Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D2042962	(X3) Date Survey Completed 02/12/2019
Name of Provider or Supplier Unity Health After Hours Clinic	**Street Address, City, State** 2904 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 quality control documented on the "All Sample Report" for September and November of 2018 as well as January 2019, through lack of documentation, and through interviews with laboratory staff, it was determined the laboratory failed to document all control procedures performed. Survey findings include: A. At 5:38 on 2/12/2019 the surveyor requested September 2018, November 2018, and January 2019 Levey-Jennings graphs for monitoring quality control over time. None was provided. B. The surveyor reviewed "All Sample Reports" for September 2018, November 2018, and January 2019 which were presented to the surveyor as evidence of quality control documentation. The "All Sample Reports" do not include target values for the quality control. Target values are needed in order to evaluate data for shifts or trends C. At 6:00 on 2/12/2019 the surveyor requested package inserts with quality control target values for quality control lots used in September 2018, November 2018, and January 2019. At the time of the interview the

	technical consultant (as listed on the form CMS-209 stated the package insert was not available for the quality control lots #2180821, #2180822, and #2180823 used in November 2018 (not available for one of three months requested).