Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D2074398	06/23/2023
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
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Through a review of the blood gas laboratory policy and procedure manual, co-oximetry quality control for 2022 and 2023, review of proficiency testing results, instrument service records, review of patient activity report for 2023, and through interviews with laboratory personnel, it was determined the laboratory failed to monitor Methemoglobin quality control accuracy over time from January through May 2023. Survey findings follow: A. Through a review of quality control policies and procedures in the blood gas laboratory policy and procedure manual it was determined the procedure manual failed to include policies or procedures for monitoring quality control, over time, for accuracy and precision. B. A review of January 2023 co-oximetry quality control revealed three of three levels of Methemoglobin quality control were shifted above the mean the entire month. Thirty-three of thirty-three consecutive results for Quality Control (QC) lot #S7335 were 1 Standard Deviation (SD) above the mean during the month of January 2023. Thirty-three of thirty-four consecutive results for QC lot #S7345 were 1 SD above the mean during the month of January 2023. Thirty-seven of thirty-seven results for QC lot

	#S7355 were above the mean up to 1 SD during the month of January 2023. C. A review of February 2023 co-oximetry quality control revealed three of three levels of Methemoglobin quality control were shifted above the mean the entire month. Thirty-one of thirty-one consecutive results for Quality Control (QC) lot #S7335 were between 1 SD and 2 SD above the mean during the month of February 2023. Twenty-eight of twenty-eight consecutive results for QC lot #S7345 were between 1 SD and 2 SD above the mean during the month of February 2023. Forty-one of forty-one results for QC lot #S7355 were 1 SD above the mean during the month of February 2023. D. A review of March 2023 co-oximetry quality control revealed three of three levels of Methemoglobin quality control were shifted above the mean. Thirty-four of thirty-four consecutive results for Quality Control (QC) lot #S7335 were between 1 SD and 2 SD above the mean during the month of March 2023. Thirty-two of thirty-three consecutive results for QC lot #S7345 were between 1 SD and 2 SD above the mean during the month of March 2023. Thirty-three of thirty-three results for QC lot #S7355 were 1 SD above the mean during the month of March 2023. E. A review of April 2023 co-oximetry quality control revealed three of three levels of Methemoglobin quality control were shifted above the mean. Thirty-one of thirty-one consecutive results for Quality Control (QC) lot #S7335 were between 1 SD and 2 SD above the mean during the month of April 2023. Thirty of thirty consecutive results for QC lot #S7345 were between 1 SD and 2 SD above the mean during the month of April 2023. Twenty-nine of thirty results for QC lot #S7355 were between 1 SD and 2 SD above the mean during the month of April 2023. F. A review of May 2023 co-oximetry quality control revealed three of three levels of Methemoglobin quality control were shifted above the mean through 5/10/2023.. Thirty-three of thirty-three consecutive results for Quality Control (QC) lot #S7335 were 2 SD or more above the mean between 5/1/2023 and 5/10/2023 with twenty-five results documented outside of acceptable 2 SD range. Ten of ten consecutive results for QC lot #S7345 were 2 SD above the mean during from 5/1/2023 through 5/10/2023. Eleven of eleven results for QC lot #S7355 were between 1 SD and 2 SD above the mean from 5/1/2023 through 5 /10/2023. G. A review of proficiency testing results for the first event of 2023 revealed all five sample results were above the expected target value. H. Quality control records for May 2023 include documentation that service was called on 5/10 /2023 due to the failure of lot #S7335 and inability to get the result within the 2 SD range. Instrument service records from that date show that the co-oximetry module was replaced as well as other parts of the instrument. I. A review of "Procedure Activity Report" revealed 1,123 patients had blood gas testing in January, February, and March of 2023. During this time period, co-oximetry results were reported (including Methemoglobin) on every patient blood gas report (1,123 of 1,123). J. In an interview, on 6/22/2023 at 1:05 p.m., laboratory employee #??????? (as listed on the form CMS-209) stated that she didn't know to be looking for shifts and confirmed that there is no policy for evaluating quality control over time for shifts or trends in results.
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 September and December of 2022 and for May 2023 and interview with laboratory staff it was determined that the request for release of uncrossmatched blood in two of thirty-two requests to release blood on an uncrossmatched basis during the three months reviewed 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 Transfusion Requests for September and December 2022 and May of 2023 revealed that thirty-two requests for the emergency release of uncrossmatched blood products were received and that two of the requests were not signed or counter signed by the requesting physician. C) In an interview on 6/23/2023 at 2:10 p.m., laboratory employee #???????? (as listed on the CMS 209 form) confirmed that the requests for emergency release of uncrossmatched blood forms had been not been signed by the physician. This is a repeat deficiency from the survey conducted on 6/23/2021.
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 manual, the Quality Control (QC) Log, notes of corrective action, patient result reports, and interviews with laboratory staff it was determined that the laboratory failed to evaluate patient results back to the last successful performance of QC, on 2 of occasions in 3 months of operation when QC failed criteria for acceptability for Total Bilirubin (TBIL), and Unsaturated Iron Binding Capacity (UIBC)analyses and corrective action required changes to the analytic systems. Finding follow: A) Review of the laboratory policy and procedure (Chemistry Quality Control) revealed that "Random samples of patients since last successful QC run must be retested and checked for clinical significant changes" following a recalibration. B) Review of the QC log for May 2023 revealed that chemistry controls for TBIL were flagged as unacceptable on 5/12/23 03: 36:07 am with a corrective action of "repeat QC" and were subsequently flagged as unacceptable on 5/12/23 05:30 am with a corrective action of " recalibrated." The corrective action represented a change in the analytic system. The previous passing QC was on 05/12/23 at 03:36:03 am. Review of the QC log for May 2023 revealed that chemistry controls for UIBC were flagged as unacceptable on 5/24/23 10:40 am with a corrective action of "repeat QC" and were subsequently flagged as unacceptable on 5/24/23 1:33 pm with a corrective action of " recalibrated." The corrective action represented a change in the analytic system. The previous passing QC was on 05/23/23 at 09:12am. C) Review of patient result reports revealed that TBIL tests were performed and reported on 2 patients, identified as numbers 1-2 on a

	separate patient identification list, on 5/12/23 during the time described above. Review of patient result reports revealed that UIBC tests were performed and reported on 1 patient, identified as number 3 on a separate patient identification list, on 5/23/23 during the time described above. D) Upon request, the laboratory was unable to provide documentation that, in the event of an instrument recalibration, the patient results reported back to the last successful QC had been evaluated for the above listed events and dates. E) In an interview on 6/21/23 at 10:45am the laboratory staff member, identified as number 10 on the CMS 209 form, confirmed that no patient assessments were performed for chemistry in May of 2023.