

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2209422	(X3) Date Survey Completed 01/03/2023
Name of Provider or Supplier Dxlabs Inc	Street Address, City, State 11755 Victory Blvd Ste 216, North Hollywood, 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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy and procedure, patient test results, panic value log and interview with the laboratory technical consultant on January 3, 2023, at 1:20 pm, the laboratory testing person failed to follow the panic value reporting policy & procedure. The findings include: 1. The laboratory obtained a critical value of CREA, 6.3 mg/dL (sample # 221227028) on 12/28/2022 at 14:47 which was verified by repeat analysis. A total of 10 patients data reviewed. The laboratory's critical results reporting policy stated that it will provide important test information immediately to the referring physician. However, the laboratory reported the above critical result to the physician on 12/29/2022 at 10:49. without any further analysis. Therefore, the delay in reporting the critical value might have harmed the patient. 2. The laboratory technical consultant on January 3, 2023, at 1:00 pm, affirmed that the laboratory testing person #1 did not follow the laboratory's critical value reporting procedure. 3. The laboratory's testing declaration form, signed by the laboratory director on 1/3/2023, stated that the laboratory performs approximately 62,000 routine chemistry tests, annually.</p>
D6004	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(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</p>

test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, 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 laboratory's policy and procedure, patient test results and interview with the laboratory technical consultant on January 3, 2023, at 1:00 pm, it was determined that the laboratory director failed to oversee overall operation and administration of the laboratory. The findings include: See D5401.

D6070

TESTING PERSONNEL RESPONSIBILITIES
CFR(s): 493.1425(b)(1)

Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results.

This STANDARD is not met as evidenced by:
Based on Surveyor review of laboratory's policy and procedure, patient test results and interview with the laboratory technical consultant and testing person on January 3, 2023, at 1:00 pm, it was determined that the laboratory testing person #1 failed to follow the laboratory's procedures for reporting of patient test results. The findings include: See D5401.