Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D2258126	07/16/2026
Name of Provider or Supplier	**Street Address, City, State**	
Harmony Health Clinic	1920 N Falls Blvd, Wynne, 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
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation and interview with laboratory staff, the laboratory had supplies available for use after their expiration date. Findings follow: A) During a tour of the laboratory on 7/16/26 at 2:20pm, two (of two) containers of "Vitros Chemistry Calibrator Kit 2 3mL" (Ortho-Clinical Diagnostics, lot: 02141-B1, CD906321P, expiration date 2026-07-01) were observed in the laboratory, available for use beyond the expiraton date. B) In an interview on 7/16/26 at 2:21am the technical consultant confirmed that the items, identified above, had exceeded their expiration date and were available for use in the laboratory.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. This STANDARD is not met as evidenced by: Based on policy, lack of documentation and an interview, the laboratory failed to follow established written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in analytic systems. Findings include: A. Policy titled "Quality Assessment Program" states " Corrective Action, as outlined

	in the procedure manual, will be taken when problems are identified in calibration, controls, instrument functions, reagents and temperatures." B. Policy titled "Quality Control" states "controls results should be investigated when a shift or trend is noted. Calibration will be reviewed and if needed, the instrument will be recalibrated. If calibration is found to be acceptable, a mean adjustment may be neccessary." B. Hematology records showed control results above the mean for hematocrit level one controls in 18/20 runs for January 2026, 17/17 runs for February 2026, 14/26 runs in March 2026, 21/21 runs in April 2026, 21/21 runs in May 2026, and 23/24 runs in June 2026. Hematology records showed control results above the mean for hematocrit level two controls in 18/20 runs for January 2026, 17/17 runs for February 2026, 10 /27 runs in March 2026, 21/21 runs in April 2026, 21/21 runs in May 2026, and 20/24 runs in June 2026. Hematology records showed control results above the mean for hematocrit level three controls in 20/20 runs for January 2026, 18/18 runs for February 2026, 18/27 runs in March 2026, 21/21 runs in April 2026, 21/21 runs in May 2026, and 21/24 runs in June 2026. C. Quality assurance records noted that the hematocrit controls were shifted high for January, February, April, May, and June 2026. D. Quality assurance records noted recalibration was performed during a service call on March 20, 2026. C. At 1:07pm 7/16/26, the technical consultant confirmed that the hematocrit controls were shifted high and the situation had not been addressed to resolution.