Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0687360	11/06/2020
Name of Provider or Supplier	**Street Address, City, State**	
Unity Health Newport	1205 Mclain, Newport, 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 instrument manuals, lack of documentation, and interview it was determined that the laboratory failed to monitor required appropriate operating humidity levels in the room in which instruments used for hematology and chemistry testing with an operating humidity requirement were utilized. Findings follow: A) Review of the manufacturer's instrument manuals revealed the following humidity requirements for instruments in use in the laboratory; the AU 480 chemistry analyzer 15% to 90%, the Sysmex XN 1000 Hematology analyzer 20% to 80% and the Elite Coagulation analyzer less than 90%. B) Upon request the laboratory could not produce humidity level records for the calendar year of 2020. C) In an interview on 11/5/20 at approximately 09:45 AM, the laboratory staff member, identified as number two on the CMS 209 form, stated that the laboratory does not record the laboratory humidity level.
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 observation, and interview it was determined that phlebotomy supplies that had exceeded their date of expiration were present and available for use on one of two phlebotomy trays in the outpatient phlebotomy area. Findings follow: A) During a tour of the laboratory on 11/5/20 at approximately 11:00 AM twelve BD EDTA blood collection tubes lot # 9126972 expiration date 2020-08-31 and twelve BD EDTA blood collection tubes lot # 9184902 expiration date 2020-10-31 were observed on one of two phlebotomy trays in the outpatient phlebotomy area . B) In an interview on 11/5/20 at approximately 11:00 AM, the laboratory staff member, identified as number two on the CMS 209 form, confirmed that the items identified above had expired and were available for use.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Through a review of the manufacturer's Maintenance Schedule List for the Beckman Coulter AU480, lack of documentation, and interviews with laboratory staff, it was determined the laboratory failed to document required daily maintenance on one of thirty days in September 2020 and two of thirty-one days in October 2020. Survey findings include: A. The manufacturer's Maintenance Schedule List for the Beckman Coulter AU480 includes the following required daily maintenance: Inspect the Syringes for leaks; Inspect the Wash Solution Roller Pump for Leaks; Inspect, Clean, and Prime the Sample Probe, Reagent Probe, and Mix Bars; Inspect the Wash Solution and Replenish; Inspect the Printer and Printer Paper; Replace the DI water or diluent in the Pre-dilution Bottle; ISE Cleaning; and ISE Calibration. B. On the following dates in September and October 2020 the daily maintenance listed above was not documented: September 30,2020; October 1, 2020; and October 8, 2020. C. In an interview on 11/5/2020 at 10:00 a.m., employee #2 (as listed on the form CMS-209) confirmed that the laboratory was unable to produce documentation that daily maintenance was performed on the AU480 chemistry analyzer on the days listed.
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 quality control records for March, July, and September 2020 for the RapidPoint 500 blood gas analyzer, lack of documentation, and interviews with laboratory staff, it was determined the laboratory had no documentation of monitoring over time the accuracy and precision of blood gas quality control results. Survey findings include: A. Quality control records for the RapidPoint 500 blood gas analyzer consisted of printer tapes with each individual result of quality control and calibrations during the day. B. In an interview at 10:59 on 11/4/2020 the surveyor requested documentation of monitoring over time the precision an accuracy of the blood gas quality controls. At that time employee #2 (as listed on the form CMS-209) stated that he reviewed Levey-Jennings Graphs on the instrument and did not print them because the printed format was such that it was not useful for determining if shifts and trends had occurred. C. During a tour of the laboratory at 2:45 on 11/4/2020 employee #2 was asked to show the surveyor the Levey-Jennings Graphs for blood gas quality control on the RapidPoint 500 analyzer. The surveyor asked specifically to see March, July, and September of 2020. The RapidPoint 500 analyzer only had the September 2020 Levey-Jennings Graphs (one of three months requested). D. In an interview at 10:00 on 11/5/2020 employee #2 confirmed he was unable to obtain Levey-Jennings Graphs from any months prior to August 2020.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Through a review of laboratory policy and procedures manual, quality control data, patient testing logs, lack of documentation, as well as interview with staff, it was determined the laboratory failed to perform positive and negative controls on days when patients were analyzed. Survey Findings Follow: A. A review of the laboratory quality control policy for MedTox Drugs of abuse test revealed "perform external positive and negative liquid controls per day of testing and with new box." B. A review of quality control data for March, July and September (three of nine months) of 2020 revealed on July 1, 2020 MedTox Control 2 for the test of Opiates and Amphetamines produce a control results of "invalid." There was no documentation that the laboratory repeated MedTox Control 2: on July 10, 2020 (one of thirty days) the laboratory had no Quality Control documentation for MedTox drug of abuse test: on July 29, 2020 MedTox Control 1 for the test of THC (Tetrahydrocannabinol), PCP (Phencyclidine) and COC (Cocaine) produce a control result of "invalid" for Positive Control. There was no documentation that the laboratory repeated MedTox Control 1. C.A review of patient testing logs for the July 2020 (one of seven months) revealed on July 1, 2020 the following patients had urine drug screens performed and reported: patient # 60265, patient #60885, patient #61282 and patient # 62311; on July 10, 2020 the following patients had urine drug screens performed and reported without documentation of quality control: patient # 74757 and patient #74732: on July 29, 2020 the following patients had urine drug screens performed and reported: patient

	#08807, patient #08960, patient #09158, patient #09856, patient #10645, patient # 10868 and patient #10262. D. In an interview on 11/4/2020 at 10:00, laboratory personnel #2 (as listed on form CMS 209) confirmed patients were tested and reported for urine drug screens on July 1 and 29, 2020 with only one level of quality control documented and on July 10, 2020 without documentation of quality control.
