

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0709721	(X3) Date Survey Completed 06/26/2018
Name of Provider or Supplier Patients Hospital Of Redding	Street Address, City, State 2900 Eureka Way, Redding, 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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy & procedure, quality control data and random patient testing records, and interview with the laboratory testing person, the laboratory failed to retain quality control records including instrument printouts documenting the analytic system activities for at least 2 years. The findings include: a. The laboratory reported an ABO/Rh typing and antibody screening test results on 03/08/2018 for the patient record # 28475 / 278737. The laboratory did not provide any document showing that the quality control was performed on the day of patient testing. Due to the lack of quality control records, it could not be assured that the quality control was performed and the reported patient test result was accurate. b. On June 26, 2018 at 2:40 pm laboratory testing person affirmed that the laboratory did not have any quality control test records for the above date. c. The laboratory's testing declaration form, signed by the laboratory Director on June 6, 2018, stated that the laboratory performs 500 tests annually.</p>
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)</p>

Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

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 testing person, 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 a BUN test results on 06/19/2018 for the patient accession # 180301. The laboratory provided the reference range on the test report for BUN as 7 - 25 mg/dL. However, the test manufacturer's guideline values are 7.9 - 20.2 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 26, 2018 at 3:00 pm laboratory testing person 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 6, 2018, stated that the laboratory performs 2040 tests annually.

D6079

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(a)(b)

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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on Surveyor review of patient testing records, lack of analytical data and documentation, and interview with the laboratory staff, the laboratory Director failed to assure compliance with the regulations. The findings include: a. See D3031 and D5421.