Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2062413	03/10/2020
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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on lack of manufacturer's assay information sheets presented for review for C. Diff testing and interview with the facility personnel, the laboratory failed to retain the manufacturer's package insert for each lot of C. Diff test kits used by the laboratory. Findings include: 1. The laboratory began C. Diff testing on patient specimens using the Alere Techlab C. Diff test kit in March 2019, with an approximate annual test volume of 2,400. 2. During the survey conducted on March 10, 2020, the laboratory could not produce evidence of the manufacturer's package inserts for each lot of C. Diff test kit that was used for testing by the laboratory since March 2019. The manufacturer's package insert contains information specific to the lot number and expiration date of the test kit and external control material. 3. The facility personnel confirmed that the laboratory failed to retain the manufacturer's package insert for each lot of C. Diff test kit that was used by the laboratory for patient testing since March 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 the laboratory's established Quality Assessment policies, review of employee competency records and interview with the facility personnel, the laboratory failed to identify errors found within the personnel competency process. Findings include: 1. The laboratory performs patient testing under the specialties of Microbiology, Diagnostic Immunology, Chemistry and Hematology, with an approximate annual test volume of 1,156,800. At the time of the survey conducted on March 10, 2020, the laboratory used approximately 7 different test systems for patient testing. 2. The laboratory utilized a personnel competency form titled, "Tech Competency 3 month - CCL AZ" during 2019 to document testing personnel competency evaluations. 3. The form indicated above failed to include information specific to each test system for which personnel competency was evaluated. 4. The facility personnel confirmed that the competency form used to document personnel competency during that time period failed to include information specific to each test system.
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 review of the laboratory's established procedure manual, review of patient test reports and interview with the facility personnel, the laboratory failed to follow their established test procedure for Ammonia testing. Findings include: 1. The laboratory performs patient testing, including Ammonia testing, in the specialty of Chemistry, with an approximate annual test volume of 876,000. 2. The laboratory's established test procedure, Policy# 6008, for Ammonia testing performed on the Siemens Atellica analyzer states, "Separated specimens may be stored for up to 2 hours at 2-8 degrees Celsius. The tube should be completely filled, stored tightly capped on ice and centrifuged without delay. Samples should be analyzed within 30 minutes of centrifugation. Concentrations may more than double in plasma when stored at room temperature for 6 hours". 3. Review of patient test results for ammonia testing on 03/02/2020 (Lab # 5423885) indicated the specimen was collected on 3/02 /20 at 04:40am, received on 3/02/20 at 12:50pm, resulted on 3/02/20 at 01:16pm and reported on 3/05/20 at 01:23pm. 4. The facility personnel acknowledged that the laboratory failed to follow the established procedure for Ammonia testing and failed to test the specimen within the acceptable timeframe.
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 lack of quality control (QC) documentation and interview with the facility personnel, the laboratory failed to perform and document control procedures using the number and frequency as required for testing performed in the specialty of Microbiology. Findings include: 1. The laboratory began C. Difficile (C Diff) testing on patient specimens in March 2019, using the Alere C Diff Techlab test kit under the specialty of Microbiology. On the date of the survey, March 10, 2020, the laboratory's quality control procedure consisted of performing two levels of external control material, each new kit or shipment. 2. No QC documentation was provided for review during the survey to indicate the laboratory performed two levels of control material of different concentrations, each day of patient testing as required since January 1, 2016. 3. During the survey, review of C Diff QC records indicated the laboratory performed and documented QC with the number and frequency described above (see #1), and as of January 1, 2016, the laboratory had not implemented an Individualized Quality Control Plan (IQCP) for this test system. 4. The facility personnel confirmed that the laboratory did not perform and document controls as required since January 1, 2016 and confirmed that the laboratory had not implemented an Individualized Quality Control Plan (IQCP) for testing performed on the Alere C Diff test kit. 5. Approximately 2400 patients were tested using the C Diff test kit.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and interview with the laboratory personnel, the laboratory failed to have a specific policy in place that addressed the accuracy of results sent to the LIS from both interfaced systems and manually entered test results. Findings include: 1. The laboratory presented a policy that outlined the monitoring for data entry accuracy of test orders, but no policy was presented that monitored the accuracy of test result entries into the LIS. 2. The laboratory did perform periodic monitoring of test results for all tests except for C. Diff test results for patient testing that began in July 2019. 3. The laboratory personnel acknowledged that the laboratory lacked a specific policy that outlined the monitoring of the accuracy of test results both interfaced and manually entered.
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 performance evaluation documentation and interview with the facility personnel, the technical consultant failed to evaluate and document the performance of testing personnel, at least semiannually during the first year the individual tested patient specimens. Findings include: 1. No semiannual competency evaluation documentation was presented for review for one out of one testing personnel who began patient testing in March 2019. 2. No semiannual competency evaluation documentation specific to the Siemens Atellica analyzer was presented for review for two out of two testing personnel who began patient testing on the Atellica analyzer in May 2019. 3. No semiannual competency evaluation documentation specific to the LH500 Hematology analyzer was presented for review for one out of one testing personnel who began patient testing on the LH500 analyzer in March 2019. 4. No semiannual competency evaluation documentation specific to the DXH Hematology analyzer was presented for review for one out of one testing personnel who began patient testing on the DXH in March 2019. 5. The facility personnel confirmed that the laboratory did not have documentation of semiannual competency evaluations for the testing personnel indicated above.