Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	02D0873639	06/30/2022
Name of Provider or Supplier	**Street Address, City, State**	
Cdc Arctic Investigations Program	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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a surveyor's review of the CMS-209 laboratory personnel form and interview with the technical supervisor on June 30, 2022 the laboratory failed to establish and follow written policies and procedures to assess competency for the technical and general supervisor duties annually. Findings include: 1. Review of CMS 209 and personnel competency records revealed that one technical supervisor, and two general supervisors, did not have annual competencies performed to assess their ability to perform the duties and responsibilities as Technical Supervisor or General Supervisors as delegated by the laboratory director for 2022. 2. A interview conducted on June 30, 2022 at approximately 9:00 AM with the technical supervisor confirmed the lack of competency assessments. It was stated that she believed the delegation of duties documentation was a competency assessment.
D5219	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2) At least twice annually, the laboratory must verify the accuracy of any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on a surveyor's review of the Proficiency Testing(PT) policy, competency

	assessment records and an interview with the technical supervisor, the laboratory failed to have a system for verifying the accuracy of the testing for H.pylori in gastric biopsy at least twice yearly for the last two years. Findings: 1.A review of the PT policy revealed that the laboratory performed an internal assessment for accuracy of testing due to lack of availability of a suitable PT product. 2. A review of personnel competency records, revealed the laboratory did not perform their internal method for assessing the accuracy of culture results for H. pylori and susceptibility testing twice annually. Assessments were performed once annually as follows: a. Identification of Helicobacter pylori- 12/20/21 & 11/4/20 b. H.pylori susceptibility testing- 11/22/21 & 10/21/20 c. H.pylori Levofloxacin susceptibility- 7/2/21 & 12/10/20 3. An interview conducted on June 30, 2022 at approximately 10:00 AM with the technical supervisor, confirmed that the laboratory does not assess the accuracy of testing twice annually.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on a surveyor's review of the patient test reports and an interview with the technical supervisor, the laboratory failed to include pertinent reference intervals, normal or expected values on the final test reports. Findings: 1. A review of final test reports for cultures on gastric biopsies revealed that no normal or expected values were available on the final test reports. 2. The laboratory test menu changes according to the needs of the research team and other specialties/analytes are added and removed to the CLIA certificate that also would not contain reference intervals, normal or expected values on the final test reports. 3. An interview conducted on June 30, 2022 at approximately 9:30 AM with the technical supervisor, confirmed that the final reports for all analytes do not include reference intervals, normal or expected values or any comments. 4. The laboratory reports performing approximately 17 patient samples in 2022.