

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2101212	(X3) Date Survey Completed 04/26/2018
Name of Provider or Supplier Afc/Doctors Express North Bergen	Street Address, City, State 2100 88th Street, North Bergen, 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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Technical Consultant (TC), the laboratory failed to maintain a copy of all records for Hematology events performed with the American Proficiency Institute (API) in 3-2017 and 1-2018. The finding includes: 1. The attestation statements were not signed by the Laboratory Director for PT events 3-2017 and 1-2018. 2. The TC #3 confirmed on 4/26/18 at 10:30 am that all PT records were not maintained.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p>

	<p>This STANDARD is not met as evidenced by: Based on surveyor review of the Competency Assessment (CA) records and interview with the Technical Consultant (TC), the laboratory failed to perform CA correctly on ten out of ten TP in the calendar years 2016 and 2017. The finding include: 1. The laboratory did not document what records were reviewed. 2. The TC #3 listed on CMS form 209 confirmed on 4/26/18 at 10:00 am that the CA was not performed correctly.</p>
<p>D5211</p>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Technical Consultant (TC), the laboratory failed to evaluate coded results obtained in 2-2017 for Hematology events performed with the American Proficiency Institute (API) at the time of survey. The finding includes: 1) The laboratory did not evaluate Not Graded 2 (lack of consensus) results on Monocyte % samples HEM-07 and HEM-10. 2) The TC # 3 listed on CMS form 209 confirmed on 4/26/18 at 9:50 am that the laboratory failed to evaluate coded results.</p>
<p>D5429</p>	<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> <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 used for Hematology tests from August 2017 to the date of the survey. The findings include: 1. A review of the MR revealed monthly maintenance was not performed in August, October, November 2017 and January, February and March 2018. 2. The TC #3 listed on CMS form 209 confirmed on 4/26/18 at 11:15 am that maintenance as specified by the manufacturer was not performed.</p>
<p>D5805</p>	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p>

	<p>This STANDARD is not met as evidenced by: Based on surveyor review of the Final Report (FR) and interview with the Technical Consultant (TC), the laboratory failed to ensure that the Test Report Date (TRD) was indicated on the FR from 11/9/16 to the date of survey. The TC #3 listed on CMS form 209 confirmed on 4/26/18 at 11:30 am that the TRD was not on the FR.</p>
<p>D6029</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</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)(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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Personnel Files (PF) and interview with the Technical Consultants (TC), the Laboratory Director failed to have training documented for two out of ten TP from 11/9/16 to the date of the survey . The TC # 3 listed on the CMS form 209 confirmed on 4/26/18 at 10:10 am that all TP did not have training records.</p>
<p>D6046</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p> <p>(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Personnel Files and interview with the Technical Consultant (TC), the TC failed to ensure Competency Assessment (CA) was evaluated by a qualified individual in the calendar years 2016 and 2017. The finding includes: 1. CA assessment on ten out of ten Testing Personnel was performed by the Office Manager who had an Associate Degree. 2. The TC #3 listed on CMS form 209 confirmed on 4/26/18 at 10:40 am that the TC did not ensure who must perform CA.</p>