Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0466767	05/27/2022
Name of Provider or Supplier	**Street Address, City, State**	
Unity Health Family Practice Associates	3130 E Race St, Suite 100, 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
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Through observation, review of manfacturer's package insert and interview it was determined that the laboratory failed to amend the expiration date of three of three vials of Boule Con Diff hematology control material after opening and and placing the vials in use. Findings follow: A) Review of the Boule Con Diff hematology control material package insert revealed that the vials had "14 consecutive day open tube stability". B) During a tour of the laboratory on May 27, 2022 at 1:45 pm , three vials of Boule Con Diff hematology control vials lot numbers 2220131, 2220132, and 2220133 were observed in a plastic cup in the laboratory refrigerator with no date of opening or amended expiration date on the vials or the container the vials were in. C) When asked at the time, the testing personnel, identified as number three on the CMS 209 form stated that the vials were currently the hematology controls in use and the date of opening or amended expiration date was not on the vials or the container the vials were in.
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 the laboratory's policy and procedure for quality control (QC) , quality control documentation for June 2021, September 2021, and January 2022, lack of documentation and interviews with laboratory staff, it was determined the laboratory failed to document all corrective actions taken when results of control material failed to meet established criteria for acceptability. Survey findings follow: A) Review of the laboratory's policy and procedure for QC revealed "all corrective action should be documented on the appropriate corrective action form". B) On 1/26 /22 the Level 2 AST control was run 3 times before the result was acceptable.There were no documented corrective actions taken to bring the controls into the acceptable range. C) Upon request, the laboratory was unable to provide documentation of corrective action taken to bring level 2 control within acceptable range. D) In an interview at 01:55 pm on 5/27/22, laboratory employee #3 (as listed on the form cms-209) confirmed there were no documented corrective actions for the quality control failures.