

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D2071729	<b>(X3) Date Survey Completed</b>  06/12/2019
<b>Name of Provider or Supplier</b>  Cec Fossil Creek Llc	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	<p>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 to be 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 the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.</p>
<b>D6019</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(4)(iv)</p> <p>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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute's proficiency testing records for 2019 Microbiology 1st event and staff interview, it was revealed the laboratory failed to have documentation of performing corrective action for the analyte Respiratory syncytial virus (RSV). Findings include: 1. A review of the laboratory's procedure titled "Laboratory Procedure Proficiency Testing" states, 'Should any result(s) be evaluated as "UNACCEPTABLE", corrective action should</p>

be initiated within one week. An Unacceptable Proficiency Test Results Evaluation Form should be completed by the Technical Consultant or designee to document investigation and projected corrective actions.' 2. A review of the laboratory's American Proficiency Institute's Microbiology proficiency testing records from 2019 1st event revealed an unsatisfactory score of 50% for the analyte RSV. 3. The laboratory was asked to provide documentation of performing corrective action for the unsatisfactory score. No documentation was provided. 4. An interview with the technical consultant on 6/12/19 at 12:30 in the conference room revealed the laboratory did not perform the corrective action for the unsatisfactory score. This confirmed the above findings.