

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  02D0640982	<b>(X3) Date Survey Completed</b>  03/30/2021
<b>Name of Provider or Supplier</b>  Kodiak Area Native Association	<b>Street Address, City, State</b>  2414 Mill Bay Road, Kodiak, AK	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The laboratory is in substantial compliance with the CMS Interim Final Rule (CMS-3401-IFC) on Coronavirus Disease 2019 (COVID-19) Public Health Emergency (PHE) effective August 25, 2020. No deficiencies were cited.
<b>D5411</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on observation and Lab Director Interview, the laboratory failed to follow manufacturer's instructions for SARS-CoV-2 testing on the Cepheid GeneXpert. Findings: 1. The laboratory was using the Cepheid GeneXpert for SARS-CoV-2 testing. 2. On 3/30/2021 at 11:00 am it was observed that patient samples were pooled prior to running on the GeneXpert. 3. The GeneXpert Instructions for Use states "Authorized laboratories using your product will use your product as outlined in the Xpert Xpress SARS-CoV-2 Instructions for Use - For Use with GeneXpert Dx or GeneXpert Infinity systems. Deviations from the authorized procedures, including the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use the Xpert Xpress SARS-CoV-2 test are not permitted." 4. The laboratory began pooling specimens on 10/13/2020 and discontinued the pooling practice at the time of the survey. 5. The laboratory performs approximately 4500 SARS-CoV-2 tests annually. 6. The laboratory director confirmed these findings on 3/30/2021 at 12:00 pm.</p>