Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2071729	01/12/2023
Name of Provider or Supplier	**Street Address, City, State**	
Cec Fossil Creek Llc	22250 Bulverde Road, Suite 120, San Antonio, TX	

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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions in the CLIA program, and recertification is recommended.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's American Proficiency Institute's (API) proficiency testing records from 2022, and staff interview, it was revealed the laboratory failed to ensure 5 of 8 testing personnel participated in proficiency testing. The finding include: 1. A review of the laboratory's submitted Form CMS 209 revealed the laboratory identified 8 testing personnel. 2. A review of the laboratory's American Proficiency Institute's proficiency testing records from 2022 (hematology events 1, 2, and 3, chemistry core events 1, 2, and 3 and microbiology events 1, 2, and 3) revealed 5 of 8 testing personnel did not participate in proficiency testing. They were (as listed on Form CMS 209): Testing personnel number 1 Testing personnel number 2 Testing personnel number 5 Testing personnel number 6 Testing personnel number 8 3. The laboratory was asked to provide documentation of the identified 5 testing personnel participating in proficiency testing. No documentation was provided. 4. An interview with the technical consultant on 1/12/2023 at 1130 hours in the nurse's station - after her review of the records- confirmed the findings.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)

	The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute's (API) chemistry core proficiency testing records from 2022, and staff interview, it was revealed the facility failed to have documentation of testing personnel signing 1 of 3 attestation statements. The findings include: 1. A review of the laboratory's American Proficiency Institute's chemistry core proficiency testing records revealed testing personnel number 7 signed the attestation statement as having performed testing. 2. Further review of the records revealed testing personnel number 3 and testing personnel number 4 initialed the instrument printouts as documented they performed the testing. 3. The laboratory was asked to provide documentation of testing personnel number 3 and testing personnel number 4 signing the attestation statement. No documentation was provided. 4. An interview with the technical consultant on 01/12 /2023 at 11:30 hours in the nurse's station - after her review of the records- confirmed the findings.
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 laboratory's verification studies performed on the Sysmex XP-300 analyzer and staff interview, it was revealed the laboratory's studies failed to support the current reportable ranges in use. The findings include: 1. A review of the laboratory's verification studies performed on the Sysmex XP-300 analyzer revealed the manufacturer's reportable ranges were in use by the laboratory: HGB Low: 0.1 High: 25.0 HCT Low: 10.0 High: 60.0 2. Further review of the laboratory's verification studies revealed the laboratory's data for reportable range only prove the instrument was able accurately report up to the following values: HGB: High: 21.7 HCT: High: 57.6 3. The laboratory was asked to provide documentation of studies to support the manufacturer' ranges. No documentation was provided. 4. An interview with the technical consultant on 01/12/2023 at 1300 hours in the office - after her review of the records- confirmed the findings.
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's individualized quality control plan (IQCP) for MetLac 12 testing performed on the Piccolo analyzer, review of the laboratory's verification studies, review of the laboratory's quality control records, and staff interview, it was revealed the laboratory failed to have documentation of performing an IQCP on a new Piccolo analyzer. The findings include: 1. A review of the laboratory's individualized quality control plan (IQCP) for Piccolo analyzer serial number 10265 revealed the study was performed in 2020. 2. A review of the laboratory's verification studies performed on Piccolo analyzer serial number 26002 revealed the studies were performed in August 2022 when this analyzer replaced Piccolo analyzer serial number 10265. 3. A review of the laboratory's quality control records from August 2022 to December 2022 revealed the laboratory performed quality control testing with each new shipment/new lot or 30 days on the new analyzer. 4. The facility was asked to provide documentation of developing an IQCP for the new analyzer. No documentation was provided. 5. An interview with the technical consultant on 01/12/2023 at 1530 hours in the office confirmed a new IQCP had not been developed. This confirmed the findings.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of the laboratory's room temperature records from January 2022 to December 2022, and staff interview, it was revealed the laboratory failed to have documentation of performing corrective actions for 40 days when the documented room temperature was outside the laboratory's acceptable range. The findings include: 1. A review of the laboratory's room temperature records from January 2022 to December 2022 revealed the laboratory's defined acceptable room temperature range was defined as 20-24 degrees Celsius. 2. Further review of the laboratory's room temperature records revealed the following 40 days which the laboratory testing personnel and quality assurance review failed to identify as being out to range and corrective actions were not documented as being performed: Date Temp 2/4 17.9 3/5 25.7 3/15 25.4 3/18 24.4 3/20 24.3 3/21 24.4 3/28 24.4 4/4 26.3 4/6 25.7 4/8 24.2 4/14 25.3 4/15 25 5/5 25.8 5/11 24.4 5/21 24.2 5/22 25.1 6/1 25.1 6/2 24.1 6/4 24.2 6/6 25.1 6/7 25.1 6/8 24.3 7/1 24.5 7/2 24.3 7/3 24.5 7/11 24.1 7/25 24.1 8/18 24.7 8/23 24.2 8/24 24.6 8/30 25.0 8/31 24.3 9/15 24.1 10/2 24.4 10/4 25.3 10/5 27.4 10/18 24.2 12/4 24.2 12/25 25.3 3. The laboratory was asked to provide documentation of performing corrective actions on the days listed. No documentation was provided. 4. An interview with the technical consultant on 1/12/2023 at 1400 hours in the office - after her review of the records- confirmed the findings.

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 a random review of the laboratory's patient results for Cardiac testing, and staff interview, it was revealed the laboratory failed to have documentation of the testing personnel who performed testing for 7 of 9 results. The findings include: 1. A random sampling of patient test records from November 2022 to January 2023 for Cardiac results revealed the laboratory failed to have documentation of the testing personnel who performed the testing for 7 of 9 results. They were: DOS: 12/08/2022 Account number: 52924 DOS:12/08/2022 Account number: 52921 DOS: 12/08/2022 Account number: 52911 DOS: 12/14/2022 Account number: 53041 DOS: 12/20/2022 Account number: 53194 DOS: 01/04/2023 Account number: 53534 DOS: 01/04/2023 Account number: 53541 2. The laboratory was asked to provide documentation of the testing personnel who performed the testing. No documentation was provided. 3. An interview with the technical consultant on 01/12/2023 at 1430 hours at the nurse's station - after her review of the records- confirmed the findings. Key: DOS - Date of Service