Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0713371	04/21/2021
Name of Provider or Supplier	**Street Address, City, State**	
Central Healthcare Laboratory	2901 Sillect Ave Ste 100, Bakersfield, CA	

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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of the laboratory test records on 04/21/2021 at 1:00 p.m. (survey date) for ten (10) randomly selected patients results from 01/22/2019 to 04/20/2021, proficiency testing (PT) result reports, and interview with the laboratory staff, it was determined that the laboratory failed to enroll and participate in a proficiency testing (PT) program that meets the criteria in subpart H of 42 CFR part 493 and is approved by HHS. The findings included: 1. The laboratory performed routine chemistry testing [(serum creatinine (CR), sodium (Na) and potassium (K)] using the i-STAT 1 portable non-waived analyzer and failed to show evidence of enroll in a PT program for routine chemistry testing events using a CMS approved PT program for 2019 and 2020 (which meets the criteria in subpart H of 42 CFR part 493). The laboratory analyzed and reported routine chemistry patient test results during the approximate time of non-enrollment in a proficiency testing (PT) program. 2. The laboratory staff confirmed on 04/21/2021 4:00 p. m. that patient test results were reported for the routine chemistry analytes serum creatinine, sodium, and potassium yet the laboratory had not enrolled in an accredited PT program for 2019 and 2020. 3. The laboratory

	annual testing declaration (04/20/2021) estimated total volume of 1,000 routine chemistry (serum creatinine) results as well as in 2019 a total of nine (9) sodium and potassium were resulted and reported.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on review of ten (10) randomly selected patient (PT) test results on 04/21/2021 at 1:00 p.m. (survey date) for serum creatinine (CR), sodium (Na) and potassium (K) using the i-STAT 1 portable non-waived analyzer from 01/22/2019 to 04/20/2021, patient final testing report (medical records), and interview with a laboratory staff, it was determined that on patients testing records reviewed, the laboratory failed to establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimem from the time of collection or receipt of the specimen through completion of testing and reporting of results. The findings included: 1. Review of one (1) patient results on 04/02/2019, PT # 218999 for CR, Na and K transcribed on patent test result log were not documented in the final patient report (MR). 2. On 04/21/2021, 4:00 p. m., the laboratory staff confirmed that the manually transcribed patient test results found on the patient's test log not documented in the patient's final report (MR). 3. The laboratory annual testing declaration (04/20 /2021) estimated total volume of 1,000 routine chemistry (serum creatinine) results as well as in 2019 a total of nine (9) sodium and potassium were resulted and reported.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on record review of the laboratory's hematology activated clotting time low range testing (ACT-LR) test records on 04/21/2021 at 1:00 p.m. (survey date), for eight (8) randomly selected patient reports from 01/08/2019 to and an interview with the laboratory staff on 04/21/2021, the laboratory failed to establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1), "to at least twice annually verify the accuracy of any test or procedure it performs that is not included in subpart I". The findings included: 1. The laboratory failed to enroll in a proficiency testing (PT) program or verify by an alternative performance the accuracy of the ACT-LR tests performed in 2019. 2. The laboratory staff confirmed on 04/21 /2021 at 4:00 p.m. that the laboratory failure to perform and document twice annual verification for the ACT-LR tests reported and resulted in 2019. 3. Based on the laboratory staff declaration on 04/21/2021 estimated 70 ACT-LR tests were reported and resulted in 2019.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT

	CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of eighteen (18) random patient reports on 04/21/2021 at 1:00 p.m (survey date) for serum creatinine (CR), sodium (Na) and potassium (K) and activated clotting time low range (ACT-LR) testing from 01/08/2019 to 04/20/2021, review of quality control documents, written laboratory policies and procedures and an interview with the laboratory staff, it was determined that the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the general laboratory systems. The finding included: 1. On 04/21/2021 (survey date) no documentation could be retrieved to show that the laboratory had followed a written policy for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified. This correction process must involve identification and resolution of the problem, and development of policies that will prevent recurrence. Policies for preventing problems that have been identified must be written as well as communicated to the laboratory personnel, other staff, and clients. (See laboratory's i-STAT 1 analyzer's procedure: VII: "SPECIMEN REQUIREMENTS A., and XI. "REPORTING RESULTS" A-D. and ACT-LR Hemochron signature elite procedure: Results B. "Reporting Results, C. "Procedures for Abnormal Results, D. "Calculations" and E. "Results Review") 2. The laboratory staff confirmed on 04/21 /2021 at 4:0 0 p. m. that the laboratory did not follow a written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the general laboratory systems. 3. The annual testing declaration 03/20/2021 estimated 1,000 for serum creatinine (CR), sodium (Na) and potassium (K) as well as seventy (70) ACT-LR in 2019 test results reported. .
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on Surveyor's review of quality control (QC) testing records on 04/21/2021 at 1: 00 p.m. (survey date) for serum creatinine (CR), sodium (Na) and potassium (K) performed on the i-STAT 1 portable non-waived analyzer, 10 randomly selected patients test records from 01/22/2019 to 04/20.2021, and interview with the laboratory

