

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 46D1060326	<b>(X3) Date Survey Completed</b> 03/28/2019
<b>Name of Provider or Supplier</b> Wee Care Pediatrics-Roy	<b>Street Address, City, State</b> 5682 S 3500 W Suite A, Roy, 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>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on instrument internal control record review, lack of documentation and interview with staff, the laboratory failed to retain Piccolo instrument daily internal control test performance documentation for 1 of 9 test days reviewed. The laboratory performs approximately 2 to 4 bilirubin tests per week. Findings include: 1. The Piccolo manufacturer requires daily "IQC" performance for instrument function checks. 2. The laboratory failed to retain the " IQC" instrument printouts for a liver function panel test performed on 04/11/2018 for patient date of birth 04/04/2018. 3. In an interview with staff on 03/28/2019 staff stated they forgot to print the internal control and were unable to retrieve the "IQC" data on the day of survey due to the instrument having been returned to the manufacturer on 5/18/2018 to 06/28/2018 for repairs and memory was wiped clean.</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> <p>This STANDARD is not met as evidenced by:</p>

Based on Individual Quality Control Plan (IQCP) review, lack of documentation and interview with staff, the laboratory failed to establish and follow a written policy for review of the IQCP on a regular basis to identify problems that may require more frequent quality control performance. The laboratory performed approximately 1000 piccolo liver function tests annually. Findings include: 1. The laboratory implemented an IQCP for routine chemistry testing using the Piccolo liver function testing cartridge for total bilirubin testing for neonatal patient samples in 2017. The laboratory director failed to review the IQCP to determine if the laboratory bilirubin testing required more frequent quality control performance to ensure the Piccolo bilirubin testing was performing accurately. 2. In an interview with staff on 03.28/2019 at approximately 3:00 P.M. staff confirmed the director had not reviewed the IQCP since it was implemented.