Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0466068	05/05/2025
Name of Provider or Supplier	**Street Address, City, State**	
Chi St Vincent Medcial Group Hot Springs	320 Luzerene St, Mount Ida, 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) (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. This STANDARD is not met as evidenced by: Based upon observation, the manufacturer's user's manual for Sysmex XP 300 hematology instrument, review of temperature records, lack of documentation, and interview, the laboratory failed to monitor the temperature on each day of operation in one refrigerator in which supplies with storage temperature requirements were stored and the humidity in one room in which equipment with an operating humidity requirement was used on 2 of 63 working days reviewed . Findings follow: A) During a tour of the laboratory on 5/5/25 at 10:34 a.m., the surveyor observed a Sysmex XP 300 hematology analyzer in the main laboratory room. B) Review of the humidity requirment for the Sysmex XP 300 analyzer revealed an operating humidity requirement of 20% to 80% non-condensing humidity C) A review of the laboratory's humidity records revealed that no humidity values were recorded for the main laboratory room on 2/6/25 and 3/25/25. D) During a tour of the laboratory on 5/5/25 at 11:45 a..m. a case of three levels of Eightcheck - 3WP XTRA hematology controls lot # 510607 with a storage temperature requirement of 2 degrees Centigrade (C) to 6 degrees C was observed in the laboratory refrigerator. E) A review of the laboratory's temperature records revealed that no temperature values were recorded for the laboratory refrigerator on 2/6/25 and 3/25/25. F) Upon request, the laboratory could

	not provide the temperature or room humidity records for 2/6/25 or 3/25/25.. G) In an interview on 5/5/25 at 12:10 p.m., the laboratory staff member (# 1 on form CMS 209) confirmed that refrigerator temperature and room humidity values were not recorded on 2/6/25 and 3/25/25 and that the laboratory was in operation on those days..