Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 02D0641826	**(X3) Date Survey Completed** 05/05/2021
Name of Provider or Supplier Cordova Community Medical Center	**Street Address, City, State** 602 Chase Avenue, Cordova, 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.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of the laboratory's 2019 American Proficiency Institute (API) proficiency testing (PT) records and an interview with the technical consultant, the laboratory failed to maintain and provide the PT provider's participant results and document their review for nine of fourteen PT events. Findings include: 1. The proficiency records for 2019 did not include the participant results or review for these surveys: a. 2019 1st event: Chemistry Core and Chemistry Miscellaneous participant reports missing b. 2019 2nd event: Chemistry Core, Chemistry Miscellaneous, Hematology/Coagulation, Immunology, and Microbiology participant reports missing c. 2019 3rd event: Chemistry Core, Immunology, and Microbiology participant reports missing 2. The laboratory performs approximately 6,600 Chemistry tests, 2,550 Hematology tests, and 3,700 Microbiology tests annually. 3. The technical

	consultant confirmed the participants reports were missing and had not been reviewed, on 5/5/21 at 11:30 am.
D3025	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(d) Investigation of transfusion reactions. The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities. This STANDARD is not met as evidenced by: Based on review of laboratory blood transfusion policies, and interview with the technical consultant, the laboratory did not have a procedure for the completion of patient testing, including cross-matches, following emergency transfusions. Findings include: 1. The laboratory's policy # LAB 104 entitled 'Transfusion of O negative, Uncrossmatched Blood' did not include instructions for obtaining the subsequent completion patient testing including cross-matches following emergency transfusions. 2. The laboratory performs approximately one emergency transfusion event per year. 3. The technical consultant confirmed these findings on 5/5/21 at 11:30 am.
D3035	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)(ii) In addition, the laboratory must retain immunohematology records, blood and blood product records, and transfusion records as specified in 21 CFR 606.160(b)(3)(ii), (b)(3)(iv), (b)(3)(v), and (d). This STANDARD is not met as evidenced by: Based on a review of immunohematology patient results and interview with technical consultant, the laboratory failed to maintain records of subsequent completion of cross-matches in two of two emergency transfusions reviewed. Findings include: 1. A review of two of two emergency transfusions (patient #BB966674 on transfused on 10/31/20 and patient #BB966669 on transfused on 2/27/19) did not contain compatibility records between the recipient and donor blood units. 2. The laboratory performs approximately one emergency transfusion event per year. 3. The technical consultant confirmed these findings on 5/5/21 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 the Sysmex XP-300 Hematology analyzer verification records from November 2018, and an interview with the technical consultant, the laboratory failed to verify the manufacturer's specifications for precision of complete blood analytes. Findings include: 1. The laboratory had no records showing precision was assessed for red blood cell counts, white blood cell counts, hemoglobin, hematocrit, platelet counts, and differential as part of the verification prior to patient testing. 2. The laboratory began using the Sysmex XP-300 for testing patients on 11/21/18. 3. The laboratory performs approximately 2,250 hematology tests annually. 4. The technical consultant confirmed these findings on 5/5/21 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 SARS-CoV-2 assay from July 2020 to survey date, and an interview with the technical consultant, the laboratory did not test, at a minimum two levels of external quality control (QC) material to assess the test performance of the SARS-CoV-2 assay each day of patient testing. Findings include: 1. Quality control records for Cepheid GeneXpert SARS-CoV-2 showed external positive and negative controls were not performed each day of patient testing. 2. The laboratory performs approximately 2,500 SARS-CoV-2 annually. 3. The technical consultant confirmed these findings on 5/5/21 at 11:30 am.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of Alanine Aminotransferase (ALT) and Aspartate Aminotransferase (AST) quality control records for September 2020, and an interview with the technical consultant, the laboratory failed to document remedial action for 24 days in September 2020 when the ALT controls were outside the acceptable ranges and for 10 days in September 2020 when the AST controls were outside the acceptable ranges.

	Findings include: 1. The laboratory's procedure for chemistry testing entitled Lab 403 Chemistry - Alfa Wassemann ACE Alera states "control values must be in acceptable range prior to reporting patient results.' 2. The Alfa Wasserman Level 1 Chemistry Control lot number 1213 UNCM was out of acceptable range for ALT on 9/1/20, 9/2/20, 9/3/20, 9/4/20, 9/5/20, 9/6/20, 9/8/20, 9/10/20, 9/11/20, 9/12/20, 9/14/20, 9/15/20, 9/16/20, 9/17/20, 9/18/20, 9/21/20, 9/22/20, 9/23/20, 9/24/20, 9/25/20, 9/28/20, 9/29/20, and 9/30/20 without any corrective action documented. 3. The Alfa Wasserman Level 2 Chemistry Control lot number 937 UNCM was out of acceptable range for ALT on 9/2/20, 9/5/20, 9/6/20, 9/8/20, 9/12/20, 9/14/20, 9/15/20, 9/16/20, 9/17/20, 9/22/20, 9/23/20, 9/24/20, 9/25/20, and 9/28/20 without any corrective action documented. 4. The Alfa Wasserman Level 1 Chemistry Control lot number 1213 UNCM for AST was out of acceptable range on 9/1/20, 9/3/20, 9/4/20, 9/5/20, 9/6/20, 9/8/20, 9/9/20, 9/14/20, 9/15/20, 9/16/20, 9/22/20 without any corrective action documented. 5. The Alfa Wasserman Level 2 Chemistry Control lot number 937 UNCM was out of acceptable range for AST was out of acceptable range on 9/17/20 and 9/28/20 without any corrective action documented. 6. The laboratory performs approximately 350 ALT and 350 AST tests annually. 7. The technical consultant confirmed these findings on 5/5/21 at 11:30 am.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of testing personnel education records and an interview with the technical consultant, the laboratory did not obtain copies of diplomas and/or transcripts from an accredited institution for one of four testing personnel performing non-waived testing. Refer to D6065.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of testing personnel education records and an interview with the technical consultant, the laboratory did not obtain copies of diplomas and/or transcripts from an accredited institution for one of four testing personnel performing

	non-waived testing. Findings include: 1. A review of educational records revealed that one of four testing personnel hired after the previous CLIA survey on 9/18/2018 did not have an evaluation of their credentials to determine equivalency of a foreign to United States education. 2. The technical consultant confirmed these findings on 5/5 /21 at 11:30 am.