Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D2212097	06/18/2024
Name of Provider or Supplier	**Street Address, City, State**	
Armo Diagnostics	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
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: Review of the proficiency test attestation records for three events in 2023 and 2024, lack of documentation, and interviews with laboratory staff, determined that personnel failed to attest to the routine integration of proficiency test samples in the patient workload on two of the three events reviewed. Survey findings follow: A) Review of the attestation forms for the College of American Pathologists (CAP) Drug Monitoring for Pain Management (DMPM) proficiency testing program 2023 event A, 2023 event B, and 2024 event A, revealed that the attestations for 2023 event A and 2024 event A lacked the signatures of the laboratory director or designee and the testing personnel. B) In an interview, at 11:28 a.m. on 6/18/24, the laboratory staff member (# 1 as identified on a separate staff identification list) confirmed the attestation form was not signed by the laboratory director and testing personnel for CAP DMPM event A in 2023 and CAP DMPM event A in 2024.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in

	electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Observations made during a tour of the laboratory, review of temperature records, review of specimen and reagent storage requirements, and interview with laboratory staff determined that the laboratory failed to monitor the temperatures of two of five freezers in which patient urine samples and reagents were stored. Findings follow: A) During a tour of the laboratory at 09:15 a.m. on 6/18/24 the surveyor observed a freezer in the specimen accession room, four freezers (labeled freezer #1 through freezer #4) in the main laboratory, and an unlabeled freezer, which was empty and not running, in the main laboratory. B) In an interview at 09:15 a.m. on 6/18/24, the laboratory staff member (# 1 on the CMS 209 form) said that the unlabeled freezer was not in use since it "quit working" in early May of 2024 and was replaced by a new freezer. C) Review of temperature records for May 2024 revealed computer recorded spread-sheets were provided with device names of 'Freezer 1", "Freezer 2", "ARMO Freezer", "ARMO Room 4", and "ARMO Refrigerator". D) Review of the temperature records for May 2024 revealed a computer recorded spread-sheet labeled Freezer 2. The temperatures ranged from a low of 22.5 degrees centigrade (C) to a high of 24.7 degrees C. all or within range of expected ambient room temperature (not freezer temperature). E) When asked to verify the identity of the devices reported on the temperature records, the laboratory staff member (#1 on the CMS 209 form) noted the monitor serial numbers on the temperature sensing devices and confirmed with the conrtacted firm which monitors the temperatures remotely that the records for "Freezer 2" were for the unlabeled freezer, the records for "ARMO freezer" were for the freezer labeled #2, and the temperatures for "Freezer 1" were for the freezer labeled #4. F) When asked for the temperature recordings for the freezers labeled #1 and #3 on 6/18/24 at 2:55 p.m., the laboratory staff member (#1 on the CMS 209 form) confirmed they were not available. G) On 6/18/24 at 2:45 p.m. the laboratory staff member #1 said that if temperatures were outside of acceptable range, that laboratory staff would be notified and corrective action could be taken. H) When asked if the laboratory was notified when the unlabeled freezer stopped operating the laboratory staff member (#1 on the CMS 209 form) said that the laboratory was not notified and she found that the freezer was not working "some time in May" when she noticed the temperature seemed warm and she noted that patient samples in the freezer were thawed. I) Review of urine sample storage requirements revealed sample were stable at 4-6 degrees C. for seven days and must be frozen for storage longer than seven days. J) During a tour of the laboratory on 6/18/24 at 2:45 p.m., it was noted that greater than 1,000 paient samples and 2 bottles of ISTD drug standard lot #240745 expiration date 8.2024 with a temperature storage requirment of -10 degrees C. to -30 degrees C. were stored in freezers labeled #1 and #3.