

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  06D0514895	<b>(X3) Date Survey Completed</b>  09/27/2018
<b>Name of Provider or Supplier</b>  Boulder Valley Women's Health	<b>Street Address, City, State</b>  2855 Valmont Rd, Boulder, CO	
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>D2009</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's proficiency testing (PT) records, and staff interview, the laboratory failed to ensure PT attestation statements for Rhesus (Rh) typing were signed by the appropriate personnel for all three PT events in 2017. Findings include: a. Records showed the lab director had not signed the attestation statement for the 1st, 2nd, or 3rd PT event of 2017. b. Records showed the testing personnel had not signed the attestation statement for the 1st or 2nd PT event of 2017. c. Staff stated there had been some changes of laboratory personnel and confirmed the 2017 PT attestation statements had not been signed by appropriate personnel as required by federal CLIA regulation.</p>
<b>D2015</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during</p>

the PT event.

This STANDARD is not met as evidenced by:

Based on a review of proficiency testing (PT) records and staff interview, the laboratory failed to document each step in the testing and reporting of results for Rhesus (Rh) typing PT samples for the 1st and 3rd event of 2017. Findings include: a. PT records for the 1st and 3rd event of 2017 did not contain a copy of the test results reported to the PT provider. b. Staff confirmed the laboratory had not maintained a copy of all records of proficiency testing in 2017 as required by federal CLIA regulation.

**D5211**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**

CFR(s): 493.1236(a)

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records and staff confirmation, the laboratory failed to document the review and evaluation of the scores obtained on all three of the PT challenges of 2017 for Rhesus (Rh) typing.