

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 02D0873639	(X3) Date Survey Completed 02/10/2021
Name of Provider or Supplier Cdc Arctic Investigations Program	Street Address, City, State 4055 Tudor Centre Drive, 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
D3007	<p>FACILITIES CFR(s): 493.1101(b)</p> <p>The laboratory must have appropriate and sufficient equipment, instruments, reagents, materials, and supplies for the type and volume of testing it performs.</p> <p>This STANDARD is not met as evidenced by: Based on record review of patient testing, proficiency testing records from the College of American Pathologists (CAP) and interview with the laboratory technical supervisor (TS) on 02/10/2021, the laboratory failed to have appropriate and sufficient reagents, materials, and supplies for the Hepatitis testing performed. The findings include: 1. The laboratory performs Hepatitis B core antibody testing for research projects, in which the individual test reports are provided to the research participants. 2. The laboratory has not been able to perform proficiency testing (PT) for 3/3 testing events in 2020, 2/3 testing events in 2019, and 3/3 testing events in 2018 due to no reagents available for testing. 3. The laboratory has not been able to evaluate 2/2 testing personnel for annual competency for 2018, 2019 and 2020 assigned to Hepatitis B testing due to lack of reagents. 4. The laboratory technical supervisor confirmed by interview on 02/10/2021 at 11:00 a.m. that the laboratory only purchases the Hepatitis reagents when there is a research study being performed and does not maintain the reagents in house to perform PT or annual personnel competency evaluations. 5. The laboratory reports performing no patient testing since January of 2019 (30), and no patient testing in 2018.</p>
D6120	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8)</p> <p>(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8)</p>

Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on employee record review, the CMS-209 personnel report, and interview with the laboratory technical supervisor (TS) on 02/10/2021, the laboratory failed to evaluate the competency of 2/2 testing personnel performing Hepatitis B antibody testing and assuring that the testing personnel maintain their competency to perform Hepatitis B antibody testing. Findings include: 1. The laboratory CMS-209 personnel form lists two testing personnel for Hepatitis B testing. The laboratory has no documentation of annual competency for 2 of 2 testing personnel for 2020, 2019 and 2018. 2. The laboratory is enrolled in the College of American Pathologists (CAP) proficiency testing (PT), but has not performed 3/3 PT events for 2020, 2/3 PT events in 2019, 3/3 PT events in 2018, resulting in inability to evaluate testing personnel annual competency. 3. The laboratory technical supervisor confirmed by interview on 02/10/2021 at 11:00 a.m., that the laboratory does not have annual competency for the two personnel assigned to perform Hepatitis B antibody testing due to lack of reagent. 4. The laboratory reported performing 30 Hepatitis B antibody tests in 2019.