

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0505487	(X3) Date Survey Completed 10/05/2023
Name of Provider or Supplier Adc, Pllc, North Laboratory, The	Street Address, City, State 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 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.
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, the laboratory's policy and procedure, on-line service manual, observation, instrument print-outs, patient reports, and interview, the laboratory failed to ensure specimens were performed within 4 hours of collection for the Complete Blood Count (CBC) performed on the Sysmex XN-2000 (XN-20/XN-10) for 6 of 18 outpatient samples reviewed from October 3, 2023. Finding follow. A. Review of the Sysmex XN Series (XN-2000) Instructions for Use, CJ410539 rev 09/2017, on page 148 at 9.2 Prepare the Sample, 9.2.1 Sample types and handling under Handling whole blood stated, "The sample should be analyzed within 4 hours after collection. If it is not possible to analyze the sample within 4 hours, store it in a refrigerator at 2 to 8 degrees Celsius until it can be analyzed." And on page 398 at Chapter 15 Technical Information under Whole blood stability stated, "Long term stability is determined by comparing the results of the initial analysis (within 2 hours of collection) to results from samples stored at controlled room temperature (18-26 degrees Celsius) for 24 hours and refrigerated temperature for 48 hours." B. Review of the Sysmex Resource Manual for the Sysmex</p>

XN-series, doc no 1002-LSS Rev 2 01/2013, on page 10 of Section 5 Additional Studies for Reference under Stability Study stated, " Stability studies may be performed to determine the readiness of a sample for CBC, differential and reticulocyte count analysis. Short term stability may be performed with fresh samples drawn and analyzed at intervals within one (1) hour. Long term stability is conducted under storage conditions over a period of time defined by the laboratory as acceptable specimen analysis..." C. Review of the laboratory's policy and procedure titled Whole Blood and Synovial Fluid Analysis, approved 03/23/2021, under E. Specimen Stability and Storage stated, "1. Stored at 2-8 degrees Celsius, EDTA whole blood samples with normal results may be analyzed up to 48 hours without significant loss of differential stability. 2. Whole blood stability at room temperature is 24 hours..." D. Review of the on-line Order Choice Catalog in Harvest for the CBC w/auto diff under Specimen Storage and preservation stated, "Room Temperature (20 to 25 degrees Celsius) 24 hours Refrigerated (2 to 8 degrees Celsius) 48 hours." E. On October 3, 2023 at 1500, the surveyor observed in the laboratory posted at the Hematology work station, a Hematology Sample Stability Chart that stated for the CBC "24 hrs at RT (room temperature) and 48 hrs refrigerated." F. Review of out-patient instrument print-outs that showed the date and time performed against the patient reports that showed date and time of collection for out-patient specimens run on October 3, 2023 revealed 6 of 18 exceeded the manufacturer's stability of 4 hours as listed by Sample No, date and time of collection, date and time of run, and elapsed time: Sample Number Collection date and time Run date and time Elapsed Time 1. 10691898 10/03/2023 1200 10/03/2023 1648 4 hours 48 minutes 2. 10718457 10/03/2023 1027 10/03/2023 1646 6 hours 19 minutes 3. 10719135 10/03/2023 1015 10/03/2023 1647 6 hours 32 minutes 4. 10474529 10/03/2023 0703 10/03/2023 1123 4 hours 20 minutes 5. 10711627 10/03/2023 1111 10/03/2023 1546 4 hours 35 minutes 6. 10662690 10/03/2023 0704 10/03/2023 1124 4 hours 20 minutes G. Interview with general supervisor #3 (as listed on the CMS form 209) on October 3 2023 at 1430 hours confirmed a stability study to exceed the 4 hour stability of the CBC was not performed.

