

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D2212097	(X3) Date Survey Completed 03/30/2026
Name of Provider or Supplier Armo Diagnostics	Street Address, City, State 7550 Hwy 107, Sherwood, 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	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>(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.</p> <p>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 3/30/26 at 2:40pm, 1 of 1 Drug Alteration Test Strips, lot: HUAD-164, B30764-06, AR2403001, expiration date 2/28/26, and 1 of 1 Phase Scientific Indicaid Covid-19 Rapid Antigen Test, lot: 24090030, REF 2110400, expiration date 12/18/25 were observed in the laboratory, available for use beyond the expiration date. B) In an interview on 3/30/26 at 2:40pm the technical supervisor confirmed that the items, identified above, had exceeded their expiration date and were available for use in the laboratory.</p>
D5791	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control Levy-Jennings charts for January and February of 2026, review of QA review notes, lack of documentation, and interview it was determined that the laboratory failed to assess or take corrective</p>

action when the Amphetimine controls exhibited a shift. Findings follow: A) Review of Levy Jennings reports from January and February controls (High, Medium, Low and End Run) for Amphetimine assays performed in the lab showed a negative bias on 107 of 112 data points. B) Upon request, the laboratory was unable to provide documentation that the shift noted by the surveyor, had been identified or corrective action taken. C) In an interview on 3/30/25 at 12:24 pm the technical supervisor confirmed that the above shift occurred and no assessment or corrective actions were documented.