

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 02D0640982	(X3) Date Survey Completed 11/02/2022
Name of Provider or Supplier Kodiak Area Native Association	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of 2022 patient test log and interview with the laboratory director, the laboratory did not test, at a minimum, two levels of external control material to monitor the accuracy and precision of the Quidel QuickVue One-Step HCG Combo assay each day of patient testing. Findings include: 1. The 2022 patient log for HCG tests revealed patient HCG tests performed on 1/19/22, 1/21/22, 4/21/22, 5/4/22, 6/7/22, 6/17/22, 7/13/22, 7/19/22, 9/1/22, 9/13/22, 9/27/22, 10/11/22, 10/20/22, and 11/28/22 with no corresponding external control documentation. 2. The laboratory director confirmed on 11/2/22 at 12:00 PM the external controls were not run on the days patients were tested. 3. The laboratory reported performing 17 serum HCG tests annually.</p>