Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0666802	11/10/2021
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
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Through a review of proficiency test results and corrective actions for four proficiency test events in 2021, lack of documentation, as well as interviews with laboratory personnel, it was determined the laboratory failed to take corrective actions for proficiency testing failures in four of four events with transcription errors. Survey findings include: A. Proficiency testing failures in the following events were caused by transcription errors: Chemistry Core 1st Event 2021 had a 0% score for B12, which included a note that stated it was a transcription error; Chemistry Core 2nd Event 2021 had a 50% score for Testosterone, which included a note that stated it was a typo; Immunology 1st Event 2021 had a 0% score for SARS CoV2 IgG, which included a note that stated it was a transcription error; and Chemistry Miscellaneous 1st Event 2021 had a 33% score for Microalbumin which included a note that stated, "results of MA2 and MA3 switched. B. Proficiency test documentation for Chemistry Core 1st Event 2021, Chemistry Core 2nd Event 2021, Immunology 1st Event 2021, and Chemistry Miscellaneous 1st Event 2021 did not include documented corrective actions for the transcription errors noted in proficiency test results. C. In an interview at 2:35 on 11/9/2021, laboratory employee #3 (as listed on the form CMS-209) confirmed there was no documented corrective action for transcription errors in proficiency testing results.
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 Levey-Jennings graphs from February, June, and September, for thirteen chemistry tests, and interviews with laboratory staff, it was determined the laboratory failed to have control procedures that monitor over time the accuracy of test performance. Survey findings include: A. A review of Levey-Jennings graphs for September 2021 revealed the graphs for September were not printed until 10/22/2021. Due to the changes made in test means between the end of September and the time the graphs were printed, it was not possible to evaluate for shifts or trends in quality control. Examples of mean changes are as follows: the mean on the graph for Free T4 for Control BR381 was 1.289 but the mean listed in the data at the end of September was 1.530; the mean on the graph for Magnesium for Control 1U8105 was 2.04 but the mean listed in the data at the end of September was 1.92; the mean on the graph for Free T4 for Control BR381 was 1.289 but the mean listed in the data at the end of September was 1.530; the mean on the graph for TSH for Control BR381 was 0.3363 but the mean listed in the data at the end of September was 0.3280; and the mean on the graph for TSH for Control BR383 was 29.9 but the mean listed in the data at the end of September was 29.48. B. In an interview at 10:50 on 11/10/2021, employee #3 confirmed the Levey-Jennings graphs were printed after means had been changed which made it impossible to evaluate for shifts and trends.
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 policies and procedures, chemistry quality control results for February, June, and September, and the record of problems for Hemoglobin A1c, a lack of documented corrective actions, and interviews with laboratory staff, it was determined the laboratory failed to document corrective actions when results of quality control were out of the acceptable range. Survey findings include: A. The policy titled "Investigating QC Errors states, "when a result exceeds the limits, reanalyze the same control immediately...if the reanalyzed control falls within

	acceptable limits, patient results may now be reported." B. The laboratory failed to document corrective actions on one of seven days in September 2021 when A1c quality control level 2 was unacceptable. On 9/24/2021 quality control level 2 was documented as 9.529 and flagged outside of 2 standard deviations. The acceptable range in use was documented as 9.6 to 10.568. The quality control documentation failed to include reanalyzed results or actions taken to correct the failed quality control. C. In an interview at 10:50 on 11/10/2021, employee #3 confirmed the lack of documented corrective actions for the quality control failure on 9/24/2021, and confirmed that patients were reported on that date.