Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D2074398	12/13/2018
Name of Provider or Supplier	**Street Address, City, State**	
Unity Health Wcmc	3214 East Race Street, Searcy, 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 manufacturer's instrument user manual, lack of documentation, and interview it was determined that the laboratory failed to monitor humidity level in the Blood Bank laboratory for the entirety of 2018. Survey findings follow: A. Review of the Ortho Vision Blood Bank instrument manufacturer's user manual revealed the following warning; "In extreme laboratory conditions such as 15% relative humidity and a temperature of 30 degrees C. excessive evaporation of Ortho reagent red cells maybe observed with errors in results". B. Upon request, the laboratory could not provide records of relative humidity in the Blood Bank laboratory for 2018. C. In an interview on 12/13/18 at approximately 09:15 AM the testing personnel identified as number six on the CMS 209 form confirmed that the relative humidity in the Blood Bank laboratory had not been documented.
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this

	section. This STANDARD is not met as evidenced by: Through a review of quality control documentation on Levey - Jennings Reports for D-Dimer performed in March, July, and November 2018, a review of patient test records in November 2018, and interviews with laboratory staff, it was determined the laboratory failed to perform two levels of quality control for D-Dimer each 8 hours of testing in 92 of 92 days reviewed. Survey findings include: A. A review of Levey - Jennings Reports for March, July, and November 2018 revealed that quality control was documented once each day of testing (instead of each 8 hours of testing) in three of three months. B. A review of patient test records revealed the following examples of patients tested greater than 8 hours after quality control was performed: Patient #1868549 tested at 10:49 p.m. on 11/2/2018 (last quality control at 9:47 a.m.); Patient #1868785 tested at 6:35 p.m. on 11/4/2018 and Patient #1868806 tested at 10:25 p.m. on 11/4/2018 (last quality control at 10:12 a.m.); Patient #1869115 tested at 8:07 p.m. on 11/5/2018, Patient #1869119 tested at 8:52 p.m. on 11/5/2018, Patient #1869072 tested at 10:19 p.m. on 11/5/2018 and Patient #1869141 tested at 11:45 p.m. on 11/5 /2018 (last quality control at 11:05 a.m.); Patient #1869449 tested at 8:39 p.m. on 11/6 /2018 (last quality control at 9:55 a.m.); and Patient #1869708 tested at 6:24 p.m. on 11/7/2018 and Patient #1869729 tested at 8:49 p.m. on 11/7/2018 (last quality control at 10:21 a.m.). C. During an interview at 10:44 on 12/12/2018 the employee #14 (as listed on the form CMS-209) confirmed that the laboratory failed to perform D-Dimer quality control each eight hours of patient testing.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Through a review of the Chemistry Policy and Procedure Manual, a review of quality control documentation on Levey-Jennings Reports for March, July, and November of 2018, a review of the Corrective Action Log, lack of documentation, and interviews with laboratory staff, it was determined the laboratory failed to evaluate patient results since the last acceptable quality control as directed in their corrective action policy in six of six times the surveyor observed calibration as a corrective action. Survey findings include: A. Chemistry policy #7020.1202 titled Chemistry Quality Control states, as part of the corrective actions for quality control failure, "If instrument requires major maintenance or calibration, 10% of specimens run since last successful QC run must be retested and checked for clinical significant changes." B. A review of November 2018 quality control documentation for the Architect 8200 chemistry analyzer revealed on 11/19/2018 Uric Acid Level 1 quality control result was flagged as unacceptable (1-3s). The Corrective Action Log includes the note "ok after calibration". The surveyor requested documentation of the 10% retesting of patients due to the calibration but none was provided. C. A review of July 2018 quality control

	documentation for the Architect 4100 chemistry analyzer revealed on 7/31/2018 Carbon Dioxide (CO2) Levels 1 and 2 quality control results were flagged as unacceptable (1-2s) twice and Urine Protein Level 1 was flagged as unacceptable (1-3s). The Corrective Action Log includes documentation that CO2 and Urine Protein were both calibrated on 7/31/18 as part of the corrective actions. The surveyor requested documentation of the 10% retesting of patients due to the calibration but none was provided. D. A review of November 2018 quality control documentation for the Architect 4100 chemistry analyzer revealed on 11/11/2018 D-Dimer Levels 1 and 2 quality control results were flagged as unacceptable (1-3s). The Corrective Action Log includes the note "still out, new pack and recal and ok". The surveyor requested documentation of the 10% retesting of patients due to the calibration but none was provided. E. A review of November 2018 quality control documentation for the Architect 4100 chemistry analyzer revealed on 11/22/2018 Magnesium Level 1 and Level 2 and TSH Level 1 and Level 3quality control results were flagged as unacceptable (1-2s). The Corrective Action Log includes the note that both tests were recalibrated twice on that date. The surveyor requested documentation of the 10% retesting of patients due to the calibration but none was provided. F. In an interview, at 1:38 p.m. on 12/12/2018, laboratory employee #14 (as listed on the form CMS-209) stated, "If patients were retested, it should be on the corrective action log, so if it's not on the log it wasn't done."
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Through review of laboratory room humidity level records, manufacturer's instrument user manuals, lack of documentation and interview with laboratory staff it was determined that the laboratory failed to document corrective action when humidity levels fell below the acceptable range on seven of thirty-one days in January 2018 in two laboratory rooms in which instruments with an operating relative humidity range were operated Survey findings follow: 1. The laboratory failed to document corrective action when room humidity levels were outside of acceptable range in the Microbiology laboratory on seven of thirty-one days in January 2018. A. Review of the laboratory's room humidity level readings for the Microbiology laboratory revealed that the room humidity level was documented as 16% on 1/1/18 through 1/7 /18 inclusive with an acceptable range of 30% to 60%. B. Review of the manufacturer's user manual for the Virtuo-BacT Alert instrument revealed an operating humidity requirement of 20% to 85%. C. Upon request, the laboratory was unable to provide documentation of corrective action taken when humidity was recorded at less than acceptable levels on 1/1/18 through 1/7/18. D. In an interview on 12/11/18 at approximately 01:45 PM the testing personnel identified as number four on the CMS 209 form confirmed that humidity levels were below acceptable range on the dates identified above and there was no documentation of corrective action. 2. The laboratory failed to document corrective action when room humidity levels were outside of acceptable range in the Hematology laboratory on seven of thirty-one days in January 2018. A. Review of the laboratory's room humidity level readings for the Hematology laboratory revealed that the room humidity level was documented as 16% on 1/1/18 through 1/7/18 inclusive with an acceptable range of 30% to 60%. B.

	Review of the manufacturer's user manual for the Sysmex XN-2000 complete blood count instrument and the Sysmex CA 500 coagulation instrument revealed an operating humidity requirement of 30% to 85% for both instruments. C. Upon request, the laboratory was unable to provide documentation of corrective action taken when humidity was recorded at less than acceptable levels on 1/1/18 through 1/7/18. D. In an interview on 12/13/18 at approximately 11.00 AM the technical supervisor identified as number two on the CMS 209 form confirmed that humidity levels were below acceptable range on the dates identified above and there was no documentation of corrective action.