Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0505487	08/03/2018
Name of Provider or Supplier	**Street Address, City, State**	
Adc, Pllc, North Laboratory, The	12221 North Mopac 4th Floor South, Austin, TX	

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 following deficiencies are a result of a desk review of proficiency testing scores obtained from the CMS (Center for Medicare Services) national database and verified with the proficiency testing company, College of American Pathologists (CAP). The facility was found to be out of compliance with the conditions of participation of the CLIA program. The following CONDITION LEVEL DEFICIENCIES were found to be out of compliance: 493.803 successful participation in a proficiency testing program 493.1403 laboratories performing moderate complexity testing; laboratory director
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by:

	Based on a desk review of proficiency testing records obtained from the CMS (Center for Medicare Services) national database and verified with the proficiency testing company, College of American Pathologists (CAP) , it was determined the laboratory had not successfully participated in a proficiency testing program approved by HHS, for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. The laboratory did not successfully participate in the specialty of toxicology for carbamazepine, digoxin, phenytoin and valproic acid. Refer to D2119.
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on a proficiency testing desk review of CMS form 155 and CAP records found that the laboratory failed to attain a satisfactory score of at least 80% of acceptable responses for each analyte in the subspecialty of chemistry for Cholesterol - HDL. Findings: 1. CAP 2016 - 2nd event the laboratory received the unsatisfactory score of 0% for cholesterol HDL.
D2111	TOXICOLOGY CFR(s): 493.845(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Review of the CMS report 155 and CAP proficiency testing records found that the laboratory failed to participate in the 2018 1st Testing Event and the 2018 2nd Testing Event for Toxicology, resulting in a score of 0% for all regulated analytes for the speciality of Toxicology, constituting unsatisfactory performance. Findings: 1. Laboratory received the following scores from CAP 2018 - 1st event: Carbamazepine - 0% Digoxin - 0% Phenytoin - 0% Valproic Acid - 0% 2. Laboratory received the following scores from CAP 2018 - 2nd event: Carbamazepine - 0% Digoxin - 0% Phenytoin - 0% Valproic Acid - 0%
D2115	TOXICOLOGY CFR(s): 493.845(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

	This STANDARD is not met as evidenced by: Review of the CMS report 155 and CAP proficiency testing records found that the laboratory failed to participate in the 2018 1st and 2nd Testing Events for Toxicology, resulting in an event score of 0%, constituting unsatisfactory performance. Findings: 1. CAP 2018 - 1st event the laboratory received an unsatisfactory event score of 0%. 2. CAP 2018 - 2nd event the laboratory received an unsatisfactory event score of 0%.
D2118	TOXICOLOGY CFR(s): 493.845(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on desk review of proficiency testing records, it was determined the laboratory failed to achieve satisfactory performance (80% or greater) for the same analyte in two consecutive testing events or two out of three consecutive testing events in the specialty of Toxicology for the analytes carbamazepine, digoxin, phenytoin and valproic acid. Two out of three unsatisfactory scores results in unsuccessful PT performance. 1. Laboratory received the following scores from CAP 2018 - 1st event: Carbamazepine - 0% Digoxin - 0% Phenytoin - 0% Valproic Acid - 0% 2. Laboratory received the following scores from CAP 2018 - 2nd event: Carbamazepine - 0% Digoxin - 0% Phenytoin - 0% Valproic Acid - 0%
D2119	TOXICOLOGY CFR(s): 493.845(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on desk review of proficiency testing records, it was determined the laboratory failed to achieve satisfactory performance (80% or greater) for the speciality of Toxicology in two consecutive testing events or two out of three consecutive testing events. Two out of three unsatisfactory scores results in unsuccessful PT performance. Findings: 1. CAP 2018 - 1st event the laboratory received an unsatisfactory event score of 0%. 2. CAP 2018 - 2nd event the laboratory received an unsatisfactory event score of 0%.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by:

	Based on a desk review of laboratory proficiency testing performance it was revealed that the laboratory director failed to provide overall management and direction of the laboratory services. Refer to D6016
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on a desk review of proficiency testing results it was revealed that the laboratory director failed to ensure the overall quality of the laboratory services provided. The laboratory director failed to ensure successful participation in a HHS approved proficiency testing program. Refer to D2118 and D2119