Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D2090071	01/03/2024
Name of Provider or Supplier	**Street Address, City, State**	
Apollo Medical	111 Cordoba Center, Hot Springs Village, 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Through a review of the laboratory test menu, a review of CASPER 155 reports for 2023, lack of documentation, and interviews with laboratory personnel, it was observed the laboratory failed to enroll in proficiency testing for CBC (complete blood count). Survey findings include: A. A review of the laboratory's test menu revealed the laboratory performed CBCs on the Sysmex XN-430. B. No proficiency test results for the facility were shown for 2023 in the CASPER 155 reports. C. In an interview, at 12:32 on 1/3/24, testing person #1 (as listed on the form CMS-209) confirmed the laboratory was not enrolled in proficiency testing for CBC.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems

	specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Through a review of the personnel records, patient testing logs, lack of documentation as well as interviews with staff, it was determined the laboratory failed to meet the general laboratory systems requirements and to monitor and evaluate the overall quality of the general laboratory systems as cited at: D5203: The laboratory failed to follow written policies for positive identification of blood samples D5291: The laboratory failed to to follow written Quality Assessment policies and procedures to monitor, assess and correct problems identified in the laboratory
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Through a review of the laboratory Policy and Procedure Manual, observations made during a tour of the laboratory, lack of documentation, as well as interviews with laboratory staff, it was determined the laboratory failed to follow written policies for positive identification of blood samples. As evidenced by: A. A review of the laboratory policy section for specimen collection and handling revealed "Label the tube with the patient's name and date of birth." B. During a tour of the laboratory, at 13:34 on 01/03/24, seven blood tubes were observed on the lab countertop. Seven of seven blood samples were labeled with the patients last name only. C. In an interview at 13:34 on 01/03/24, testing person #1 confirmed the urine containers were labeled with only the patient's last name.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on the laboratory's policy and procedure manual, lack of documentation, and interviews, it was determined the laboratory failed to follow written Quality Assessment (QA) policies and procedures to monitor, assess and correct problems identified in the laboratory. Findings Follow: A. The laboratory policy and procedure manual states "All quality assessment activities including problems identified and corrective action take are documented and filed in the laboratory for a period of two years." B. In an interview on 12:32 on 01/03/24, testing person #1 confirmed that no records of quality assessment for the year of 2023 were available.
D5441	CONTROL PROCEDURES

	CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Through a review of the laboratory policy and procedure manual, lack of documentation, and through interviews with laboratory personnel, it was determined the laboratory failed to monitor complete blood count (CBC) quality control accuracy over time from September through December 2023. Survey findings follow: A. Review of Quality Control documentation showed a lack of Levy-Jennings graphs, or similar monitoring of accuracy and precision over time, for September through December of 2023. B. Upon request of documents monitoring accuracy and precision over time, or anything like a Levy-Jenning graphs; testing person #1 (as listed on the CMS-209 form) said they were unsure what I meant. Upon further explanation, they said no.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: . Through a review Policy and Procedure Manual, quality assurance documentation, the lack of documentation, and interviews with laboratory staff, it was determined the laboratory director failed to provide overall management and direction as evidenced by: D6015 - the Laboratory Director failed to ensure the laboratory is enrolled in an approved proficiency testing program D6021 - the Laboratory Director failed to ensure quality assessment programs were maintained D6029 - the Laboratory Director failed to maintain documentation of training for testing personnel D6032 - the Laboratory Director failed to give written authorization to perform testing for testing personnel
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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)(4) Ensure that the laboratory is enrolled in an HHS approved

	proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Through a review of patient testing logs, lack of documentation, as well as interviews with staff, it was determined the Laboratory Director failed to ensure the laboratory is enrolled in an approved proficiency testing program as cited at: D2000 - the Laboratory failed to enroll in proficiency testing for the Specialties of Hematology
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the available documentation, laboratory policy, and interviews with laboratory staff, it was determined the Laboratory Director failed to ensure quality assessment programs were maintained to assure quality of laboratory services. Failure to assure quality of laboratory services had the potential to affect all patient test results reported Survey findings follow: The laboratory failed to follow written policies to monitor, assess, and correct problems in the general laboatory systems as cited at D5203 and D5291.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Through a review of the CMS-209 form presented at the time of the survey, a review of personnel records, and through interviews with laboratory staff, it was determined one of one failed to have documented training on the test systems used by the laboratory. Survey findings include: A. Through a review of the CMS- 209 form, it was determined that one person was designated as testing personnel. B. A review of personnel records revealed that there was no training documented on the test systems in use for current testing personnel. C. In an interview at 10:45 on 01/03/24, employee #1 (as listed on the entrance exit conference sheet) confirmed that the laboratory did not have documented training for employees.

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 one of one testing personnel listed on the form CMS-209, lack of documentation and through interviews with hospital staff, it was determined the laboratory director failed to give written authorization to one of one testing person performing moderately complex procedures. Survey findings include: A) The surveyor reviewed personnel records for testing personnel #1 (as listed on the CMS-209) who perform moderately complex procedures and no authorization to perform testing was present. B) Upon request, the laboratory was unable to provide authorization to perform moderately complex testing for testing personnel #1 (as listed on the CMS-209) the CMS 209 form. C. In an interview at 10: 45 on 01/03/24, employee #1 (as listed on the entrance exit conference sheet) confirmed that the laboratory did not have documented authorization to perform testing for employees.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Through a review of personnel records for all testing personnel listed on the form CMS-209 and through interviews with laboratory staff, it was revealed the technical consultant failed to perform competency assessments using the six required methods for one of one testing personnel. Survey findings include: A. During document review, competency assessments were not available. B. During an interview, at 10:48 on 01/03/24, laboratory employee #1 (as on the entrance /exit conference sheet) stated "if the records you're looking for aren't in that binder we don't have it" when I asked for employees records and training documentation.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed.

	This CONDITION is not met as evidenced by: Through a review of personnel files for one of one laboratory testing personnel listed on the CMS-209, through a lack of documentation, and through interviews with staff, it was determined that one of one laboratory testing personnel failed to meet qualification requirements as testing personnel as evidenced by: D6065 - one of one laboratory testing personnel lacked documentation of appropriate education to qualify as a testing personnel D6066 - one of one laboratory testing personnel lacked documentation of appropriate training to qualify as a testing personnel D6069 - one of one laboratory testing personnel lacked documentation of authorization to perform testing
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Through a review of laboratory personnel records for one of one testing person, lack of documentation, and interviews with laboratory staff, it was determined the laboratory failed document that one of one testing personnel (#1 as listed on the CMS 209 form) met educational requirements to perform moderate complexity testing. Survey findings follow: A) The laboratory failed to have documentation of education that would qualify testing personnel (#1 as listed on the CMS 209 form) to perform moderate complexity testing. C) In the interview, at 10:26 on 01/04/24 , laboratory employee #1 (as noted on the entrance and exit conference sheet) confirmed the lack of documentation of highest level of education, which would qualify employee to perform moderate complexity testing.
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Through a review of personnel records for one of one employee listed as testing personnel, lack of documentation, and interviews with laboratory staff, it was determined that one of one employees lacked documented training prior to analyzing patient samples. Survey findings include: A. During a review of personnel records for

	one employee listed as testing personnel on the form CMS-209, it was determined there was no documentation of training in the personnel record of testing personnel #1 (as listed on the CMS 209 form) as listed on the form. B. In an interview, at 10:21 on 01/03/24, laboratory employee #1 (as listed on the entrance/exit conference sheet) confirmed the laboratory had no documentation of training for testing person #1 (as listed on the CMS-209 form).
D6069	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(a) Each individual performs only those moderate complexity tests that are authorized by the laboratory director and require a degree of skill commensurate with the individual's education, training or experience, and technical abilities. This STANDARD is not met as evidenced by: Through a review of the form CMS-209, a review of personnel files and interviews with laboratory staff, it was determined one of one testing personnel failed to perform only those moderate complexity tests that are authorized by the laboratory director. Survey findings include: The laboratory director failed to give written authorization to perform testing without supervision in one of one testing personnel as cited at D6032.