

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2051583	(X3) Date Survey Completed 12/11/2018
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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: a) Based on surveyor review of the Procedure Manual (PM) and interview with the Technical Consultant (TC), the laboratory failed to follow the procedure for Quality Assurance in the calendar year 2018. The findings include: 1. The PM stated Levy Jennings (LJ) charts are to be reviewed monthly but the laboratory reviewed LJ charts as follows: a. February & March LJ were reviewed in June 2018. b. April, May, June, & July LJ were reviewed in October 2018. 2. The TC confirmed on 12/11/18 at 11:50 am that the PM was not followed. b) Based on surveyor review of the PM and interview with the TC, the laboratory failed to follow the procedure for verification of controls used on the Medonic M series analyzer in the calendar year 2018. The findings include: 1. The PM stated to run controls five times before using but the laboratory ran controls two or three times before using. 2. Control verification was not performed on controls received in March and June 2018. 3. The TC confirmed on 12 /14/18 at 12:00 pm that the PM was not followed.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p>

This STANDARD is not met as evidenced by:
Based on surveyor review of the Maintenance Records (MR) and interview with the Technical Consultant (TC), the laboratory failed to perform and document maintenance as specified by the manufacturer on the Medonic M series analyzer in the calendar year 2018. The findings include: 1. There was no documented evidence that monthly maintenance was performed in February, March, April, May, July, September, October and November. 2. The TC confirmed on 12/11/18 at 10:15 am that monthly maintenance as specified by the manufacturer was not performed.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:
Based on surveyor review of the Personnel Files and interview with the Technical Consultant (TC), the Laboratory Director failed to have training documented for four out of ten Testing Personnel (TP) from 7/11/17 to the date of the survey. The TC confirmed on 12/11/18 at 9:20 am that all TP did not have training records.