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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>01D0862701 | <b>(X3) Date Survey Completed</b><br><br>07/20/2021 |
| <b>Name of Provider or Supplier</b><br><br>Afterhours Clinic Inc   | <b>Street Address, City, State</b><br><br>1800 Birmingham Ave, Jasper, AL  |   |
| 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>D2007</b>              | <p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b><br/>CFR(s): 493.801(b)(1)</p> <p>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</p> <p>This STANDARD is not met as evidenced by:<br/>Based on a review of API (American Proficiency Institute) proficiency testing (PT) records, and an interview with Testing Personnel #1, the surveyor determined the laboratory failed to ensure proficiency testing samples were rotated between all personnel who performed patient testing. Testing Personnel #1 performed five out of seven events and Testing Personnel #4 performed two out of seven events from 2019 - 2021 (a total of seven Testing Personnel performed patient testing in the Laboratory). The findings include: 1. A review of API attestation statements revealed the following: a) Testing Personnel #1 performed 2019 Hematology 2nd Event, 2019 Hematology 3rd Event, 2020 Hematology 1st Event, 2020 Hematology 2nd Event, and 2020 Hematology 3rd Event. b) Testing Personnel #4 performed 2020 Hematology 2nd Event and 2021 Hematology 1st Event. 2. During an interview on 07/20/2021 at 11:00 AM, Testing Personnel #1 confirmed the proficiency testing was not rotated among all personnel that performed patient testing.</p> |
| <b>D2128</b>              | <p><b>HEMATOLOGY</b><br/>CFR(s): 493.851(e)</p> <p>(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be</p>   |

maintained by the laboratory for two years from the date of participation in the proficiency testing event.

This STANDARD is not met as evidenced by:

Based on a review of Proficiency Testing records and an interview with Testing Personnel #1, the laboratory failed to document corrective action for unacceptable analytes. This was noted on three out of seven 2019 - 2021 Hematology Proficiency Testing Events. The findings include: 1. A review of Proficiency Testing records revealed the following: a) 2019 Hematology 1st Event 67% White Blood Count Differential (60% Monocytes/mixed and 40% Neutrophils/ Granulocytes) the corrective action stated "reviewed printoffs and recorded correctly." No remedial action was taken or documented. b) 2019 Hematology 3rd Event 80% Red Blood Cells had no corrective action documented. c) 2020 Hematology 1st Event 93% White Blood Count Differential (80% Monocytes/mixed) had no corrective action documented. 2. During an interview on 07/20/2021 at 11:00 AM, Testing Personnel #1 was unaware corrective action was required for one analyte being unacceptable for 2019 Hematology 3rd Event and 2020 Hematology 1st Event. Also, Testing Personnel #1 stated for 2019 Hematology 1st Event a different personnel was in charge of the Laboratory and was unsure why more corrective action wasn't done.