

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0244697	(X3) Date Survey Completed 09/29/2021
Name of Provider or Supplier Cpn, Inc DbA Atrium Health Urgent Care-Arboretum	Street Address, City, State 7810 Providence Road, Suite 102, Charlotte, NC	
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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES 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: Based on review of the CMS-209 and review of 2019, 2020, and 2021 CAP (College of American Pathologists) proficiency testing records 9/29/21, the laboratory failed to ensure proficiency testing was rotated among personnel who routinely perform patient testing. Review of the CMS-209 Laboratory Personnel Report (CLIA) revealed 46 TP (testing personnel) were listed on the form. Review of 2019, 2020, and 2021 CAP proficiency testing records revealed proficiency samples for 3 of 12 events were tested by 1 TP who is no longer employed. Samples for 9 of 12 events were tested by 4 of the 46 testing personnel - TP #1, TP #2, TP #4, and TP #5. a. TP #1 tested all samples for the 2020 FH2-B hematology event, the 2020 AQI-C chemistry event, the 2021 FH2-B hematology event, and the 2021 AQI-B chemistry event. b. TP #2 tested all samples for the 2019 FH2-C hematology event, the 2020 AQI-B chemistry event, and the 2021 FH2-A hematology event. c. TP #4 tested all samples for the 2019 FH2-B hematology event. d. TP #5 tested all samples for the 2020 FH2-A hematology event.</p>
D5783	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must</p>

be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policies and procedures and review of 2019, 2020, and 2021 Coulter AcT diff calibration records 9/29/21, the laboratory failed to take and document corrective action when reproducibility failed during calibration of the Coulter AcT diff hematology analyzer during 2 of 9 calibrations performed from 5/25/19 - 7/31/21. Review of the laboratory's procedure manual revealed reproducibility instructions with the title "IMPORTANT NOTICE To AcTDiff Hematology Users". The instructions state "... 4. If your reproducibility fails, the problem may be with the sample! You must obtain another sample or use your normal control (but be aware of the 35 'dip rule'). 5. If you have problems doing the reproducibility, do not hesitate to call Technical Service, but be aware that the sample being used or incorrect specimen handling can be the problem." Review of 2019, 2020, and 2021 calibration records revealed hemoglobin failed on the reproducibility performed 12/1/20 and WBC (white blood cell count), RBC (red blood cell count), and hemoglobin failed on the reproducibility performed 2/24/21. There was no documentation that the testing personnel recognized the failures, contacted Coulter Technical Service, or contacted the technical consultant for assistance. The laboratory proceeded with calibration of the analyzer. The technical consultant documented review of the 12/1/20 and the 2/24/21 calibration records on 5/14/21. There was no documentation of corrective action.