Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0666802	03/14/2019
Name of Provider or Supplier	**Street Address, City, State**	
Unity Health Searcy Medical Center	2900 Hawkins Drive, 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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Interviews with laboratory staff and lack of documentation, determined the laboratory failed to retain instrument maintenance records for at least 2 years. Survey findings follow: A. On an initial tour of the laboratory on 3/12/19 at approximately 09:30 AM, Vitros 5.1, Vitros ECI and Vitros 5600 chemistry instruments were observed in the chemistry section of the laboratory. B. In an interview on 3/12/19 at approximately 09: 30 AM, when asked about which tests were performed on each instrument, the laboratory manager, identified as number 1 on a separate staff identification sheet, and the technical consultant, identified as number 2 on the CMS 209 form, stated that since June 2018 all chemistry tests are performed on the Vitros 5600. The Vitros 5.1 and the Vitros ECI were used for testing in 2018 until replaced by the Vitros 5600 in June 2018. C. On 3/14/19 at 10:30 AM the surveyor requested maintenance documentation for the chemistry instruments Vitros 5.1, Vitros ECI and Vitros 5600 for the calendar year of 2018. B. In an interview at 10:45 AM on 3/14/19, the laboratory manager, identified as number one on the separate staff identification list, stated that the instrument maintenance records for 2018 for the Vitros 5.1 and Vitros ECI could not be located and were unavailable.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a

	procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Through review of manufacturer's package inserts, "Laboratory Policy and Procedure: Vitros Chemistry Analyzer Quality Control", Quality Control Reports, patient result reports, previous survey findings, lack of documentation and interview it was determined that the laboratory failed to meet analytic systems requirements or monitor and correct problems in the analytic systems, even though elements were cited on the previous survey conducted on 8/24/17, as evidenced by: D5441 - The laboratory failed to employ a method to detect assay error over time; D5469- The laboratory failed to establish its own quality control acceptable range as required by the manufacturer's package insert. D5481 - The laboratory reported patient results when quality control failed to meet criteria for acceptability. This deficiency was previously cited in the survey conducted on 8/24/17.
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 review of the laboratory's "Quality Control Reports", the "Laboratory Policy and Procedure: Vitros Chemistry Analyzer Quality Control", lack of documentation, and interview it was determined that the laboratory failed to employ an effective method for detecting errors over time in quality control performance , such as shifts or trends for chemistry testing. This has the potential of affecting all chemistry testing. Findings follow: A. Review of the laboratory's "Quality Control Report" for total bilirubin (TBil) assays for February 2018 revealed that Performance Verifier level 1 (PV1) lot# T5608 expiration date 3/1/19 was recorded as resulting below the target /mean on twenty-four of twenty-four consecutive runs; and Performance Verifier 2 (PV2) lot# U5612 expiration date 3/1/19 was recorded below the target/mean on twenty-four of twenty-four consecutive runs. B. Review of the laboratory's "Quality Control Report" for Albumin (ALB) assays for February 2018 revealed that Performance Verifier level 1 (PV1) lot# T5608 expiration date 3/1/19 was recorded as resulting below the target/mean on sixteen consecutive runs from 2/8/18 through 2/28 /18; and Performance Verifier 2 (PV2) lot# U5612 expiration date 3/1/19 was recorded below the target/mean on sixteen consecutive runs from 2/8/18 through 2/28 /18. C .Review of the laboratory's "Quality Control Report" for Triglyceride (TRIG) assays for August 2018 revealed that PV1 lot# W5903 expiration date 6/26/19 was

	recorded as resulting below the target/mean on thirteen consecutive runs from 8/13/18 through 8/31/18; and PV2 lot# U5612 expiration date 3/1/19 was recorded below the target/mean on twenty-three of twenty-three runs from 8/1/18 through 8/31/18. D. Review of the "Laboratory Policy and Procedure: Vitros Chemistry Analyzer Quality Control" revealed that "the problems that will be evident on the QC charts are excessive scatter, test bias, drifting of results, shifting of results or a trend" and "document all actions taken on the appropriate instrument troubleshooting log" and no definition of what constitutes "drifting of results, shifting of results, or a trend" was present. E. Upon request, the laboratory was unable to produce a Levey-Jennings Chart or other method of determining changes in test performance over time or documentation that a shift or trend had been recognized and corrective action had been taken. in the examples identified above F. In an interview on 3/13/19 at approximately 11:00 AM, the technical consultant identified as number 2 on the CMS 209 report confirmed that Levey-Jennings Charts are not utilized and no documentation of recognizing or taking corrective actiion for a shift or trend is available for the examples identified above.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Through review of quality control records, control manufacturer ' s product inserts, and interview, it was determined that the laboratory did not establish the statistical parameters (mean and standard deviation) for TSH and PSA control materials over time. Findings follow: A. Package inserts for Bio-Rad Lyphochek Immunoassay Plus controls state that " it is recommended that each laboratory establish its own acceptable ranges and use those provided only as guidelines " . B. "Quality Control Report" records reviewed for September 2018 did not include a target mean and acceptable range. C. Upon request, the laboratory was unable to provide documentation of how it established acceptable ranges for Bio-Rad Lyphochek Immunoassay Plus controls. D. In an interview on 3/13/19 at approximately 1030, the technical consultant testing identified as number 2 on the CMS 209 form, when asked how personnel determined if quality control results for TSH and PSA assays met criteria for acceptability, stated that values supplied on package inserts for Bio-Rad Lyphochek Immunoassay Plus controls were used to establish performance specifications for TSH and PSA assays.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g)

