

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0643486	(X3) Date Survey Completed 05/17/2022
Name of Provider or Supplier Kern County Public Health Laboratory	Street Address, City, State 1800 Mt Vernon Ave, 3rd Fl, Bakersfield, 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
D5891	<p>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.</p> <p>This STANDARD is not met as evidenced by: Based on review of patient test records, laboratory's policy and procedure manual, and interview with the general supervisor (GS); it was determined that the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the post analytic systems. The findings included: 1. The laboratory did not have a written policy or procedure for turnaround time (TAT) established for all the tests performed in the laboratory. 2. Based on the laboratory's annual test declaration submitted and signed by the laboratory director at the time of the survey on May 17, 2022; the laboratory analyzed and reported 29,207 test results for which there was no TAT established policy to monitor timely test results reporting during the postanalytic phase of testing. 3. The GS on May 17, 2022, at approximately 12:45 p.m. affirmed that the laboratory did not have a written policy or procedure for monitoring TAT for each test performed in the laboratory.</p>
D6079	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b)</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 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</p>

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 review of laboratory's policies and procedures, five (5) randomly chosen patients, and interview with the general supervisor; it was determined that the laboratory director failed to be responsible for the overall operation and administration of the laboratory including assuring compliance with applicable regulations by delegating responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. See D5891.