

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2105688	(X3) Date Survey Completed 11/28/2018
Name of Provider or Supplier Kaweah Health Specialty Clinic	Street Address, City, State 325 S Willis St, Visalia, 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 I-Stat analyzers (serial numbers 378215, 378132), review of patients test records for BNP (Brain natriuretic peptide) and Prothrombin Time; the lack of laboratory documents for laboratory testing personnel demonstrating performance specifications, and interview with the Technical Consultants, the laboratory testing persons failed to verify that they could obtain the Reportable ranges established by the manufacturer. Findings include: a. The laboratory utilized I-Stat analyzers to test for moderate complexity BNP and Prothrombin Time. b. The laboratory failed to provide for review records and instrument printouts documenting laboratory testing personnel verifying the Reportable ranges established by the manufacturer. c. The Technical Consultants affirmed (11/28/18) that the manufacturer's representative had tested the I-Stats; and subsequently, the failure to have laboratory testing personnel verify their abilities to obtain performance specifications comparable to those established by the manufacturer, specifically for Reportable ranges. d. The reliability and quality of results reported could not be assured. Based on the stated annual tests volumes (CMS116 CLIA Application, LAB144A Laboratory Testing Declaration; 11/28/18), the laboratory reported approximately 50 BNP and 200 Prothrombin Time each year in 2017 and 2018. A few examples are as follows: Date CHG Account Test</p>

----- 1/17/17 974440979 BNP 3/01/17
974488120 PT 4/20/17 974544549 BNP, PT 5/30/17 974585284 PT 6/16/17
974465042 BNP 9/26/17 974716433 PT 11/08/17 974763198 PT 5/07/18 975008976
BNP 5/15/18 975019864 PT 6/22/18 975082968 BNP 7/17/18 975109592 PT 8/30/18
975156934 BNP

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:

The Laboratory Director is herein cited for deficient practice in the overall administration of the laboratory to ensure that test verification procedures determining the accuracy, precision, and other pertinent test performance characteristics are performed by laboratory testing personnel. Findings include: a. The laboratory failed to have a policy and practice requiring laboratory testing personnel to verify new tests' performance characteristics. b. See D5217

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:

The Technical Consultants are herein cited for deficient practice in their responsibility to ensure that laboratory testing personnel perform test procedures to verify test performance characteristics, including accuracy, precision, and reportable range for FDA-approved analyzers prior to testing patients. See D5217.