	staff, the laboratory failed to perform QC each day of patient testing or to establish an IQCP (Individual Quantity Control Plan). The findings include: 1. Laboratory QC testing records could not be retrieved to showed that the laboratory performed QC for each day of patient testing or established an Indicvidaul Quality control Plan IQCP. See D-5445 (i-STAT 1 portable non-waived analyzer procedure) 2. On 14/21/2021 at 4:00 p.m. the laboratory staff confirmed that the laboratory had not run QC everyday of patient testing or established an IQCP.
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 the laboratory quality control (QC) records for serum creatinine (CR), sodium (Na) and potassium (K) testing using i-STAT 1 portable non-waived analyzer and an interview with the laboratory staff on 04/21/2021 at 1:00 p.m. (survey date), it was determined that the laboratory failed to perform control procedures as defined per manufacturer's guidelines, or CLIA regulation 493.1256 (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" (d)(3) "At least once each day patient specimens are assayed or examined perform the following for:" (whichever is more stringent). The laboratory also had not instituted an alternate "Individual Quality Control Plan" (IQCP) including Risk Assessment, Quality Control and Quality Assessment. The findings included: 1. Manufacturer's guidelines under IX. "QUALITY CONTROL" C. Aqueous (external) Controls stated: "2. Once a week, test cartridges with the appropriate controls on the one i-STAT 1, rotating the i-STAT used on a regular basis. 3. Values that are outside the manufacture's acceptance range must be repeated and corrective action documented. Patient samples cannot be run unless all controls are within range. 4. Test each shipment of i-STAT cartridges with all levels of controls designated for the specific cartridge you are using. Therefore, it is acceptable to run the liquid controls only once a week provided the automatic internal electronic QC is successfully performed every 8 hours of patient testing. These regulations require that during the initial validation of the analyzer, liquid QC results were acceptable for 10 consecutive testing days." 2. The laboratory staff confirmed on 04/21/2021, 4:00 p.m. that QC was not performed in accordance with manufacturer's guidelines, or CLIA regulation 493.1256 (d) (2), (d) (3) and that no alternative IQCP program was instituted for the serum creatinine (CR), sodium (Na) and potassium (K) testing using i-STAT 1 portable non-waived analyzer testing performed and reported. 3. The laboratory annual testing declaration (04/20/2021) estimated total volume of 1,000 routine chemistry (serum creatinine) results as well as in 2019 a total of nine (9) sodium and potassium were resulted and reported.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR

	CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on the severity of the deficiencies cited herein, the Condition: Laboratories Performing Moderate Complexity Testing: Laboratory director was not met. The laboratory director, moderate complexity testing, failed to ensure that laboratory was enrolled in an HHS approved proficiency testing program (See D 6015), failed to ensure that the quality control services provided (See D 5441, D 5445, D6020); failed to ensure that quality control programs were established and maintained to assure the quality of laboratory services provided (See D6021).
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on review and the lack of documentation of enrollment in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS, and interview with the laboratory supervisor, it was determined that the laboratory director failed to ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the routine chemistry analytes testing performed. (See D-2000)
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on interview with the laboratory staff on 04/21/2021 at 1:00 p.m. (survey date), review of policies/procedures, quality control documents, instrument manual test result logs, and ten (10) random patient testing records from 01/22/2019 to 04/20 /2021, it was determined that the laboratory director failed to ensure that a quality control program was established and maintained to assure quality test results. The findings included: 1. The laboratory director failed to ensure that a written quality

