Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2071729	11/10/2021
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 representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on review of the laboratory's instrument startup quality control (QC) records for the Horiba ABX Micros 60 hematology analyzer for May and June of 2021, review of patient test logs and staff interview it was determined the laboratory failed to document acceptable startup of the instrument 1 of 20 reviewed days testing was performed. Findings included: 1. Review of the laboratory's instrument startup QC records for the Horiba ABX Micros 60 hematology analyzer for May and June of 2021 revealed instrument startup QC for 05/25/2021 was performed as follows: 05/25 /2021 08:45 AM Status: Failed 05/25/2021 08:47 AM Status: Failed 05/25/2021 08:49

	AM Status: Failed Note: There was no documentation of acceptable instrument startup QC for that date. 2. Review of patient test logs for 05/25/2021 revealed the following patient samples were tested: Patient: PETCH000 Sample:052501 Analyzed: 10/25/2021 at 09:26 AM Patient:DECPA001 Sample:052503 Analyzed:05/25/2021 at 01:53 PM 3. In an interview on 11/10/2021 at 1050 hours in the conference room the Technical Consultant, after review of the data, confirmed the findings.
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 review of the laboratory's Horiba ABX Micros 60 hematology analyzer's calibration documentation for February of 2020 to February of 2021, review of the analyzer's maintenance logs from February of 2020 to February of 2021, review of the Horiba ABX Micros 60 user manual and staff interview it was determined the laboratory failed to document performance of pre-calibration protocols per manufacturer requirements for three of three calibrations reviewed. Findings included: 1. Review of the laboratory's Horiba ABX Micros 60 hematology analyzer's calibration documentation for February of 2020 to February of 2021 revealed calibrations were performed on: 02/14/2020 01/11/2021 02/22/2021 2. Review of the laboratory's Horiba ABX Micros 60 maintenance logs for February of 2020 to February of 2021 revealed no documentation of performance of pre-calibration protocols for those dates calibrations were performed. 3. Review of the Horiba Micros 60 User Manual (RAB043MUS) under "Quality Assurance, 2. Calibration, 2.1.1. Preliminaries" page 11 revealed: " Before carrying out a calibration, it is essential to make sure that the instrument is in perfect condition of operation, and to follow the following steps: 1- Carry out a Concentrated cleaning procedure (see Section 6, 1.3.6. Concentrated Cleaning, page 6-11). 2- Perform two blank cycles to check cleanliness of the instrument. 3- Check the repeatability of the instrument by running a fresh normal whole blood sample 11 times with no alarms. Discard the first result and calculate the CV on the remaining 10 runs. 4- Check that the CV calculated using the remaining 10 runs meets or exceeds the specifications in "3.2 Precision Claims*, page 9" 5- Run a control blood and check that the values are within acceptable limits. If not, run a new control blood." 4. In an interview on 11/10/2021 at 1000 hours in the conference room the Technical Consultant, after review of the data, 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: A. Based on review of the laboratory's Piccolo Xpress Metlac 12 chemistry analyzer's user manual, review of the analyzer's quality control (QC) records for January to March of 2021, review of patient test logs for the same interval and staff interview it was determined the laboratory failed to document performance of QC every 30 days as per manufacturer requirements for instrument's Individualized Quality Control Plan (IQCP) for 1 of 30 day intervals reviewed. Findings included: 1. Review of the laboratory's Piccolo Xpress Metlac 12 chemistry analyzer's user manual, under "C. EXTERNAL QUALITY CONTROL SAMPLES", page 15, revealed: "2. QC Frequency Testing with the Liquid Assayed Control Material is performed: - Once every 30 days after expected iQCP performance has been established." 2. Review of the Piccolo Xpress Metlac 12 chemistry analyzer's quality control (QC) records for January to March of 2021 revealed QC was performed as follows: Control Lot#: 2004021 Date of Study:01/15/2021 Control Lot#: 2004021 Date of Study: 02/08/2021 Interval from last QC: 24 days Control Lot#: 2007036 Date of Study: 03/23/2021 Interval from Last QC: 43 days 3. Review of patient test logs from January 15th to March 23rd of 2021 revealed the following patient samples were tested after 03/10 /2021, beyond the IQCP established QC validity: Patient: BAKVL001 Date/time tested: 03/13/2021 at 20:59 Patient: BALAN001 Date/time tested: 03/19/2021 at 12: 10 4. In an interview on 11/10/2021 at 1245 hours in the conference room the Technical Consultant, after review of the data, confirmed the findings.
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 of the laboratory's October 2021 quality control records for the Horiba ABX Micros 60 hematology analyzer, review of patient test logs and staff interview it was determined the laboratory failed to run controls at least once each day of testing for 1 of 31 days reviewed. Findings included: 1. Review of the laboratory's October 2021 quality control records for the Horiba ABX Micros 60 hematology analyzer revealed there were no controls performed on 10/17/2021. 2. Review of the laboratory's test logs for 10/17/2021 revealed the laboratory performed Complete Blood Count testing on the following patients: Patient:WEIXI000 Sample:101705 Patient:PETKE000 Sample:101706 Patient:CARCI000 Sample:01111 Patient:40814

