

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 02D0717499	(X3) Date Survey Completed 08/27/2018
Name of Provider or Supplier Harbir S Makin Md	Street Address, City, State 3300 Providence Drive 114, Anchorage, 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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing record review and staff interview, the laboratory did not establish and maintain the accuracy of its urine tests at least twice annually. Findings: 1. A review of the API Proficiency testing for 2016, 2017, and 2018 showed the laboratory discontinued proficiency testing for urine creatinine, microalbumin, and urine sediments in 2018 and did not have other procedures to establish and maintain their accuracy. 2. The lab performed 120 urine creatinine and microalbumin tests on the DCA Vantage analyzer and 120 urine sediments in 2017. 3. The Laboratory Director confirmed these findings during an interview on 8/27/18 at 12:30 pm.</p>
D6029	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</p> <p>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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of education, training and competency records and staff interview, the lab director did not ensure the laboratory testing personnel had appropriate education and training for non-waived testing. Findings 1. The testing person was hired in August of 2017. 2. The testing person had a foreign diploma and did not have an evaluation of her credentials determining equivalency to a United States education. 3. There was no documented training for the testing person for any laboratory testing. 4. The laboratory performed 28,402 tests in 2017. 5. The Laboratory Director confirmed these findings during an interview on 8/27/18 at 12:30 pm.

D6053

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 semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Based on review of training and competency records and staff interview, the technical consultant failed to evaluate and document the performance of the testing person at least semiannually during the first year the individual tests patient specimens. Findings: 1. The testing person was hired in August of 2017 2. The technical consultant failed to document the testing person's competency semiannually during the first year of patient testing. 3. The Laboratory Director confirmed these findings during an interview on 8/27/18 at 12:30 pm.