Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D2074398	06/23/2021
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: . 1. Through a review of the monthly documentation titled, "Temperature Reviews and Eyewash Station Checks", and interviews with laboratory staff, it was determined the laboratory failed to document Temperature and Humidity on three of thirty days in November 2020. Survey findings include: A. The "Temperature Reviews and Eyewash Station Checks" is the document the laboratory uses to document temperatures of seven refrigerators, three freezers, laboratory room temperature, storage room temperature, and laboratory humidity as well as weekly eyewash checks. B. On three of thirty days in November 2020 (11/11, 11/12, and 11/30), the laboratory failed to document temperatures or humidity of any of the areas monitored. C. In an interview at 2:45 p.m. on 6/22/2021, laboratory employee #2 (as listed on the form CMS-209) confirmed the lack of temperature documentation on the three days listed. 35451 . 2. Through observations, lack of documentation and interviews with staff, it was determined the laboratory failed to monitor and document room temperature in Phlebotomy drawing room separated from main laboratory. Survey Findings follow: A. During a tour of the Phlebotomy drawing room on 06/22/2021 at 0930, the following supplies were observed stored at room temperature: One box of BD Vacutainer Purple Top Tubes Lot #1074760 (storage requirements 4-25 degrees Celsius); one box of BD Yellow Top Tubes Lot #106822 (storage requirements 4-25

	degrees Celsius) one box of BD Vacutainer Dark Blue Top Tubes (storage requirements 4-25 degrees Celsius); one box of BD Vacutainer Plain Red Blue Top Tubes Lot #1137557 (storage requirements 4-25 degrees Celsius); one box BD Vacutainer Green Top Tubes Lot #1040964 (storage requirements 4-25 degrees Celsius); two Blood Culture Bottles Lot #0004100106 (storage requirements 15-30 degrees Celsius); four MRSA Nasal swabs lot #201722100 (storage requirements 15-30 degrees Celsius) and four COVID-19 collection swabs Lot #B003308 (storage requirements 15-30 degrees Celsius). B. The surveyor requested room temperatures documentation for the Phlebotomy drawing room. None was provided. C. In an interview on 6/22/2021 at 10:30, laboratory personnel #1 (as listed on CMS form 209) confirmed the laboratory failed to monitor and document room temperatures of the Phlebotomy drawing room.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Through a review of July 2020, November 2020, and March 2021 Levey-Jennings Reports for twenty different chemistry tests performed on the two Architect Chemistry Analyzers, and through interviews with laboratory staff, it was determined the laboratory used expired chemistry control material for three of twenty tests reviewed. Survey findings include: A. A review of the Levey-Jennings Reports for BHB (beta-hydroxybutyrate) tests performed in July 2020 and November 2020 revealed that Level 1 and Level 2 quality controls in use were documented as Lot #09581 with an expiration documented as 3/31/2020. Lot #09581 control material was documented in use eight months after the expiration date. B. A review of the Levey-Jennings Reports for iPTH (intact Parathyroid Hormone) tests performed in July 2020, November 2020, and March 2021 revealed that, in July 2020, Low, Medium, and High quality controls in use were documented as Lot #05919F000 with an expiration documented as 3/27/2020. Lot #05919F000 control material was documented in use four months after the expiration date. In March 2021 the laboratory documented using, until 3/6/2021, Low, Medium, and High quality control material with Lot #00320E000 and an expiration date of 2/7/2021. Lot #00320E000 was documented in use twenty-seven days after the expiration date. C. A review of the Levey-Jennings Reports for D-dimer tests performed in November 2020 revealed that from 11/1/2020 through 11/13/2020, Level 1 and Level 2 quality controls in use were documented as Lot #070K with an expiration documented as 11/10/2020. Lot #070K control material was documented in use three days after the expiration date. D. During an interview, at 2:31 p.m. on 6/21/2021, laboratory employee #11 (as listed on the form CMS-209) confirmed that the only documentation available shows that the controls were used after the expiration date.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a

