Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2248778	04/23/2024
Name of Provider or Supplier	**Street Address, City, State**	
The Adc, Pllc, Leander	505 St David'S Loop Ste 320, Leander, 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 laboratory was surveyed and found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, and recertification is recommended.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on observation, review of manufacturer's instructions, patient testing logs, and interview, the laboratory failed to ensure expired Abbott ID Now Respiratory Syncytial Virus (RSV) kits were not used for patient testing beyond expiration for 12 of 12 months reviewed. Findings follow. A. During a tour of the laboratory on April 23, 2024 at 1240 hours, the surveyor observed the only available RSV kits were expired, Lot M182303, expiration 04/24/2023 (elapsed time 365 days), with 13 out of 24 kits remaining. B. Review of the Daily Testing and Miscellaneous QC Log from 11 /28/2023 - 04/23/2024 showed 5 patient tests were performed as listed by date of service and accession number: 1. 12/15/2023 8X800439851 2. 02/05/2024 8X800559751 3. 02/06/2024 8X703037809 4. 03/11/2024 8X800614010 5. 03/15 /2024 8X800474699 C. Interview with the Technical Consultant (as listed on the CMS-209) on April 23, 2024 at 1240 hours confirmed the findings.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (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. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure, proficiency testing (PT) records and interview, the laboratory failed to sign and/or retain the attestation statement attesting that proficiency testing samples were handled in the same manner as patient testing for 3 of 5 Hematology events. Findings follow. A. Review of the laboratory's policy and procedure titled Proficiency Testing Guidelines, approved 03 /09/2022, under Testing Survey Samples stated, "7. The person who submits the results to API, will verify that required signatures are documented on the attestation statement form by the testing personnel (they should have signed upon completion of testing) and will have the Lab Director sign the form. 8. Retain a copy of the complete result form for a minimum of 2 years and ensure results are submitted on-line to the PT program before the stated deadline." The laboratory's policy and procedure was not followed. B. Review of the American Proficiency Institute (API) proficiency testing records from the 3rd event of 2022, and the 1st, 2nd, and 3rd events of 2023 and the 1st event of 2024 revealed three Hematology events- 1st & 3rd events from 2023 and the 1st event from 2024, were lacking signed testing personnel attestation statements for Hematocrit, Hemoglobin, Lymphocytes, Mid, Granulocytes, Mean Corpuscular Hemoglobin, Mean Corpuscular Hemoglobin Concentration, Mean Corpuscular Volume, Platelet Count, Red Cell Count, and White Cell Count. Review of the Attestation Statement page stated, " We certify that as closely as possible, these proficiency testing samples were tested in the same manner as patient specimens." 1. Attestations for the 1st event of 2023 and 2024 could not be located. 2. Attestation for the 3rd event of 2023 was not signed by the testing personnel. C. Interview with the Technical Consultant (as listed on the CMS-209) on April 23, 2024 at 1055 hours in the office confirmed the findings.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) 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. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, the laboratory's policy and procedure, test reports, and interview, the laboratory failed to follow its own policy for redacting Complete Blood Counts (CBCs) test results with Histogram flags performed on the Sysmex XP-300 for four (4) out of 10 test reports reviewed. Findings follow. A. Review of the Sysmex XP-300 Instructions For Use, Nov 2017, at 8.3 Histogram Flags stated, "Various information can be obtained from the histograms. The XP-300 extracts the characteristics for the histogram and displays

	them as histogram flags. When the histogram flags are displayed, perform analysis again. If afterwards the flags are still displayed, the sample is considered to correspond to one of the following. Flag [WL] Probable sample cause Incomplete lysing of red blood cells, presence of nucleated red blood cells, increase of large platelets, platelet aggregation or agglutination, precipitation of fibrin, etc. Correction 1) Centrifuge sample and replace the plasma with equal volume of saline of CELLPACK and repeat analysis. 2) Check smear, etc. Flag [T2] Probable sample cause Presence of CML or other immature granulocytes, incomplete lysing of red blood cells, aged sample, etc. Correction 1) Check smear, etc. 2) Centrifuge sample and replace the plasma with equal volume of saline of CELLPACK and repeat analysis, warm sample at 37 degrees Celsius for 30 minutes and repeat analysis, etc. Flag [AG] Probable sample cause Presence of nucleated red blood cells, effects of fragmented red blood cells, increase of large platelets, platelet aggregation or agglutination, precipitation of fibrin, etc. Correction 1) Check smear, etc. B. Review of the laboratory's policy and procedure titled CBC Sysmex XP-300, approved 3/09 /2022, on page 2 under Patient Testing stated, "g. Results will be transmitted to the EMR via the instrument interface when used. 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, when the interface is used, the results are transmitted to the EMR. Any result with a Histogram flag will be reported as "unable to report" in the EMR. Additionally, the applicable age specific normal ranges will be applied to the results. ii. In the event that the instrument interface or EMR is down or not used the CBC results should be 1) printed on the pre-printed XP-300 paper with patient normal ranges, 2) a patient label is affixed to the report and, 3) any result with Histogram flag must be marked through with a single dark line (use a Sharpie). The report is then scanned in to the EMR and a notation is made to the order "see scanned report". C. Review of 4 of 10 patient test reports revealed results with Histogram Flags were reported as found below with the date of testing, accession number, and the indicy with the Histogram flagged on the instrument print-outs: 1. 06/08/2023 8X703011034 PLT [AG] 2. 09/18/2023 8X703624163 WBC, LYM%, LYM# [WL] 3. 12/04/2023 8X800476633 PLT [AG] 4. 02/07/2024 8X702988870 WBC, LYM%, LYM# [WL] D. Interview with the Technical Consultant (as listed on the CMS-209) on April 23, 2024 at 1400 hours in the office confirmed the results with the Histogram flag should be marked out on the instrument print-out. KEY: EMR = Electronic Medical Record PLT = Platelets WBC = White Blood Cells LYM% = percent Lymphocytes LYM# = absolute Lymphocytes
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) 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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, the laboratory's policy and

	procedure, test reports, and interview, the laboratory director failed to ensure the laboratory policy was followed for redacting Complete Blood Counts (CBCs) test results with Histogram flags performed on the Sysmex XP-300 for four (4) out of 10 test reports reviewed (refer to D5401).
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's pre-survey paperwork, laboratory records, and interview, the laboratory director failed to specify the duties and responsibilities for one of one technical consultant. Findings follow. A. Review of the CMS-209 showed the laboratory identified 1 technical consultant. B. Review of the laboratory's personnel records revealed the laboratory director failed to have documentation of the duties and responsibilities for the technical consultant. C. Interview with the Technical Consultant (as listed on the CMS-209) on April 23, 2024 at 1015 hours in the office acknowledged she started as Technical Consultant in May or June of 2023 (elapsed time 10 months) and confirmed, after a review of the findings, there were no duties and responsibilities listed for her as Technical Consultant.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, the laboratory's policy and procedure, test reports, and interview, the technical consultant failed to ensure the laboratory policy was followed for redacting Complete Blood Counts (CBCs) test results with Histogram flags performed on the Sysmex XP-300 for four (4) out of 10 test reports reviewed (refer to D5401).