

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0698417	(X3) Date Survey Completed 08/26/2025
Name of Provider or Supplier Adc, Pllc, Extended Care At Cedar Bend, The	Street Address, City, State 2400 Cedar Bend Drive 1st Floor, 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. Standard level deficiencies were cited.
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by:</p> <p>I. Based on review of manufacturer's instructions, temperature charts, patient testing logs, interview, and pre-survey paperwork, the laboratory failed to monitor the temperature for the Sysmex XP-300 Hematology analyzer for performing CBC (Complete Blood Count) testing for two out of 13 days of patient testing reviewed. Findings follow. A. Review of the Sysmex XP-300 Instructions for Use, AU553517 October 2012, at 14. Technical Information, 14.1 Specifications, stated, "Operating Environment... Ambient temperature: 15 to 30 degrees Celsius". B. Review of the laboratory's Room Temperature/Humidity Log from 03/01/2025 - 05/31/2025 showed no temperatures recorded for 1. 03/10/2025 2. 04/14/2025. C. Review of the Daily Testing Log showed the CBCs tested: Date Account # 1. 03/10/2025 8X800695309 2. 04/14/2025 8X702981216 D. Interview with the Technical Consultant on August 26, 2025 at 1120 hours in the office confirmed the findings. E. Review of the CMS-Form 116 showed an annual test volume of 408. II. Based on review of manufacturer's</p>

instructions, humidity charts, patient testing logs, interview, and pre-survey paperwork the laboratory failed to monitor the humidity for the Sysmex XP-300 Hematology analyzer for performing CBC (Complete Blood Count) testing for two out of 13 days of patient testing reviewed. Findings follow. A. Review of the Sysmex XP-300 Instructions for Use, AU553517 October 2012, at 14. Technical Information, 14.1 Specifications, stated, "Operating Environment... Relative humidity: 30% to 85%". B. Review of the laboratory's Room Temperature/Humidity Log from 03/01/2025 - 05/31/2025 showed no humidity recorded for 1. 03/10/2025 2. 04/14/2025. C. Review of the Daily Testing Log showed the CBCs tested: Date Account # 1. 03/10/2025 8X800695309 2. 04/14/2025 8X702981216 D. Interview with the Technical Consultant on August 26, 2025 at 1120 hours in the office confirmed the findings. E. Review of the CMS-Form 116 showed an annual test volume of 408.

D5447

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(i)(g)

(d)(3)(i) Each quantitative procedure, include two control materials of different concentrations;

This STANDARD is not met as evidenced by:
Based on review of QC (quality control) records, patient testing records, interview, and pre-survey paperwork, the laboratory failed to run controls every day of patient testing for the Complete Blood Count (CBC) tested using the Sysmex XP-300 Hematology analyzer for one out of 13 days of patient testing reviewed. Findings follow. A. Review of monthly QC printouts from 03/01/2025 - 05/31/2025 showed there was no QC run on 03/18/2025. B. Review of the Sysmex XP-300 data log from 03/01/2025 - 05/31/2025 showed 13 days of patient testing with 1 patient, 8X701637913, reported on 03/18/2025 for the CBC. C. Interview with the Technical Consultant on August 26, 2025 at 1105 hours in the office confirmed the findings. D. Review of the CMS-Form 116 showed an annual test volume of 408.

D5481

CONTROL PROCEDURES
CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratorys and, as applicable, the manufacturers test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on the review of quality control (QC) records, patient testing records, and interview, the laboratory failed to ensure 2 levels of QC were within range for the Red Blood Cell (RBC), Hemoglobin (HGB), and Hematocrit (HCT) before performing and reporting patient test results using the Sysmex XP-300 Hematology analyzer for one out of 13 days of patient testing reviewed. Findings follow. A. Review of the monthly QC printouts from 03/01/2025 - 05/31/2025 showed the Normal and High levels of QC were out of range on 04/14/2025 for RBC, HGB, and HCT. Controls were not repeated. B. Review of the Sysmex XP-300 data log showed 13 days of patient testing with 1 patient, 8X702981216, reported on 04/14/2025 for RBC, HGB, and HCT. C. Interview with the Technical Consultant on August 26, 2025 at 1115 hours in the office confirmed the findings.

D5805**TEST REPORT**

CFR(s): 493.1291(c)

(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 the laboratory test reports, interview, and pre-survey paperwork, the laboratory failed to include the patient's name and identification number for one out of eight Complete Blood Count (CBC) test reports reviewed. Findings follow. A. Review of eight random patients' CBC test reports showed one without a name and complete identification number, 8X8005945, tested on 11/16/2024. B. Interview with the Practice Manager on August 26, 2025 at 1215 hours in the office confirmed the findings. C. Review of the CMS-Form 116 showed an annual test volume of 408.