

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 02D0917382	(X3) Date Survey Completed 07/06/2022
Name of Provider or Supplier Peacehealth Medical Group	Street Address, City, State 1800 Craig-Klawock Highway, Craig, 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 a review of chemistry quality control records, a patient report, and an interview with Testing Person 1 (TP #1), it was determined the laboratory failed to perform and document two levels of external quality control each day patient specimens are tested using non-waived CG4+ cartridges on the Abbott i-STAT analyzer. Findings: 1. A review of patient records showed i-STAT tests were performed on 5/25/2022. The laboratory reported this had been the only patient tested at the time of the survey since the initiation of moderate complexity testing on 4/14 /2022. 2. Quality control records records did not show documentation of external i-STAT controls for the patient testing date 5/25/2022 . 3. TP #1 confirmed these findings on 7/7/2022 at 15:30.</p>