Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0687360	11/09/2022
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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Through review of proficiency testing attestation forms and interview it was determined that the laboratory's testing personnel failed to sign attestation forms for three of twenty American Proficiency Institue (API) proficiency testing events reviewed. Findings follow, A. Through review of proficiency testing doumentation for 2021 and 2022 it was determined that testing attestation forms were not signed by all testing personnel for API Hematology/Coagulation 1st event of 2021, API Chemistry Core 1st Event of 2021, and API Hematology/Coagulation 2nd event of 2022. B. In an interview on 11/9/22 at 2:15 pm, the laboratory testing personnel identified as number 2 on the CMS 209 form verified that the attestation forms were not signed by the testing personnel.
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 observations made during a tour of the laboratory, a review of manufacturer's package inserts, and interviews with laboratory staff, it was determined the laboratory failed to label reagents with expiration dates. Survey findings include: A. A review of manufacturer's package inserts for the Triage D-dimer and Cardiac test cartridges revealed the cartridges must be stored at refrigerator temperature (2 - 8 degrees Celsius) or may be kept at room temperature for 14 days. B. During a tour of the laboratory, at 10:18 a.m. on 11/8/2022, the surveyor observed 9 each of Triage D-Dimer cartridges (lot T13203 expiration 10/17/23), and 2 each of Triage Cardiac cartridges (lot T13048 expiration 10/20/22) stored on the counter top at room temperature. The cartridges were not labeled with the date that they had been stored at room temperature or with the expiration date (14 days after placed at room temperature). C. During an interview, at 10:18 a.m. on 11/8/2022, laboratory employee #1 confirmed the Triage cartridges were stored at room temperature and were not labeled with the new expiration date.