

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 02D0717499	(X3) Date Survey Completed 07/29/2020
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
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: 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 May of 2020. 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.. The laboratory performed approximately 2,000 tests per month in 2020. 5. The Laboratory Director confirmed these findings during an interview on 7/29/20 at 12:30 pm.</p>