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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>06D2128458      | <b>(X3) Date Survey Completed</b><br><br>12/28/2023 |
| <b>Name of Provider or Supplier</b><br><br>Afc Urgent Care Denver Leetsdale  | <b>Street Address, City, State</b><br><br>850 S Monaco Pkwy, Ste 10, Denver, CO |   |
| 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>   |
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| <b>D6018</b>              | <p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b><br/>CFR(s): 493.1407(e)(4)(iii)</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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;</p> <p>This STANDARD is not met as evidenced by:<br/>Based on a record review and an interview with the Quality Manager, the laboratory director failed ensure that proficiency testing (PT) failures were evaluated and corrective actions were taken where necessary, since the last survey on 10/29/2021. Findings include: 1. A record review of the laboratory's PT reports from API (American Proficiency Institute), showed that event 2 of 2022 was graded as 80% for Hematology, Red Blood Cell Count, Hemacrit, Hemoglobin, and Platelet count tests and 60% for White Blood Cell Count. 2. A review of the laboratory's evaluation report for this PT event showed that the lab did not investigate the reasons for any of the 80% scores. 3. A review of the laboratory's evaluation report for this PT event showed that the lab did identify the cause of the 60% score, but did not establish any corrective actions to mitigate this issue in future events. 4. An interview with the laboratory's quality manager on 12/28/2023, at 12:30 p.m., confirmed that there were no investigations or corrective actions established for the 80% scores and that the investigation report for the 60% score did not establish a corrective action to address the cause of the failure.</p> |