	function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Through a review of periodic maintenance documentation provided by the biomedical engineering department, a review of documentation on stickers attached to the centrifuges, and through interviews with laboratory staff, it was determined the laboratory failed to document that centrifuge speeds were within established limits. Survey findings include: A. The surveyor requested documentation that the laboratory had checked the speed of all laboratory centrifuges and was provided periodic maintenance (PM) documentation, by the biomedical engineering department. The PM documentation included a separate document for each centrifuge that listed the dates that PM was performed on each centrifuge. The PM was documented every 6 months. The documentation did not include the speed that was verified by tachometer, to insure the centrifuges were spinning at the appropriate speeds for the specific use of each centrifuge. B. In an interview, at 9:41 a.m. on 6/23/2021, laboratory employee #3 (as listed on the form CMS-209) stated that the only documentation of centrifuge speed checks is the sticker on the side of the centrifuge that has the last documented verification of speed using a tachometer. She further confirmed the previous speed verifications using a tachometer are not available for the PM performed every six months. C. The surveyor observed thirteen centrifuges within the laboratory. Thirteen out of thirteen centrifuges had stickers that recorded speed checks in December 2020 but did not have stickers to document other speed checks performed every six months.
D5553	IMMUNOHEMATOLOGY CFR(s): 493.1271(b)(f) (b) Immunohematological testing and distribution of blood and blood products. Blood and blood product testing and distribution must comply with 21 CFR 606.100(b)(12); 606.160(b)(3)(ii) and (b)(3)(v); 610.40; 640.5(a), (b), (c), and (e); and 640.11(b). (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Through review of laboratory policy for "Emergency Transfusion Request", Emergency Requests for Uncrossmatched Blood for the first quarter of 2021 and interview with laboratory staff it was determined that the request for release of uncrossmatched blood in five of twenty-three requests to release blood on an uncrossmatched basis from January through March of 2021 were not signed by the requesting physician as required at 21 CFR 606.160(b)(3)(v). Findings follow: A) Review of the laboratory policy and procedure for "Emergency Transfusion Request" revealed " a RN may sign the request with a verbal order of the physician; however, at some point the physician must sign the request". B) Review of Emergency Requests for Uncrossmatched Blood for January, February and March of 2021 revealed that twenty-three requests for the emergency release of uncrossmatched blood products were received and that five of the requests were not signed or counter signed by the requesting physician but were only signed by nursing personnel. C) In an interview on 6/22/21 at 10:43 a.m., laboratory employee #9 (as listed on the CMS 209 form)

	confirmed that the requests for emergency release of uncrossmatched blood forms had been signed by nursing staff and not by the physician.
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 review of the laboratory policy and procedure number: 7020.1204 "Coagulation Quality Control Procedure for PT and PTT", review of quality control (QC) data for Prothrombin Time (PT) for November 2020, list of Prothrombin Time tests performed on 11/22/20, lack of documentation and interviews with laboratory staff it was determined that the laboratory failed to evaluate prior PT tests results back to the last successful QC performance when QC failed to meet the laboratory's established criteria for acceptability on one of one occurrence when corrective action required change in the test system. Findings follow: A) Review of the laboratory's policy and procedure 7020.1204 "Coagulation Quality Control Procedure for PT and PTT" revealed that "QC should be within acceptable range prior to reporting patient results" and,under the heading of "corrective action for unacceptable QC values", " 10% of specimens run since last successful QC run must be retested and checked for clinically significant changes". B) Review of QC data for PT testing for November 22, 2020 revealed that Dade Citrol level three QC material lot# 556524 with an acceptable range of 43.5 sec. to 46.7 sec. was reported as 47.4 at 05:26 PM, 47.9 at 5: 35 PM, 48.2 at 5:55 PM before an acceptable result of 46.3 at 6:12 PM. Corrective action comment stated "QC3 out reran X 2 still out made up new innovin QC 1 & 3 OK". Replacing innovin, the reagent used for PT testing, indicated a change in the test system. C) Review of the PT tests performed on 11/22/20 revealed that eleven PT tests were peformed and reported on patients, identified as number one through eleven on a separate patient identification list, between 10:35 AM and 06:12 PM on 11/22/20 D) Upon request, the laboratory was unable to provide the documentation of the evaluation of the PT results reported on the patients identified above. E) In an interview on 6/22/21 at 01:35 PM the laboratory staff member, identified as number 5 on the CMS 209 form, said that 10% of the PT tests identified above should have been retested.