	control policy that was followed by the laboratory and corrective actions were taken and documented when quality control results failed to meet the criteria for acceptability. 2. Based on review of the lack quality control records for the routine chemistry analytes serum creatinine (CR), sodium (Na) and potassium (K), it was determined that the laboratory director failed to ensure that the quality control programs were established and maintained to assure the quality of laboratory services provided. (See D5441, D5445).
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on reviews and the lack of documentation for the verification of accuracy two times per year for the hematology activated clotting time low range testing (ACT-LR) tests, it was determined that the laboratory director failed to ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. (See D 5217).
D6048	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(ii) The procedures for evaluation of the competency of the staff must include, but are not limited to monitoring the recording and reporting of test results. This STANDARD is not met as evidenced by: On 04/21/2021 at 1:00 p.m. (survey date) based on review of 2019 and 2020 lack of laboratory competency evaluation documentation for testing personnel who performed routine chemistry serum creatinine (CR), sodium (Na) and potassium (K) performed on the i-STAT 1 portable analyzer and hematology activated clotting time low range testing (ACT-LR) test performed on the Hemochron Jr. Signature analyzer, the technical consultant (laboratory director) failed to evaluate the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. results. The findings include: 1. The laboratory staff confirmed on 04/21/2021, 4:00 p.m. that no documentation of annual competency evaluation could be retrieved for testing personnel for 2019 and 2020. 2. The laboratory's testing declaration form, signed by the laboratory Director on 04/20/2021 stated that the laboratory performs approximately 1,000 routine chemistry serum creatinine (CR), as well as a total of nine (9) sodium (Na) and potassium (K) and 70 ACT-LR/heparin patient tests in 2019. 3. The reliability, accuracy, and quality of results reported for the patient testing due to lack of technical consultant (laboratory director) monitoring routine recording and reporting of patients test results could not be assured for this period.
D6049	TECHNICAL CONSULTANT RESPONSIBILITIES

	CFR(s): 493.1413(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: On 04/21/2021 at 1:00 p.m. (survey date) based on review of 2019 and 2020 lack of laboratory competency evaluation documentation of testing personnel performing routine chemistry serum creatinine (CR), sodium (Na) and potassium (K) performed on the i-STAT 1 portable analyzer and hematology activated clotting time low range testing (ACT-LR) test performed on the Hemochron Jr. Signature analyzer, the technical consultant (laboratory director) failed to evaluate the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. results. The findings include: 1. On 04/21/2021 at 4:00 p.m. the laboratory lacked documents for the competency assessment of all testing personnel in 2019 and 2020 failed to include review of intermediate test results or worksheets (See D 5291), quality control records (See D 5441, D 5445). 2. The reliability, accuracy, and quality of results reported for routine patient testing routine chemistry serum creatinine (CR), sodium (Na) and potassium (K) performed on the i-STAT 1 portable analyzer and hematology activated clotting time low range testing (ACT-LR) test performed on the Hemochron Jr. Signature analyzer could not be assured.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review and lack of documentation of annual personnel competency records on 04/21/2021 at 1:00 p.m. (survey date) and interview with the technical consultant (laboratory director), it was determined that the technical consultant failed to evaluate and document competencies for one testing personnel responsible for moderate complexity testing. The findings included: 1. No evidence could be retrieved for annual competencies for all testing personnel of moderate complexity testing in the year 2019 and 2020 performing moderate complexity testing for routine chemistry serum creatinine (CR), sodium (Na) and potassium (K) performed on the i-STAT 1 portable analyzer and hematology activated clotting time low range (ACT-LR) testing. 2. The laboratory staff confirmed 04/21/2021 4:00 p. m. that testing personnel competency records could not be retrieved for the annual performance of the testing personnel for the year 2019 and 2020. 3. The laboratory's testing declaration form, signed by the laboratory Director on 04/20/2021 stated that the laboratory performs approximately 1,000 routine chemistry serum creatinine (CR), as well as a total of nine (9) sodium (Na) and potassium (K) and 70 ACT-LR/heparin patient tests in 2019, the reliability, accuracy, and quality of results reported for the patient testing due to lack of technical consultant (laboratory director) monitoring routine recording and reporting of patients test results could not be assured for this period.