Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0713371	08/01/2018
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
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the severity of the deficiencies cited herein, the Condition for General Laboratory Systems was not met. The laboratory failed to follow the written laboratory policy and procedure to assess employee competency (See D6054); failed to at least twice annually (D6053), verify the accuracy of any test or procedure it performs that is not included in subpart I of this part (See D5217); and failed to follow written policies and procedures to monitor, assess, and when indicated, correct problems identified in the general laboratory systems (D5391, D5891).
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 interview with the laboratory personnel on August 01, 2018 (survey date), review of twelve randomly (12) patient testing records from 06/14/2016 to 07/26 /2018, the laboratory failed to verify testing accuracy of the ACT-LR/heparin test

	performed on the Hemochron Jr. Signature analyzer at least twice annually for the years 06/14/ 2016, 2017 to August 01, 2018. The findings included: a. The laboratory was unable to provide documentation or previous records for verification of the ACT-LR/heparin testing accuracy at least twice annually from 2016 to August 2018. b. The laboratory personnel (manager) on August 01, 2018, 12:00 AM (survey date) affirmed that the laboratory failed to verify the accuracy of the test twice annually. c. The laboratory's testing declaration form, signed by the laboratory Director on July 26, 2018, stated that the laboratory performs approximately 250 ACT-LR/heparin tests annually.
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: Based on request, review of random patient sampling test orders, and interview with the testing personnel, it was determined that the laboratory failed to have a written or electronic request (ER) for patient testing from an authorized person. The findings included: a. For two (2) out of twelve (12) random patient (Pt) testing records from 06 /14/2016 to 07/26/2018, the laboratory analyzed and reported ACT-LR/heparin tests without a written or electronic request (ER) for patient testing from an authorized person. No records could be retrieved in the EMR (electronic Medical Record) system. Refer to laboratory test worksheet: Pt # Date of testing 58376 03/12/18 No record/request in the EMR 58846 03/21/18 No record/request in the EMR b. A laboratory personnel (manager) and testing personnel affirmed 08/01/2018, 12:00 AM (survey date) that the laboratory has no documentation to show for a written or electronic request for the above patient test results from an authorized person. c. The laboratory's testing declaration form, signed by the laboratory Director on July 26, 2018, stated that the laboratory performs approximately 250 ACT-LR/heparin tests annually.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on review of the laboratory policies and procedures, twelve (12) random patient testing records from 06/14/2016 to 07/26/2018, and interview it was determined that the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in the preanalytic systems for 2016 and 2018 to the date of the survey. The findings include: a. The Surveyor requested on August 08, 2018 (survey date) for documentation of the laboratory's ongoing preanalytic review process that encompasses all the facts of the laboratory's technical and non-technical functions, the laboratory failed to provide a written policies and procedures or documentation of review to monitor the quality of the preanalytic for the ACT-LR/heparin test laboratory system. b. During an interview

	on October 24, 2017, 12:00 AM (survey date) a laboratory personnel (manager) confirmed the lack of written preanalytic policies and procedures or documentation of preanalytic quality assessment of the ACT-LR/heparin test on the Hemochron Jr. Signature analyzer. c. The laboratory's testing declaration form, signed by the laboratory Director on July 26, 2018, stated that the laboratory performs approximately 250 ACT-LR/heparin tests annually.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review and the lack of quality control (QC) records, twelve (12) random patient testing records from 06/14/2016 to 07/26/2018 and interview with a laboratory staff (manager) and a testing personnel, it was determined that the laboratory failed to document and performs each quantitative procedure, include two control materials of different concentrations. The findings included: a. The laboratory performs ACT-LR /heparin test on the Hemochron Jr. Signature analyzer. The laboratory did not analyze and perform each quantitative procedure, include two control materials of different concentrations when patient testing for the period cited, nor was an equivalent individual quality control program (IQCP) set up to monitor QC. b. The testing personnel (manager) affirmed 08/01/2018, 12:30 AM that the laboratory did not have documentation to show of each quantitative procedure, include two control materials of different concentrations. c. The laboratory's testing declaration form, signed by the laboratory Director on July 26, 2018, stated that the laboratory performs approximately 250 ACT-LR/heparin tests annually and the reliability and quality of the patient results reported could not be assured.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on review of laboratory test records for six (6) of twelve (12) random patient (Pt) testing records from 06/14/2016 to 07/26/2018, and interviews with laboratory personnel, the laboratory failed to maintain a record system for positive identification, date of specimen testing and identification of the personnel performing testing. The findings include: a. The patient ACT-LR/heparin test worksheets lacked complete patient identification (unique identifiers) and/or date of testing. Refer to laboratory patient test worksheet: Date Pt# Deficiency 1/31/17 Pt # 1 No ID of staff performing

