Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 02D1088324	**(X3) Date Survey Completed** 07/20/2021
Name of Provider or Supplier Creekside Family Health Clinic, Inc	**Street Address, City, State** 1225 Tongass Ave, Ketchikan, 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**
D0000	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.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of records for the Bayer DCA Vantage analyzer and interview with the technical consultant, the laboratory did not have documentation of verification of accuracy, precision, or reportable range for urine Microalbumin on the Bayer DCA Vantage. Findings include: 1. The laboratory began testing Microalbumin on the DCA Vantage on 8/17/2020. There was no verification documentation available at the time of the survey. 2. The laboratory performs approximately 30 microalbumin tests annually. 3. The technical consultant confirmed these findings on 7/20/21 at 11:30 am.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) 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. This STANDARD is not met as evidenced by: Based on review of patient testing and quality control (QC) records from the Bayer DCA Vantage analyzer and interview with the technical consultant, the laboratory did not test, at a minimum, two levels of external quality control (QC) material to monitor the accuracy and precision of microalbumin on 7 of 7 patient testing days in 2021 (3 /10, 3/12, 4/7, 5/21, 6/7, 7/7, and 7/8). Findings include: 1. Review of the 2021 Bayer DCA Vantage patient testing and QC records indicated the laboratory performed microalbumin patient testing on 7 days in 2021 and did not perform QC. 2. The technical consultant confirmed these findings on 7/20/21 at 11:30 am.