Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D2033927	01/18/2023
Name of Provider or Supplier	**Street Address, City, State**	
Conway Regional Medical Center Vilonia	1159 Main Street, Vilonia, 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: Through review of the manufacturer's user manual for the Sysmex pocH-100i instrument, lack of documentation and interview it was determined that the laboratory failed to define the humidity level consistent with manufacturer's instructions for the Sysmex pocH-100i system. Findings follow: A) Review of the manufacturer's user manual for the Sysmex pocH-100i instrument revealed an operating humidity requirement of 30% to 85%. B) The laboratory had defined acceptable humidity levels as less than 85% with no defined lower limit. C) Review of the environmental records of the laboratory room in which the Sysmex pocH-100i instrument is used indicated the humidity was lower than 30% on 8 of 21 days in December 2022, 7 of 20 days in November 2022, and 1 of 21 days in October 2022. D) In an interview on 01/18/23 at 11:15 am, the laboratory staff member (#4 on the CMS 209 form) confirmed that the humidity level in the room in which the Sysmex pocH-100i instrument was used was out of manufacturer's designated range and no corrective actions were taken.