

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0618474	(X3) Date Survey Completed 06/27/2018
Name of Provider or Supplier Dignity Health Lassen Medical Clinic	Street Address, City, State 2450 Sister Mary Columba Dr, Red Bluff, 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 Surveyor review of laboratory's policy & procedure, random patient test records, and interview with the laboratory technical consultant, the laboratory failed to verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. The findings include: a. The laboratory reported BUN test results for the patients, accession # 172510063 and 181280153. The laboratory provided the reference range on the test report for BUN as 7 - 22 mg/dL. However, the test manufacturer's reference range varies depending on the subject's age and gender, ranging from 8.4 to 25.7 mg/dL. The laboratory did not provide any documentation of showing that the laboratory has established its own value or verified the manufacturer's provided value. b. On June 27, 2018 at 12:20 pm laboratory technical consultant affirmed that the laboratory did not verify the manufacturer's value. c. The laboratory's testing declaration form, signed by the laboratory Director on June 19, 2018, stated that the laboratory performs 150,917 tests annually.</p>
D6013	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii)</p> <p>The laboratory director is responsible for the overall operation and administration of</p>

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 Surveyor review of patient test records, lack of analytical data and documentation, and interview with the laboratory technical consultant, the laboratory Director failed to ensure that the verification procedures are used to determine the pertinent performance characteristics of the method. The findings include: a. See D5421.