

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2051583	(X3) Date Survey Completed 10/14/2021
Name of Provider or Supplier Afc Urgent Care Lyndhurst	Street Address, City, State 560 New York Avenue, Lyndhurst, NJ	
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	The survey conducted on October 14, 2021 found the laboratory in compliance with 42 CFR part 493 Requirements for Laboratories.
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Office Manage (OM), the laboratory failed to verify the accuracy of Hematology test results obtained from the American Proficiency Institute (API) for the 3rd event in 2020. The findings include: 1) The laboratory received a zero score on all Hematology analytes for nonparticipation in API event 3, 2020. 2) There was no documented evidence the laboratory verified the zero score. 3) The OM confirmed on 10/14/21 at 11:30 am that the laboratory failed to verify the accuracy of Hematology test results.</p>
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a</p>

minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on surveyor review of Calibration Verification (CV) records and interview with the Technical Consultant (TC), the laboratory failed to perform and document CV procedures at least once every six months for Hematology Testing on the Medonic M-series analyzer from 7/7/20 to the date of survey. The finding includes: 1. There was no documented evidence CV was performed after 7/7/20. 2. The TC confirmed on 10/13/21 at 11:00 pm CV was not performed every six months.