	Sample:101704 3. In an interview on 11/10/2021 at 1050 hours in the conference room the Technical Consultant stated that QC for the hematology analyzer should be performed each day of patient testing. This confirmed the findings.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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 qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the verification studies performed on the QIA-stat SARS-CoV-2 Panel, review of quality control records and staff interview, it was revealed the laboratory failed to have documentation of performing quality control testing each day of patient testing. The findings include: 1. A review of the laboratory's verification studies performed on the QIA-stat SARS-CoV-2 Panel revealed the studies were performed in May 2020 and the test was placed into use on May 15, 2020. 2. A review of quality control records for the test system from May 2020 to October 2021 revealed the laboratory performed quality control testing with each new shipment, each new lot, or at least every 30 days. 3. The laboratory was asked to provide documentation of developing an Individualized Quality Control Plan to support modifying the frequency of quality control testing. No documentation was provided. 4. An interview with the technical consultant on 11/10/2021 at 1240 hours in the office - after her review of the records- confirmed the findings.
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 laboratory's verification studies, and staff interview, it was revealed the laboratory failed to have documentation of the laboratory director approving the studies for the QIA-stat Respiratory Panel in use by the laboratory from February 2020 to May 2020. The finding include: 1. A review of the laboratory's verification studies for the QIA-stat Respiratory Panel revealed the laboratory did not have documentation of the laboratory director approving the studies. 2. The laboratory was asked to provide documentation of the laboratory director approving the studies prior to the facility performing patient testing. No documentation was provided. 3. An interview with the technical consultant on 11/10/2021 at 1315 hours in the office - after her review of the records- confirmed the finding.

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 review of the laboratory's Piccolo Xpress Metlac 12 chemistry analyzer's quality control (QC) records for July to August of 2020, review of individualized quality control plan (IQCP) establishment studies/reports, review of the patient test logs for the same interval and staff interview it was determined the laboratory director failed to ensure the laboratory's established IQCP was maintained and re-evaluated upon intermittent failure. Findings included: 1. Review of the laboratory's Piccolo Xpress Metlac 12 chemistry analyzer's QC records for July to August of 2020 revealed the following QC failures: Date: 07/19/2021 Tested: 30 day QC Controls Lot #: 1905012, expiration 12-31-2020 Results out of acceptable range for: Control 1 & 2 - K Repeat run out of acceptable range: Control 2 - K Date: 07/31/2021 Tested: New lot QC Controls Lot #: 1912005, expiration 12-31-2020 Results out of acceptable range for: Control 1 - K Date: 07/31/2021 Tested: New lot QC Controls Lot #: 1910004, expiration 02-2021 Results out of acceptable range for: Control 2 - BUN; NA; K: CA; MG Repeat run out of acceptable range: Control 2 - K Date: 08/06/2021 Tested: New lot QC Controls Lot #: 1905012, expiration 12-31-2020 Results out of acceptable range for: Control 1 & 2 - K Repeat run out of acceptable range: Control 1 & 2 - K Date: 08/11/2021 Tested: New shipment QC Controls Lot #: 1905012, expiration 12-31-2020 Results out of acceptable range for: Control 1 & 2 - K Date: 08 /12/2021 Tested: New shipment QC Controls Lot #: 1910004, expiration 02-2021 No out of range QC results. 2. Review of individualized quality control plan (IQCP) establishment studies/reports revealed the laboratory did not re-evaluate IQCP in order to keep the 30 day interval between QC. 3. Review of the patient test logs for July 19th to August 12th of 2020 revealed the following patient samples were tested after the intermittent QC failure: Patient: WAYLA001 date tested:07/23/2020 Patient: HARJA007 Date tested:07/23/2020 Patient: LOPCH001 Date tested:07/23/2020 Patient: NEWCH001 Date tested: 07/23/2020 Patient: AYAJE000 Date tested: 07/25 /2020 Patient: NEWCH001 Date tested: 07/25/2020 Patient: O0BTI000 Date tested: 07/25/2020 Patient: DORKE000 Date tested: 07/30/2020 Patient: LEDTA000 Date tested:07/30/2020 Patient: MONDE001 Date tested:07/30/2020 Patient: NICAL000 Date tested: 07/30/2020 Patient: WAYLA001 Date tested:07/30/2020 Patient: GORDA002 Date tested: 08/05/2020 4. In an interview on 11/10/2021 at 1245 hours in the conference room the Technical Consultant stated that she was unaware that IQCP must be re-evaluated after intermittent failures confirmed the findings.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating 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.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's competency assessments, and staff interview, it was revealed the laboratory failed to have documentation of the technical consultant performing the annual competencies to include observation of testing and maintenance. The findings include: 1. A review of testing personnel competency assessments from 2020 and 2021 revealed annual competencies were documented as being performed on specific days and the technical consultant signed the assessments at a much later date. Examples are: a) Testing personnel #1 Assessment performed: 06 /03/2021 Signed by Technical consultant: 11/03/2021 b) Testing personnel #2 Assessment performed: 07/27/2020 Signed by Technical consultant: 11/03/2021 Assessment performed: 12/30/2020 Signed by Technical consultant: 10/16/2021 c) Testing personnel #3 Assessment performed: 06/2020 No signature by Technical consultant Assessment performed: 06/2021 No signature by Technical consultant d) Testing personnel #4 Assessment performed: 06/2020 Signed by Technical consultant: 5/26/2021 Assessment performed: 04/18/2021 Signed by Technical consultant: 11/03/2021 e) Testing personnel #5 Assessment performed: 09/30/2021 Signed by Technical consultant: 11/03/2021 f) Testing personnel #6 Assessment performed: 06/05/2020 Signed by Technical consultant: 11/03/2021 Assessment performed: 05/26/2021 Signed by Technical consultant: 05/20/2021 2. The laboratory was asked to provide documentation of the technical consultant performing the competency assessments on the day indicated - including the necessary observations. No documentation was provided. 3. An interview with the technical consultant on 11 /10/2021 at 0930 hours in the office revealed the competency assessment were performed by other laboratory personnel and then signed off by the technical consultant on a later date. This confirmed the findings.