

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D2090071	(X3) Date Survey Completed 02/09/2021
Name of Provider or Supplier Apollo Medical	Street Address, City, State 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
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: . Through a review of new instrument validation documentation for the Sysmex XN-400 Hematology analyzer, lack of documentation, and interviews with laboratory staff, it was determined the laboratory failed to demonstrate that the Sysmex XN-400 Hematology analyzer could obtain the reportable range established by the manufacturer for their patient's population. Survey findings follow: A. A review of the validation documentation revealed the laboratory installed the new Sysmex XN-400 Hematology analyzer on 01/30/2021 and performed the accuracy and precision at the time of install. B. The surveyor requested validation documentation for verification of the reportable range for the Sysmex XN-400 Hematology analyzer. None was provided. C. In an interview on 02/09/2021 at 11:00, laboratory personnel #1(as listed on CMS form 209) confirmed the laboratory failed to verify the reportable range of the Sysmex XN-400 Hematology analyzer.</p>
D6029	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform</p>

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 personnel records, lack of documentation, and interviews with staff, it was determined the laboratory director failed to ensure testing personnel received appropriate training prior to testing patient specimens. Survey findings follow: A. A review of personnel records for testing personnel #1 (as listed on the form CMS-209) revealed there was no documentation that testing personnel #1 had received appropriate training or demonstrated that they could perform all testing operations reliably prior to testing patient specimens. B. In an interview at 10:45 on 02/09/2021, testing personnel #1 stated that she started working in the laboratory in July of 2019. She confirmed there was no documentation of on-site training prior to testing patients.

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 CMS form 209, personnel records for one of one testing personnel, and interviews with laboratory staff, it was determined the laboratory director failed to specify, in writing, which examinations and procedures each individual was authorized to perform and whether supervision was required. Survey findings follow: A. A review of CMS form 209 revealed the name of laboratory testing personnel performing moderate complexity testing. B. A review of personnel record, revealed there was no signed authorization to perform moderate complexity testing for test personnel #1 as listed on the form CMS-209. C. Upon request, the laboratory could not provide signed authorization for testing personnel listed on CMS form 209 to perform moderate complexity testing. D. In an interview at 10; 00 a.m. on 02/09/2021, the clinic manager confirmed there was no written authorization from the laboratory director stating which tests the testing personnel #1 (on the CMS form 209) are authorized to perform.

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 review of the CMS form 209, personnel records, lack of documentation, and interview, it was determined that the technical consultant failed to document personnel competency on an annual basis for one of one testing personnel identified on the CMS form 209. Survey findings follow: A. A review of personnel records revealed no competency evaluations for 2019 and 2020 were performed for moderate complexity testing personnel identified as number 1 on form CMS 209. B. Upon request, the laboratory could not provide competency evaluations for the personnel identified above. C. In an interview on 02/09/2021 at 10:30 a.m., the clinical manager confirmed that competency evaluations had not been performed on testing personnel #1(as listed on form CMS 209).