

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 02D0641380	(X3) Date Survey Completed 08/22/2019
Name of Provider or Supplier Valley Medical Care Pc	Street Address, City, State 1801 Salmon Creek Lane, Juneau, AK	
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
D2003	<p>ENROLLMENT CFR(s): 493.801(a)(2)(ii)</p> <p>For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1)</p> <p>This STANDARD is not met as evidenced by: Based on Proficiency Testing (PT) Record review and staff interview, the laboratory did not establish and maintain the accuracy for urine microalbumin and creatinine. Findings: 1. The laboratory performs approximately 375 patient urine microalbumin and creatinine tests on the DCA Vantage analyzer annually. 2. The laboratory did not establish and maintain the accuracy of microalbumin and creatinine through proficiency testing or other means. 3. The laboratory was unaware that urine microalbumin and creatinine are categorized by the FDA as Moderate Complexity. 4. The Technical Consultant confirmed these findings on 8/22/19 at 4:30 pm.</p>
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Based on Proficiency Testing (PT) record review and staff interview, the laboratory did not evaluate ungraded PT results. Findings: 1. The laboratory subscribes to PT</p>

from the American Proficiency Institute. 2. The 2018-1 Miscellaneous Chemistry Ferritin (AI-01, AI-02, AI-03) and Vitamin D results (IAT-01, IAT-02, and IAT-03) were not graded due to the incorrect analyzer peer group entered. The reported results were not evaluated by the laboratory for acceptability with the correct analyzer peer group. 3. The 2018-2 Hematology Blood Cell Identification BCI-10 was reported by the laboratory as 'Neutrophil, hypersegmented'. The performance was not graded and the PT provider report stated 'see Data Summary' for discussion and acceptable response. This result was not reviewed for acceptability. 4. The 2019-1 Hematology Coagulation Urine Sediment (US-02) was reported by the laboratory as 'Cast (hyaline) and Vaginal Wet Preparation (VKP-01) was reported as 'No yeast seen'. The performance for these tests were not graded and the PT provider report stated 'see Data Summary' for discussion and acceptable response. These results were not reviewed for acceptability. 5. The Technical Consultant confirmed these findings on 8/22/19 at 4:30 pm.

D6013

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(3)(ii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

This STANDARD is not met as evidenced by:

Based on review of verification data and staff interview, the laboratory director did not assure that performance characteristics including accuracy, precision, reportable range, and reference range on the Cepheid GeneXpert were completed and adequate. Findings: 1. The laboratory began testing patient samples for Influenza A and B, Group A Strep, Group B Strep, Chlamydia (CT), and Neisseria gonorrhoeae (NG) on the Cepheid GeneXpert analyzer in May 2018. 2. There were no verification records available for Influenza A and B. 3. There was no documentation the Laboratory Director reviewed any of the quality control, verification panels, or patient results used for the verifications, or approved of the use of the Cepheid GeneXpert for patient testing. 4. The Technical Consultant confirmed these findings on 8/22/19 at 4:30 pm.