

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2037652	(X3) Date Survey Completed 09/23/2021
Name of Provider or Supplier Epic Care	Street Address, City, State 1480 64th St Ste 100, Emeryville, CA	
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: Based on observation of the Sysmex XN430 analyzer (serial #11332), review of laboratory documents, the lack of laboratory records/documents, and interview with laboratory administrative personnel, it was determined that the laboratory testing personnel failed to verify they could obtain results comparable to manufacturer's claims in terms of Accuracy and Precision, within the reportable range, and verify the Reference Range of normal results. 1. The Sysmex XN430 analyzer was installed in August 2020. Laboratory records documented quality control materials and materials assessing the reportable range were run by a manufacturer's technical representative to reinforce manufacturer's claims of test performance specifications. 2. A laboratory record documented 44 patients specimen were tested and correlated to testing performed at Pleasant Hills. The laboratory administrator affirmed (9/23/21 at 4pm) testing the aforementioned 44 specimens; but having no responsibility to test patients specimen. 3. The laboratory failed to provide for review records/documents of testing personnel verifying that they could operate the Sysmex XN430 (sn11332) and obtain results comparable to the manufacturer's for Accuracy, Precision (Reproducibility), Reportable Range, and Reference Range of normal results. 4. The laboratory administrator affirmed (9/23/21 at 4pm) the aforementioned findings. 5. As a consequence of failing to verify their test performances prior to testing patients</p>

specimen, the accuracy, reproducibility, reliability and quality of hematology results reported could not be assured. Based on the stated annual test volume (CMS116, 9/16 /21) the testing personnel reported approximately 54,180 results each year since 2020.

D6013

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(3)(ii)

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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

This STANDARD is not met as evidenced by:

Based on the deficiency cited (D5421), the Laboratory Director is herein cited for deficient practice in ensuring test system verification procedures were compliant with the regulations at 493.1253(b)(1). Findings included: 1. Under the Laboratory Director's administration, the laboratory was allowed to test patients' specimen without requiring laboratory testing personnel to first verify they could obtain accurate and reproducible results, within the prescribed reportable range, and the reference range of normal results. .

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:

Based on review of laboratory test records and document CMS209, Laboratory Personnel Report (CLIA)[9/16/21], the lack of laboratory documents for the Sysmex XN430 Training, and interview with the laboratory administrator, it was determined that the Laboratory Director had failed to ensure that all personnel received training and demonstrated their ability to perform all aspects of operating this Sysmex XN430 (serial # 11332) reliably. Findings included: 1. Test records randomly selected from 2020 for this survey were as follows: Date Testing Person 3/26/20 CV 9/16/20 CV 12 /28/20 EV 2. The 2021 Personnel Report included two Testing Persons and two Technical Consultants. 3. The laboratory provided for review Sysmex XN430 training records in 2021 for one out of six personnel, but without documented hands-on demonstration of operating all aspects of the test system with instrument print outs (serial # 11332) as evidence of obtaining accurate results. 4. The laboratory adminsitator affirmed (9/23/21 at 5pm) that one of the testing persons in 2021 had not yet received training; and the aforementioned lack of records and documents for

the persons performing testing in 2020, and the two Technical Consultants with responsibilities to provide technical and scientific oversight and assess personnel competencies. 5. Under the Laboratory Director's administration, the laboratory failed to have a policy and practice of requiring all personnel to perform onsite hands-on demonstration of operating all aspects of a test system with instrument printouts for evidence of accurate results.

D6040

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(2)

The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

This STANDARD is not met as evidenced by:
Based on the deficiency cited (D5421), the Technical Consultants are herein cited for their insufficient responsibilities in providing scientific and technical oversight for verifying test systems, and establishing the laboratory's test performance characteristics for accuracy, precision, reportable range, and reference range prior to testing patients specimen.