Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0505253	01/20/2023
Name of Provider or Supplier	**Street Address, City, State**	
Adc, Pllc, Pediatrics At Cedar Bend, The	2400 Cedar Bend, 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	Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The facility was found to be in compliance with applicable Conditions in the CLIA program, 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: I. Based on review of manufacturer's instructions, observation, and interview, the laboratory failed to follow manufacturer's instructions for reading Multistix 10 SG urine dipsticks used to test Protein, Blood, Leukocytes, Nitrite, Glucose, Ketone, pH, Sepcific Gravity, Bilirubin, and Urobilinogen for one of one observation. Findings follow. A. Review of the Multistix 10 SG package insert, 11306391 Rev A 07-2017, under Procedure stated, "7. If reading visually: Compare each test pad to the corresponding row of color blocks on the bottle label. Read each pad at the time shown on the label, starting with the shortest time. Hold the strip close to the color blocks and match carefully." B. Review of the multistick bottle showed glucose and bilirubin were to be read at 30 seconds; ketone was to be read at 40 seconds; specific gravity was to read at 45 seconds; and blood, pH, protein, urobilinogen, nitrite, leukocytes were to be read at one minute. C. During a tour of the laboratory, the surveyor observed testing personnel #1, as listed on the CMS form 209, performing patient testing on January 18, 2023 at 1030 at Pod #3. Testing personnel #1 first dipped the dipstick in the urine cup, set the strip down on a pad on the counter, and then set the timer for 2 minutes, walked away to get a printed patient label, returned and began to read the strip with 52 seconds left on the timer, picked up the strip and held it and completed the readings. The patient tested was Account # 8x703002027.

	By the time she began to read the strip, the time elapsed for glucose and bilirubin was 68 seconds. The readings for glucose, bilirubin and ketones were made while the strip was still on the counter, about a foot from the bottle. D. Interview with the Technical Consultant on January 18, 2023 at 1045 confirmed the findings. II. Based on review of the manufacturer's instructions, training records, and interview, the laboratory failed to provide documentation of training for the Abbott ID NOW Covid-19 test for two of 13 testing personnel. Findings follow. A. Review of the ID NOW Covid-19 product insert, IN192000 Rev 1 2022/05, under Intended Use stated, "ID NOW Covid-19 2.0 is intended for use by trained operators who are proficient in performing tests using the ID NOW Instrument. The ID NOW Covid-19 2.0 assay is only for use under the Food and Drug Adminitration's Emergency Use Authorization." B. Review of the Testing Personnel Training Record for testing personnel 1) #6 and 2) #11 showed the line for Covid-19 training was blank for the date, employee initials, and trainer initials. C. Interview with testing personnel #3 on January 18, 2023 at 0935 hours acknowledged she had that.
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 manufacturer's instructions, humidity charts, patient testing logs, and interview the laboratory failed to monitor the humidity within the Sysmex XP-300 manufacturer's specifications for performing CBC (Complete Blood Count) testing for 15 of 108 days reviewed for Pod #3, Sysmex #2. Findings follow. A. Review of the Sysmex XP-300 Instructions for Use, AU553517 November 2013, 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 for Pod #3, Sysmex #2, SN A3089, had an acceptable humidity of 30-85%. Review of logs from August 2022 - December 2022 showed the laboratory exceeded the manufacturer's range on 14 of 108 days reviewed. C. Review of the Daily Testing Log showed the CBCs tested: Date % Humidity Accession#/Account # 1. 10/03/22 25 10384577 10384043 10384248 10384550 2. 10/04/22 28 10385669 10385297 10385553 10384733 3. 10/05/22 28 10386584 10386297 4. 10/18/22 29 10397431 10397958 5. 10/19/22 28 10398853 10399170 6. 10/20/22 27 10400400 7. 11/14/22 25 10421518 10421847 10422026 8. 11/15/22 28 10422805 10423448 9. 11/16/22 28 8x800317380 10424680 10424699 10424710 10424816 10424132 10424294 10424308 10. 11/17/22 27 10425564 11. 11/18/22 29 no patients 12. 12/01/22 25 13. 12/22/22 29 8x800302299 10453180 10452827 10453177 14. 12/28/22 28 10455619 10455642 8x702991620 10455795 8x800411586 D. Interview with Technical Consultant #1 on the CMS form 209, on January 18, 2024 at 1100 hours in the office confirmed the findings.