Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	02D0641830	04/13/2021
Name of Provider or Supplier	**Street Address, City, State**	
Camai Community Health Center Inc	2 School Road, Naknek, 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.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on procedure manual review and testing person interview, the laboratory failed to have a written procedure for microscopic wet mounts and KOH slides. Findings include: 1. The laboratory performs approximately 20 wet mounts and KOH slides annually. 2. The laboratory does not have a written procedure for performing these tests. 3. The testing person confirmed these findings on 4/13/21 at 11:30 am.
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 from the Cepheid GeneXpert analyzers and testing person interview, the laboratory did not have documentation of verification of accuracy, precision, or reportable range for the SARS-CoV-2 and the SARS-CoV-2/Flu/RSV assays on the Cepheid GeneXpert analyzers. Findings include: 1. The laboratory began testing SARS-CoV-2 on a Cepheid GeneXpert (serial number 837036) in June of 2020 and discontinued it's use in October 2020. There was no verification documentation available. 2. The laboratory installed 4 new Cepheid GeneXperts (serial numbers, 844556, 837039, 844646, and 844558) in November 2020 and began testing patients using the SARS-CoV-2 and the SARS-CoV-2/Flu/RSV assays in January 2021. There was no verification documentation available. 3. The laboratory performs approximately 4000 SARS-CoV-2 tests annually. 4. The testing person confirmed these findings on 4/13/21 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 quality control review of the Cepheid GeneXpert assays and testing person interview, the laboratory did not test, at a minimum two levels of external quality control (QC) material to monitor the accuracy and precision of Cepheid GeneXpert assays from June 2020 to survey date. Findings include: 1. QC records for Cepheid GeneXpert test system showed external controls were performed with each new lot or shipment as indicated in the manufacturer's package insert. 2. The laboratory performs approximately 4000 SARS-CoV-2 annually. 3. The testing person confirmed these findings on 4/13/2021 at 11:30 am.
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 testing person interview and patient record review, the laboratory failed to provide normal values for male, female, and pediatric patients for hemoglobin and hematocrit for 2 of 2 records reviewed (MRN 4683 and 3878). Findings include: 1. The laboratory uses a Sysmex Poch-100i for hemoglobin and hematocrit testing. 2. The results from the Poch-100i are manually entered in the AthenaHealth electronic medical record (EMR). 3. Review of hemoglobin and hematocrit test results from the

	EMR for male and female patients revealed the reference ranges were not age-or gender-specific. 4. The testing person stated in an interview on 4/13/2021 at 11:30 am that the EMR was not programmed with separate male, female, or pediatric reference ranges for hemoglobin and hematocrit. 5. The laboratory performs approximately 1000 hemoglobin and hematocrit tests annually.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on testing person interview and review of training and competency records for 2020 and 2021, the laboratory director did not document training and competency assessments for one of one testing personnel performing microscopic wet mounts or KOH slides. Findings include: 1. The laboratory performs approximately 20 wet mounts and KOH slides annually. 2. The laboratory does not have documentation of training or competency assessment for the testing person performing wet mounts and KOH slides. 3. The laboratory director confirmed these findings on 4/13/21 at 11:30 am.