Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2108822	12/08/2020
Name of Provider or Supplier	**Street Address, City, State**	
Adc, Pllc, Cedar Park, The	1401 Medical Parkway,Bldg C,Suite 150, Cedar Park, 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
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure, proficiency test (PT) records, and interview, the laboratory failed to test PT samples the same number of times it routinely tests patients in 2 of 3 Hematology testing events reviewed for 1 of 5 CBC (Complete Blood Count) specimens. Findings follow. Review of the laboratory's policy and procedure titled CBC Sysmex-300, rev 4/17, on page 2 under Patient Testing stated, "h. Review results for Histogram flags and critical results. If present, repeat CBC testing if there is enough sample or recollect the patient upon Provider request. (Refer to the Instructions for Use Manual for Histogram flag details and recommended actions)." Review of the American Proficiency Institute (API) Hematology PT testing records for CBCs from the 3rd testing event in 2019 and the 1st testing event of 2020 showed specimens HSY-14 and HSY-04 had been repeated by an extra test run each, respectively. Specimen HSY-14, tested by testing personnel #4 on the CMS form 209, was run three times. Platelets was flagged with AG+. Specimen HSY-04, tested by testing personnel #3, was run twice and did not meet the repeat criteria. Interview with testing personnel #1 on the CMS form 209 on December 8, 2020 at 1400 hours in the breakroom acknowledged it was discussed with testing personnel "that we do not do that".
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed

	following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure, testing records, and interview, the laboratory failed to follow its own policy for deleting test results with Histogram flags performed on the Sysmex XP-300 for Complete Blood Counts (CBCs) for 4 of 4 test reports reviewed. Findings follow. Review of the laboratory's policy and procedure titled CBC Sysmex-300, rev 4/17, on page 2 under Patient Testing stated, "g. Results will be transmitted to the EMR via the instrument interface. The report will print to the designated printer, if instrument is set for automatic printing. h. Review results for Histogram flags and critical results. If present repeat CBC testing if there is enough sample or recollect the patient upon Provider request. (Refer to the Instructions for Use manual for Histogram flag details and recommended actions). i. Report patient testing results. Results with Histogram flags cannot be reported. i. Upon completion of the test cycle, results are transmitted to the EMR. All results that have a Histogram Flag will reported as "unable to report" in the EMR. If the testing is repeated, two CBC reports will appear in the EMR. Staff must review the reports and delete one with the "filed in error" function. ii. In the event that the instrument interface or EMR is down, CBC results should be printed on the paper pre-printed with normal ranges. Results with Histogram flags must be marked through with a single dark line. Results are then subsequently entered in to the EMR (age specific normal will be applied for results flagging) when the problem is resolved." Review of 4 of 4 patient test reports showed results were reported for indices with Histogram Flags as found below with the date of testing, patient's initials and date of birth, and the indicy with the Histogram flagged on the instrument print-outs: 1. 7/03 /2020: WA, 9/30/2019: Platelets flagged with AG+ and reported as 330 2. 7/03/2020: JN, 06/02/2016: Platelets flagged with AG+ and reported as 208 3. 01/24/2020: JK, 02 /14/2018: Platelets flagged with AG+ and reported as 469 4. 01/15/2020: JB, 07/02 /2015: Platelets flagged with AG+ and reported as 358 Interview with the technical consultant on December 8, 2020 at 1530 hours in the breakroom acknowledged the result with the Histogram flag should be marked out on the instrument print-out and not reported in the EMR. KEY: EMR= Electronic Medical Record
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on review of Sysmex XP-300 instrument print-outs and interview, the laboratory failed to maintain a record system that included the positive identification of the specimens for 7 out of 9 CBC (Complete Blood Count) instrument print-outs reviewed. Findings follow. Review of the CBC instrument print-outs showed one or two letter initials to identify the patient as listed by initials and date of testing: 1. 09/08

	/2020: VT 2. 7/03/2020: WA 3. 01/24/2020: JK 4. 01/24/2020: A 5. 01/15/2020: LH 6. 01/15/2020: K 7. 01/15/2020: A. Interview with testing personnel #1 on December 8 /2020 at 1515 hours in the breakroom confirmed they use the patient's initials as the patient identifier for the testing records.
D5805	TEST REPORT CFR(s): 493.1291(c) 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. This STANDARD is not met as evidenced by: Based on review of patient test reports and interview, the laboratory failed to include the name and address and the units of measurement on the CBC (Complete Blood Count) test report for 6 of 9 and 9 of 9 test reports, respectively. Findings follow. A. Review of 6 of 9 cumulative test reports showed no name and address of the facility where the test was performed as listed below by the date of testing, patient initials and date of birth: 1. 09/08/2020: VT, 12/06/2019 2. 7/03/2020: WA, 9/30/2019 3. 7/03 /2020: JN, 06/02/2016 4. 01/15/2020: LH, 12/06/2016 5. 01/15/2020: JM, 12/06/2014 6. 01/15/2020: JB, 07/02/2015. B. Review of 9 of 9 test reports showed no units of measurement for White Blood Cell Count, Lymphocytes, Monocytes, Neutrophils, Absolute Lymphocytes, Absolute Monocytes, Absolute Neutrophils, Red Blood Cell Count, Hemoglobin, Hematocrit, MCV (Mean Corpuscular Volume), MCH (Mean Corpuscular Hemoglobin), MCHC (Mean Corpuscular Hemoglobin Concentration), RDW (Red Blood Cell Distribution Width), Platelet Count, and MPV (Mean Platelet Volume) as listed below by the date of testing, patient initials and date of birth: 1. 09 /08/2020: VT, 12/06/2019 2. 7/03/2020: WA, 9/30/2019 3. 7/03/2020: JN, 06/02/2016 4. 01/24/2020: JK, 02/14/2018 5. 01/24/2020: AB, 05/14/2019 6. 01/15/2020: LH, 12 /06/2016 7. 01/15/2020: JM, 12/06/2014 8. 01/15/2020: JB, 07/02/2015 9. 01/15 /2020: AL, 01/23/2017. Interview with testing personnel #1 on December 8, 2020 at 1540 hours in the breakroom confirmed there was no facility name and address or units of measurement on the test reports.