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:
 I. Based on review of the laboratory's policy and procedure, quality control records, validation records, and interview, the laboratory failed to follow its procedure for establishing the standard deviation (SD) used for Activated Partial Thromboplastin Time (APTT) on the ACL Elite Pro for 20 of 20 months reviewed. Findings follow.
 A. Review of the laboratory's policy and procedure titled Quality Control and Calibration of PT/APTT, approved 08/16/2016, under Quality Control stated "Two levels of control are recommended for a complete quality control program. Each laboratory should establish its own mean and standard deviation." Under Changing Lot Number of Control stated, "3. A control assay range must be established with every new lot number of controls or reagents. It is important to correctly establish a control assay range for every test that the laboratory will perform. 4. To be statistically significant, a minimum of 20 values on each control are needed. The mean, standard deviation, and %CV are calculated ... 6. Control ranges on the package

insert are only guidelines. Each individual laboratory must determine target values." B. Review of the analyzer for the current lot, N0138360/N0139022, showed the following SD were used for the quality control of APTT: Control SD Level 1 1.500 Level 3 2.000 C. Review of the validation records showed the previous lot, N0613545 /N0512850, showed the following SD for the quality control of APTT: Control SD Level 1 1.500 Level 3 2.000 D. Review of the laboratory's historical performance of QC from 10/08/21 to 06/05/23 showed the laboratory's SD over 20 months of data for APTT: Control SD Level 1 0.52 Level 3 1.1 E. Interview with technical supervisor # x on October 4, 2023 at 1030 hours acknowledged the SD was established at validation on 03/25/2019, but does not have the statistical data to support the established SDs. II. Based on review of the laboratory's policy and procedure, quality control records, validation records, and interview, the laboratory failed to follow its procedure for establishing the standard deviation (SD) used for Prothrombin Time (PT) on the ACL Elite Pro for 20 of 20 months reviewed. Findings follow. A. Review of the laboratory's policy and procedure titled Quality Control and Calibration of PT/APTT, approved 08/16/2016, under Quality Control stated "Two levels of control are recommended for a complete quality control program. Each laboratory should establish its own mean and standard deviation." Under Changing Lot Number of Control stated, "3. A control assay range must be established with every new lot number of controls or reagents. It is important to correctly establish a control assay range for every test that the laboratory will perform. 4. To be statistically significant, a minimum of 20 values on each control are needed. The mean, standard deviation, and %CV are calculated ... 6. Control ranges on the package insert are only guidelines. Each individual laboratory must determine target values." B. Review of the analyzer for the current lot, N0138360/N0139022, showed the following SD were used for the quality control of PT: Control SD Level 1 0.500 Level 3 2.000 C. Review of the validation records showed the previous lot, N0613545/N0512850, showed the following SD for the quality control of PT: Control SD Level 1 0.500 Level 3 2.000 D. Review of the laboratory's historical performance of QC from 10/08/21 to 06/05/23 showed the laboratory's SD over 20 months of data for PT: Control SD Level 1 0.3 Level 3 1.6 E. Interview with general supervisor #3 (as listed on the CMS form 209) on October 4, 2023 at 1030 hours acknowledged the SD was established at validation on 03/25/2019, but does not have the statistical data to support the established SDs.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:
Based on review of the manufacturer's instructions, humidity logs, patient reports, and interview, the laboratory failed to ensure the humidity was within manufacturers specifications on the Beckman Coulter MicroScan WalkAway 96 plus used for urine cultures 17 out of 269 days reviewed. Findings follow. A. Review of the on-board Microscan WalkAway Instrument Guide, April 2018, in the Appendix A: WalkAway Instrument Components and Specifications under WalkAway Instrument Technical

Specifications for the Recommended Laboratory Environmental Conditions stated, "humidity 30 to 80% RH (no condensation)". B. Review of the Microscan Temperature/Humidity Chart from January 2023 - September 2023 showed 17 out of 269 days the humidity exceeded the manufacturer's recommendations as listed by date and humidity in percent: Date Humidity % 1. 01/14/23 32 2. 01/19/23 31 3. 01/20/23 30 4. 01/21/23 34 5. 01/23/23 32 6. 01/24/23 34 7. 01/26/23 34 8. 01/27/23 33 9. 02/02/23 31 10. 02/11/23 32 11. 02/13/23 30 12. 02/17/23 32 13. 02/18/23 29 14. 03/14/23 34 15. 03/18/23 34 16. 03/19/23 33 17. 03/20/23 33 C. Random review of patient reports showed testing was performed on the above dates as shown by date of testing and the last 9 numerals of the patient ID: Date of testing Patient ID 1. 01/14/23 800389741 2. 01/19/23 703105786 3. 01/20/23 703015167 4. 01/21/23 703023015 5. 01/26/23 703021217 703109825 6. 01/27/23 701138693 702589572 7. 02/11/23 702981374 8. 02/13/23 800365179 9. 02/17/23 702998821 10. 02/18/23 702984485 703023957 11. 03/18/23 703109978 703014500 800275825 702999864 800226601 703014846 703025413 12. 03/19/23 703209697 703031866 703080777 800420356 13. 03/20/23 700633447 703014947 D. Interview with testing personnel #16 (as listed on the CMS form 209) on October 4, 2023 at 1515 hours confirmed the humidity was too low on a few days.

