

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  46D0523879	<b>(X3) Date Survey Completed</b>  07/27/2018
<b>Name of Provider or Supplier</b>  Wasatch Pediatrics-Cottonwood	<b>Street Address, City, State</b>  5770 S 250 E #290, Murray, 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>D2016</b>	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on proficiency testing records review and confirmation by staff, the laboratory failed to achieve successful proficiency testing participation for 1 of 1 test analyte Blood Urea Nitrogen, by failing to receive a score of greater than or equal to 80% for the 1st and 2nd American Association of Bioanalysts proficiency testing events of 2018. (See D2096)</p>
<b>D2096</b>	<p>ROUTINE CHEMISTRY CFR(s): 493.841(f)</p>

Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on proficiency testing records review and confirmation by staff, the laboratory failed to achieve successful proficiency testing performance for 1 of 1 test analytes, Blood Urea Nitrogen (BUN), by failing to receive a score of greater than or equal to 80% for the 1st and 2nd American Association of Bioanalysts (AAB) proficiency testing events of 2018. Findings include: 1. Proficiency testing records review included documentation the laboratory failed the 1st AAB proficiency test of 2018 (Q1) for BUN scoring 60%. The laboratory reported specimen #4 as 18 mg/dl and reported specimen #5 as 25 mg/dl. The acceptable range for specimen #4 was 19-23 mg/dl and for specimen #5 was 26-31 mg/dl. 2. Proficiency testing records review included documentation the laboratory failed the 2nd AAB proficiency test of 2018 (Q2) for BUN scoring 60%. The laboratory reported specimen #3 as 33 mg/dl and reported specimen #5 as 30 mg/dl. The acceptable range for specimen #3 was 34-41 mg/dl and for specimen #5 was 31-37 mg/dl. 3. In an interview conducted on 07/27/2018 at approximately 11:00 A.M. staff confirmed the laboratory failed BUN proficiency tests in the 1st and 2nd AAB testing events. The laboratory performed approximately 0 to 4 BUN tests per month.

**D5407**

PROCEDURE MANUAL  
CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:

Based on procedure manual review, lack of documentation, and interview with staff, the laboratory director failed to sign and date as approved 1 of 3 test procedures reviewed, microscopic urinalysis, before use. The laboratory tested approximately 15 to 20 specimens per year. Findings include: 1. The procedure manual review for microscopic urinalysis failed to include the director's signature and date of approval for performing microscopic urinalysis. 2. In an interview 07/26/2018 at approximately 10:30 A.M., staff confirmed the procedure manual did not include the director's signature and date the microscopic procedure was approved.