	test 1/31/17 Pt # 2 No ID of staff performing test 3/04/17 Pt # 3 No ID of staff performing test 6/12/18 Pt # 4 Lack of Pt identifiers 6/12/18 Pt # 5 Lack of Pt identifiers None Pt # 6 No date of testing b. A laboratory personnel (manager) and a testing person affirmed on 08/01/2018, 12:00 AM (survey date) the aforementioned omissions; and thus, the failure to maintain records of accurate patient ACT-LR /heparin test records (documentation). c. The reliability and quality of ACT-LR /heparin test results reported could not be assured. Based on the stated annual test volume, the laboratory reported approximately 400 ACT-LR/heparin tests annually.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on staff interviews on 08/01/2018 and review of test procedures twelve (12) random patient testing records from 06/14/2016 to 07/26/2018, it was determined that the laboratory failed to ensure that test reports included pertinent information required for interpretation as reference ranges specific to the patient population (gender/age) specific(s), if applicable and test performed. The findings included: 1a. Review of the laboratory's final patient test reports [electronic medical record (ERM)] showed that the laboratory failed to include pertinent information required for interpretation for ACT-LR/heparin tests. There was no information provided for "reference" and (patient population/gender/age) ranges specific(s), if applicable noted on the patient's final test report. . 1b. The laboratory staff affirmed on 08/01/2018 12:00 AM (survey date) that the patients' final test reports (ERM) failed to ensure that test reports included pertinent information required for interpretation. 2a. Review of the laboratory's final patient test reports (EMR) showed that the laboratory failed to ensure that the patients' test results were recorded the EMR. The laboratory scans into the EMR the patient final test reports. Refer to laboratory test worksheet: Test date PT# Test results 1. 03/04/17 81071 Heparin not in EMR 2. 03/21/17 58376 ACT-LR /heparin not in EMR 3. 03/21/17 58846 ACT-LR/heparin not in EMR 4. 03/21/17 85210 ACT-LR/heparin not in EMR 5. 04/24/18 536770 ACT-LR/heparin not in EMR 2b. The laboratory personnel (manager) and a testing person affirmed on 08/01 /2018 12:00 AM (survey date) that the patients' final test reports (ERM) failed to ensure that patients' test results were recorded the ERM. 2c. The laboratory's testing declaration form, signed by the laboratory Director on July 26, 2018, stated that the laboratory performs approximately 250 ACT-LR/heparin tests annually.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291.

	This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, random review of twelve (12) patient records from 06/14/2016 to 07/26/2018, and an interview, it was determined that the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in the postanalytic quality assessment systems for 2016 and 2018 to the date of the survey. The Findings include: a. The surveyor requested on 08/02/108 (survey date) documentation of ongoing quality assessment (QA) for the postanalytic system includes assessing practices/issues related to test report monitoring and evaluating the accuracy and completeness of the laboratory's test reports and the laboratory's turn-around times and procedures for notification of the test results. b. The laboratory personnel (manager) affirmed 08/01/108, 12:00 AM (survey date) that the laboratory did not have the written policy and procedure to assess, monitor and correct problem in the postanalytic ACT-LR/heparin test systems. c. The laboratory's testing declaration form, signed by the laboratory Director on July 26, 2018, stated that the laboratory performs approximately 250 ACT-LR/heparin tests annually.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) result report, and interview with the laboratory staff, it was determined that the laboratory director failed to ensure that the proficiency testing samples are tested as required under Subpart H of 42 CFR part 493. The findings included: See D-5217
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, review of policies/procedures, quality control documents, instrument printouts, and twelve (12) random patient testing records from 06/14/2016 to 07/26/2018, 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: a. 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. b. Based on review of quality control records, patient test records on 08/01/2018, 12:00 AM (survey date), 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 D5447).
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) 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)(8) Ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on review of the laboratory result reports, and interview with the laboratory staff, it was determined that the laboratory director failed to ensure that reports of test results include pertinent information required for interpretation. The findings included: See D-5805
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: Based on review of 2016 and 2017 laboratory documents for competency assessments of testing personnel performing ACT-LR/heparin tests, the evaluations failed to include monitoring the routine recording and reporting of patients test results. The findings include: a. The lack of documents for the competency assessments for four (4) testing persons in 2016 and 2017 failed to monitoring of routine recording and reporting of patients test results. b. The laboratory's testing declaration form, signed by the laboratory Director on July 26, 2018, stated that the laboratory performs approximately 250 ACT-LR/heparin tests annually and 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 in 2016 - 2017 could not be assured.
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:

	Based on lack of review of 2016 and 2017 laboratory documents for competency assessments of testing personnel performing ACT-LR/heparin test on the Hemochron Jr. Signature analyzer, the evaluations failed to include review of intermediate test results or worksheets, quality control records, and any applicable preventive maintenance records. Findings include: a. The laboratory lack documents for the competency assessment of four (4) testing persons in 2016 and 2017 failed to include review of intermediate test results or worksheets, quality control records, and any applicable preventive maintenance records by the technical consultant (laboratory director).
D6053	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 semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on lack of documentation for competency assessments, and interview with laboratory personnel, twelve (12) random patient testing records from 06/14/2016 to 07/26/2018, it was determined that the technical consultant (laboratory director) failed to perform and document the performance of individual(s) responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. The findings included: a. There was no documentation to show that the testing personnel were evaluated during the first six months (and annually thereafter) for the moderate complexity patient testing performed on the ACT-LR /heparin test on the Hemochron Jr. Signature analyzer b. The laboratory personnel (manager) affirmed on 08/01/2018, 12:00 A.M. (survey date) that no competency assessments evaluation (first six months) was performed and documented by the technical consultant (laboratory director). c. The laboratory's testing declaration form, signed by the laboratory Director on July 26, 2018, stated that the laboratory performs approximately 250 ACT-LR/heparin tests annually.
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 and interview with the laboratory personnel (manager), it was determined that the technical consultant (laboratory director) failed to evaluate and document competencies for one testing personnel responsible for moderate complexity testing. The findings included: a. There was no evidence of annual competencies for four (4) testing personnel for moderate complexity testing. b. The laboratory personnel (manager) affirmed 08/01/2018, 1200 AM (survey date) that the technical consultant (laboratory director) failed to evaluate and document the annual performance of the

	testing personnel for the years 2016 and 2017. The laboratory's testing declaration form, signed by the laboratory Director on July 26, 2018, stated that the laboratory performs approximately 250 ACT-LR/heparin tests annually.