D5783

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:
 Based on review of quality control records, quality control policy, and interview with laboratory personnel, the laboratory failed to evaluate all patients tested since the last acceptable quality control for two of two instances where recalibration of an assay was necessary to achieve quality controls values that were within the laboratory's established criteria for acceptability. The findings included: 1. Based on review of the "Quality Control Corrective Action Log" for August 2023, on 8/8/23, the assay Aspartate Aminotransferase (AST) was recalibrated following values outside the acceptable range for levels 2 and 3. On 8/8/23, the initial value for Level 2 was 93; this was -2.33 standard deviations from the mean. The initial value for Level 3 was 216, which was -3.16 standard deviations away from the mean. The AST assay was recalibrated, and quality control values were repeated and within laboratory established acceptability criteria at 97 for Level 2 and 223 for Level 3. There were 20 patient specimens run since the last acceptable quality control values were obtained at approximately 14:00 hours on 8/7/2023. Patient specimens included the following: 10688658, 10538451, 10688982, 10688177, 10689007, 10688880, 10689018, 10522066, 10688745, 10689009, 10491154, 10657045, 10535895, 10688990, 10688707, 10688775, 10689050, 10689096, 10689135, and 10688801. There was no documentation available for review demonstrating that these patient values had been evaluated. 2. Based on review of the "Quality Control Corrective Action Log" for June 2023, on 6/22/23, the assay Ferritin was recalibrated following values outside the acceptable range for levels 2 and 3. On 6/22/23, the initial value for Level 2 was

199.1; this was -2.15 standard deviations from the mean. The initial value for Level 3 was 437, which was -3 standard deviations away from the mean. The Ferritin assay was recalibrated, and quality control values were repeated and within laboratory established acceptability criteria at 214.1 for Level 2 and 487 for Level 3. There were 11 patient specimens run since the last acceptable quality control values were obtained at approximately 09:50 hours on 6/21/2023. Patient specimens included the following: 10519241, 10665096, 10665329, 10665358, 10665246, 10653221, 10665618, 10664277, 10665408, 10665617, and 10665236 There was no documentation available for review demonstrating that these patient values had been evaluated. 3. Based on review of the quality control policy, "QUALITY CONTROL POLICY FOR QUANTITATIVE CHEMISTRY MEASUREMENTS", the policy did not include instructions for the evaluation of all patients tested since the last acceptable control when corrective actions are performed. 4. In an interview at 12:26 on 10/04/2023 in the laboratory, General Supervisor 3 (as listed on the Laboratory Personnel Report CMS-209) stated the laboratory had not routinely evaluated all patient specimens analyzed since the last acceptable control values when corrective actions such as recalibration are required to achieve quality control results within established acceptability criteria.

D6120

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (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.

This STANDARD is not met as evidenced by:
Review of personnel files, Thin Prep 2000 System Operator's Manual and interview of facility personnel found the technical supervisor failed to ensure that four of four personnel received training for the use of the Cytoc ThinPrep 2000 System to prepare microscope slides for evaluation. The findings included: 1. Review of personnel files for the three histology technicians and one cytologist found no documentation of training for the preparation of microscope slides using the Cytoc ThinPrep 2000 System. 2. Review of the Thin Prep 2000 System Operator's Manual found on page one: "Preparation of microscope slides using the ThinPrep 2000 System should be performed only by personnel who have been trained by Cytoc Corporation or by organizations or individuals designated by Cytoc Corporation." 3. During interview of the histology supervisor conducted October 4, 2023 at 10:02 AM, she confirmed that the four personnel who use the ThinPrep 2000 System had not been trained by Cytoc Corporation to prepare microscope slides using the Thin Prep 2000 System.