	(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Through a review of chemistry quality control results for February 2018, patient result reports and interviews with laboratory staff, it was determined that patients were reported when results of control material failed to meet the criteria for acceptability. This citation was cited on the previous survey conducted on 8/24/17. Survey findings follow: A. Through a review of chemistry quality control results for February 2018 it was revealed that on 2/16/2018 the PV1 control for Albumin was reported as 4.19, as 4.17 on 2/20/18 and 4.16 on 2/28/18 with an acceptable range of 4.32 to 4.76. There was no documentation that the control was ever in acceptable range on those dates. B. Review of patient result reports revealed 24 patients, identified as numbers 64 through 87 on a separate patient identification list, had Albumin results reported on 2/16/2018, 40 patients identified as numbers 88 through 127 on a separate patient identification list, had Albumin results reported on 2/20/18 and 32 patients, identified as numbers 128 through 159 on a separate patient identification list had Albumin results reported on 2/28/18 . C. In an interview at 10:30 AM on 3/13/2018, laboratory technical consultant #2 (as listed on the form CMS-209) confirmed the patients identified above were reported when the quality control results were outside of acceptable range.
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: Review of "Laboratory Policy and Procedure: Vitros Chemistry Analyzer Quality Control", "Quality Control Reports", lack of documentation, patient results reports and interview determined that the laboratory failed to document corrective action or the evaluation of patient results back to the last successful quality control on two of two times when quality control for trigyceride (TRIG) assays failed to meet criteria for acceptability on 8/31/18 and 9/4/18. This is a repeat of the same deficiency cited on the previous survey conducted on 8/24/17. Findings follow: 1) The laboratory failed to document corrective action when quality control failed to meet criteria for acceptability. A. Review of "Laboratory Policy and Procedure: Vitros Chemistry Analyzer Quality Control" stated "document all actions taken on the appropriate instrument troubleshooting log". B. Review of the TRIG "Quality Control Report" for August and September 2018 revealed the following results: Performance Verifier (PV) 1 Lot # W5903 expiration date 6/26/19 acceptable range (121.8 to 133.8) DATE TIME RESULT FLAG 8/31/18 0911 122.8 (acceptable) 8/31/18 1523 139.2 +3S 8/31 /18 1523 140.4 +3s No Testing Between 9/4/18 0850 141.6 +3S 9/4/18 0923 138.9 +3S 9/4/18 0938 140.8 +3S 9/4/18 1211 126.9 (acceptable) PV 2 Lot # U5612

	expiration date 3/1/2018 acceptable range (243.8 to 269) DATE TIME RESULT FLAG 8/31/18 0914 244.4 (acceptable) 8/31/18 1525 273.6 +3S 8/31/18 1525 273.3 +3S No testing Between 9/4/18 0852 276.6 +3s 9/4/18 0924 273.3 +3S 9/4/18 0938 280.5 +3s 9/4/18 1211 256.1 (acceptable) C. Upon request, the laboratory was unable to provide the documentation of corrective action taken for TRIG assays when quality control failed to meet acceptable criteria identified above. D. In an interview on 3/13 /19 at approximately 10:30 AM the technical consultant identified as number 2 on the CMS 209 form confirmed that quality control results for TRIG identified above failed to meet criteria for acceptability and that corrective action was not documented. 2) The laboratory failed to evaluate sixty-three of sixty-three patient TRIG results back to the last acceptable quality control on 8/31/18 when quality control results failed to meet criteria for acceptability. A. Review of "Laboratory Policy and Procedure: Vitros Chemistry Analyzer Quality Control" stated when control or calibration results fail to meet established criteria that "patient results tested between the previous acceptable and the current unacceptable run must be evaluated to determine if the patient results had been affected". B. Review of patient results revealed that TRIG results had been performed and reported on sixty-three of sixty-three patients, identified as numbers one through sixty-three on a separate patient identification list, between 0911 on 8/31 /19 and 1523 on 8/31/19. C. Upon request, the laboratory was unable to provide documentation that TRIG results had been evaluated for the sixty-three patients identified above. D. In an interview on 3/13/19 at approximately 10:30 AM the technical consultant, identified as number 2 on the CMS 209 form, confirmed that there is no documenttion that TRIG results identified above were evaluated.