 01/14/2020 at approximately 1:30 P.M. staff confirmed the director did not evaluate the IQCP in 2019 to ensure the laboratory's quality control performance provided sufficient information to continue a reduced quality control performance to once per lot number and/or once per month and still have confidence that the test system is functioning properly.

**D6054**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:  
Based on competency assessment records review, lack of documentation, and interview with staff, the technical consultant failed to ensure competency evaluations were performed annually for 1 of 2 years of competency evaluations reviewed (2019). Findings include: 1. Competency assessments records failed to include documentation competency evaluations were performed for 5 of 5 testing personnel in 2019. 2. The laboratory manager confirmed in an interview conducted on 01/14/2020 at approximately 1:30 P.M. competency evaluations for staff who had more than one year's experience performing moderate complexity testing did not have competency evaluations performed in 2019.