Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D2275419	12/12/2023
Name of Provider or Supplier	**Street Address, City, State**	
Pain Treatment Centers Of America	108 North Shackleford Rd, Little Rock, AR	

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**
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: 1. Through observation, review of temperature records, lack of documentation and interview it was determined that the laboratory failed to monitor the temperature on each day of operation in one of three rooms in which supplies with storage temperature requirements were stored. Findings follow: A) During a tour of the laboratory on 12/12/23 at 2:13 p.m., three rooms (main lab, phlebotomy hall room, and specimen collection room) containing laboratory items with a temperature storage requirement were observed. B) During a review of the laboratory's temperature records it was noted that no temperature records were presented for the phlebotomy hall room area. , 37 two ml. Vacuette EDTA blood collection tubes lot # 82211328 expiration date 2024-03-06 with a storage temperature requirement of 4 degrees C. to 25 degrees C. were observed in the phlebotomy hall room. C) Upon request, the laboratory could not present the temperature records for the phlebotomy hall room area in which the supplies were stored. D) In an interview on 12/12/23 at 2:18 p.m., the laboratory staff member (# 4 on form personnel worksheet) confirmed that temperature records for the phlebotomy hall room area were not kept. 2 .Based on review of policy and procedure manuals, manufacturer's instruction, temperature logs, and interview with staff, the laboratory failed to follow manufacturer's instructions for operational environment relative humidity for Sysmex CS-2500 System. Findings

	follow: E) Review of the Sysmex CS-2500 System specification sheet for use revealed the operating environment for relative humidity is "30 to 85% ". F) Review of the Temperature and Humidity Log for November 2023 through December 2023 revealed 9 days out 19 days humidity below 30%. G) During an interview on 12/12/2023 at 11: 15 a.m. the laboratory staff member (# 5 on form personnel worksheet) confirmed the 9 days below 30% humidity.
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: Base on review of the CMS-209 form presented at the time of the survey, a review of personnel records for three personnel listed on the form CMS-209, and through interviews with laboratory staff, it was determined one of one testing personnel failed to have written authorization to perform testing without direct supervision. Survey findings include: A. Through a review of the CMS- 209 form, it was determined that one person was designated as testing personnel. B. A review of personnel records for three personnel listed on the form CMS-209 revealed that one of one testing personnel failed to have written authorization to perform testing without direct supervision. Laboratory personnel # 2, did not have a written authorization to perform testing without direct supervision. C. In an interview at 10:03 a.m. on 12/12/2023, Technical Consultant (listed on the form CMS-209) confirmed that the laboratory did not have documented authorization for testing for employees performing testing.