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: 35659 Through review of the laboratory policy and procedure No. 570-9001 "Quality Control ", quality control reports, corrective action logs, QC data reports for the Access 2 Immunoassay System, corrective actions documented on data reports, patient results, lack of documentation and interview with laboratory staff members it was determined that the laboratory failed to evaluate patient results back to the last successful quality control performance when quality control results failed to meet the laboratory's criteria for acceptability and corrective action required changes to the test system on one of one occasions affecting one patient for prothrombin time assays. Findings follow: A) Review of the laboratory policy and procedure No. 53 "Quality Control Program" revealed that the laboratory's policy was to reject run and troubleshoot the method involved if both controls are greater than +/= 2 SD (standard deviations) from the mean or if one control was greater than +/= 2 SD on two consecutive attempts. B) Review of quality control reports revealed that on 3/30/20 the quality control results for level 3 prothrombin time controls with an acceptable range of (41.1 to 49.3) lot# N1282421 was reported as "QC Invalid" for two consecutive runs; (49.7 at 2:17 PM, 49.7 at 3:33 PM , before being reported as acceptable at 45.1 at 3:30 PM. C) Review of corrective action logs revealed the comment " Both 2S/will rp/NPT" after the first unsuccessful attempt and "rp rgt/npt" after the second unsuccessful attempt. D) In an interview on 11/4/20 at approximately 09:45 AM, the laboratory staff member identified as number two on the CMS 209 form explained that "rp" on the corrective action logs meant to repeat the quality control, "rp rgt" meant to replace reagents and "NPT" meant no patients were tested. The comment "rp rgt" (replace reagents) indicates a change in the test system. E) Review of quality control reports revealed that the previous successful quality control was performed at 06:06 AM on 3/30/20. F) Review of patient results revealed that a prothrombin time test was performed and reported between 06:06 AM on 3/30/20 and 3:30 PM on 3/30/20 at 01:15 PM on the patient identified as number one on the separate patient identification list. G) Upon request, the laboratory was unable to provide documentation that the patient result identified above had been evaluated. H) In an interview on 11/4/20 at approximately 09:45 AM, the laboratory staff member identified as number two on the CMS 209 form confirmed that level three quality control for prothrombin time assays was unacceptable on the occasion identified above and the patient result back to the last successful quality control performance had not been evaluated and further stated that the evaluation of patient results back to

	the last successful quality control after corrective action required changes in the test system was not a policy of the laboratory and " we would probably find more instances" of this occurrence. I) A review of QC data reports for the Access 2 Immunoassay System revealed that on 3/8/20 the quality control results for level 1 HCG controls lot# 40991 was reported as "4.29" at 12:36 a.m. with a note stating "both levels out" before being reported as acceptable at 3.99 at 2:02 a.m. with a note stating "used new reagent". J) Review of QC data reports for the Access 2 Immunoassay System revealed that the previous successful quality control was performed at 01:41 a.m. on 3/7/20. K) Review of patient results revealed that an HCG test was performed and reported between at 12:32 on 3/7/20 on the patient #142989. L) Upon request, the laboratory was unable to provide documentation that the patient result identified above had been evaluated. M. In an interview at 10:00 on 11/5/20 laboratory employee #2 confirmed the laboratory did not review patient results back to the prior acceptable quality control run.