Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2062413	03/28/2018
Name of Provider or Supplier	**Street Address, City, State**	
Central Clinical Labs Incorporated	3720 E La Salle St, Suite 103, Phoenix, AZ	

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
D5393	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(b)(c) The preanalytic systems assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of preanalytic systems quality assessment reviews with appropriate staff. The laboratory must document all preanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on the review of the Laboratory Incidents log for 2017, the phlebotomy meeting agenda items for 01/23/2018 and interview with the facility personnel, the laboratory failed to provide a documented explanation and corrective action for the significant spike in Test Ordered, not performed for three out of twelve months in 2017 (October, November and December) indicated on the Laboratory Incidents log. Findings include: 1. The 2017 Laboratory Incident log indicated the following number of tests ordered, not performed for October (42), November (42), and December (35) respectively. The next highest total indicated was in June with a total of 19 tests ordered, not performed. 2. There was no specific documented explanation or corrective action for the spike in tests ordered, but not performed other than the 01/23 /2018 meeting agenda item that indicated "missing test orders-be sure to check your orders too many tests are being missed." 3. The facility personnel acknowledged that there was no documented explanation and corrective action specific to the three month spike in lab tests ordered, not performed indicated above.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling,

	storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual and interview with the facility personnel, the laboratory's test procedure for Vitamin D testing failed to include the reportable range for testing performed on the IDS-iSYS analyer. Findings include: 1. The laboratory began patient testing for Vitamin D on the IDS-iSYS analyzer in April 2017. 2. The laboratory's test procedure for Vitamin D presented for review during the survey conducted on March 28, 2018 failed to include the reportable range for test results that were performed on the analyzer indicated above. 3. Review of the laboratory's test report for Lab #5071731 on 02/28/18 indicated a reference range for Vitamin D of 30-100 ng/mL. 4. The facility personnel confirmed that the procedure manual presented for review during the survey lacked documentation of the test system's reportable range.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on lack of calibration records for the Tosoh analyzer and interview with the facility personnel, the laboratory failed to perform and document calibration procedures as required. Findings include: 1. The laboratory utilizes the Tosoh analyzer for Hemoglobin A1C testing. 2. The laboratory's established calibration requirement is to perform calibration procedures on the analyzer every 6 months. The analyzer was calibrated on 02/11/16 and the next documented calibration occurred on 03/01/17. 3. No documentation was presented for review during the survey to indicate

	the laboratory performed and documented calibration procedures for the Tosoh analyzer every 6 months as required. 4. The facility personnel confirmed that the laboratory did not have documentation indicating calibration procedures were performed on the Tosoh analyzer during the time period indicated above. 5. The number of patients tested on the analyzer during that time period could not be determined at the time of the survey.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control (QC) policy, lack of QC lot verification documentation and interview with the facility personnel, the laboratory failed to verify the criteria for acceptability of quality control materials used on the IDS-iSYS analyzer. Findings include: 1. The laboratory began Vitamin D testing on the IDS-iSYS analyzer in April 2017. It is the practice of the laboratory to test two levels of QC material each day prior to patient testing. 2. The laboratory's policy titled, "Quality Control Assessment" states on page 9, "The IDS-iSYS control material has an established mean for the instrument or reagent. A new mean will have to be determined each time a new lot of control material is to be put into use. This will be done before existing control lots expire". 3. Review of the IDS-iSYS QC records for Lot# 3501, Level 1 that was currently in use at the time of the survey conducted on March 28, 2018 indicated the laboratory's established QC range was 16.3 - 25.4, and the manufacturer's range was 13.3 - 21.7 4. No documentation was presented for review during the survey to support the laboratory's establishment of the new mean and Standard Deviation for the lot number indicated above. 5. The facility personnel confirmed that the laboratory could not produce documentation during the survey to show how the new range was established for QC Lot# 3501, Level 1, that was in use at the time of the survey.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of Quality Control (QC) records and interview with the facility personnel, the laboratory failed to establish policies and procedures for monitoring the accuracy of QC results that are manually entered into the laboratory's electronic QC system. Findings include: 1. During the survey conducted on March 28, 2018, the facility personnel stated that the QC results interface directly into the Laboratory Information System (LIS) for all test systems except the Tosoh analyzer for Hemoglobin A1C testing and the ACL 1000 coagulation analyzers. The QC results from these analyzers are manually entered from the instrument printouts into an electronic report titled, "Quality Control Report". The Quality Control Report report is used by the Technical Consultant to monitor QC results and lists the monthly QC results, as well as information specific to the QC lot number, ranges and standard deviations for each level of QC tested. 2. Review of the Quality Control Report and the instrument QC records for testing performed on the Tosoh analyzer during August 2016 indicated the QC data that was manually entered into the Quality Control Report was incorrect for two dates: On August 22, 2016 the instrument printout indicated 5.9 for control 1 and the report listed 5.8 for control 1; On August 26, 2016 the instrument printout indicated 5.9 for control 1 and the report listed 5.8 for control 1. 3. No documentation was presented for review during the survey to indicate the laboratory had established policies and procedures to monitor, assess and when indicated, correct problems identified in manually transcribing QC results into an electronic system. 4. The facility personnel confirmed that the laboratory did not have a system in place to monitor the accuracy of manually transcribed QC results.
D5893	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(b)(c) (b) The postanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of an amended report from 12/13/2017 (Lab Number 5046633), the laboratory incident form and interview with the facility personnel, the laboratory failed to have a procedure in place for documenting the reason for amending test results on test reports and for keeping track of the number of test reports amended. Findings include: 1. The test report referenced above indicated the result on the original report and the amended result, but did not indicate why the original result was amended. 2. The laboratory incident form presented for review did not reference amended reports as one of the listed incidents and no other documented reasons for amending test reports was presented for review. 3. The facility personnel explained that the test result was amended due to a mix up in lab numbers, but again there was no documented explanation of the mix up. 4. The laboratory's total annual test volume is approximately 747,000.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on review of the performance verification data for the IDS-iSYS analyzer, review of laboratory policies and interview with the facility personnel, the laboratory director failed to provide documented evidence that the laboratory director and/or technical consultant approved the performance verification data analysis prior to conducting patient sample testing. Findings include: 1. The laboratory performed verification procedures on the IDS-iSYS analyzer in April 2017. 2. The IDS-iSYS test system validation signature sheet provided for review included an area titled "Validation Data Accepted By:" which was signed and dated (4/03/17) by an individual who was not listed on the CMS-209, Laboratory Personnel Form that was submitted during the survey. The individual who signed the document was still employed by the laboratory at the time of the survey. 3. The laboratory's established policy titled "Delegation of Duties" states, "The Laboratory Director delegates to the Laboratory Supervisor/Technical Consultant the following duties/positions: ...Test /New Method Validation." The Laboratory Supervisor is not a recognized position under CLIA and therefore not included on the CMS-209, Laboratory Personnel Form. 4. The facility personnel confirmed that the test verification procedure and resulting data for the IDS-iSYS analyzer was not approved, signed and dated by the laboratory director and/or Technical Consultant prior to patient testing.