Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D2212097	09/07/2022
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
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Through review of laboratory policy and procedure, observation and interview it was determined that the laboratory failed to label three of three specimen collection containers with patient name or unique patient identifier. Findings follow: A) During a tour of the laboratory on 9/7/22 at 1:57 pm three urine specimens containers were observed in the laboratory refrigerator labeled with the patient's first name and last initial only with those labels written on the lid of the container. B) Review of the laboratory policy and procedure revealed that specimen containers are to be labeled with the patient's first and last names and a unique identifier or the patient's date of birth. C) In an interview on 9/7/22 at 2:05 pm , the laboratory staff member (#1 on the CMS 209 form) confirmed that the specimens identified above lacked proper patient identification on the containers as required by policy and procedure.
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section.

	This STANDARD is not met as evidenced by: Through lack of documentation and interview it was determined that the laboratory did not provide written instructions to clents detailing requirements for specimen collection, labeling, storage and handling/shipping requirements to the laboratory's clients. A) Upon request, the laboratory was unable to provide a copy of written instructions provided to clients for specimen collection, labeling, storage and handling /shipping. B) In an interview on 9/7/22 at 1:57 pm the laboratory staff member (#2 on the CMS 209 form) stated that a laboratory representative gave verbal instructions to clients when establishing accounts but no written instructions or manual was provided.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Through a review of seven Laboratory Results reports and interviews with laboratory personnel it was determined the laboratory test reports failed to include the address of the laboratory location where the test was performed on seven of the seven reports reviewed. Survey findings include: A) Seven of seven patient Laboratory Results reports reviewed contained results labeled "In Office Point of Care Results" for drugs of abuse screening. B) In an interview at 1:15 on 9/7/22 the laboratory staff member (#1 as listed on the form CMS-209) stated that the laboratory provides clients with kits for waived drugs of abuse screening and the clients perform the tests and list results on test order and the results are not flagged with the performing laboratory's name and address. The staff member further stated that the client having a valid CLIA certificate was not confirmed.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

	This STANDARD is not met as evidenced by: Through a review of Personnel Records for seven of twelve personnel listed on the form CMS-209, through a lack of documentation, and through interviews with laboratory staff, it was determined the laboratory director failed to give written authorization to seven of seven randomly selected testing personnel who perform highly complex drug testing. Survey findings include: A) The surveyor reviewed Staff Laboratory personnel files for seven randomly selected testing personnel (listed as #5, #8, #9, #12 and #14 on the form CMS-209) who perform highly complex quantitative drug testing and found no written authorization signed by the laboratory director to perform testing for any of the personnel. B) Upon request, the laboratory was unable to provide written authorization to perform testing signed by the laboratory director for the personnel identified above. C) In an interview, at 10:05 a.m.on 9/7/22, laboratory employee (#2 on the CMS 209 form) confirmed written authorization to perform testing signed by the laboratory director is not present.