

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0563772	(X3) Date Survey Completed 05/31/2023
Name of Provider or Supplier Sun Clinical Laboratories	Street Address, City, State 9349 Telstar Ave Ste A & B, El Monte, 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
D2109	<p>TOXICOLOGY CFR(s): 493.845(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of second quarter event in 2022 (Q2-2022) and third quarter event 2022 (Q3-2022) of the American Association of Bioanalysts (AAB) proficiency testing (PT) records, random patient sampling test results, and interview with the laboratory director (LD) and technical supervisors (TS); it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for each analyte in the Therapeutic Drug Monitoring panels. The findings included: 1. The AAB reported for Q2-2022, an unsatisfactory PT score for Phenytoin analyte of 60% and an unsatisfactory PT score for Digoxin of 20%. 2. The LD and TS affirmed on May 30, 2023, at approximately 11:30 a.m. that the laboratory received the above unsatisfactory proficiency test scores. 3. Based on the test volume declaration signed by the laboratory director on 5/15/2023 the laboratory tested 2,671 Toxicology sample tests which included both analytes Digoxin and Phenytoin.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p>

This STANDARD is not met as evidenced by:
Based on observation on the lack of calibrated thermometers in the refrigerators, freezers, heating blocks, etc. to verify digital temperature readings, missing temperature checks during weekend days, and interview with the technical supervisors (TS) and technical consultant (TC) it was determined that the laboratory failed to monitor the digital temperature readings of equipment essential for proper storage of reagents and specimens that adversely affect patient test results. The findings included: 1. On the day of the survey, May 30, 2023, at approximately 2:30 p.m. based on the surveyors' observation and interview with the TS and TC; the laboratory failed to have calibrated thermometers on the refrigerators, freezers, etc., that verify accurate digital thermometers readings which affect reagents and patients' samples testing. 2. The TS and TC confirmed on 03/30/2023, at approximately 3:00 p.m. that the laboratory has no calibrated thermometers in the refrigerators, freezer, heating blocks, etc. to verify digital temperature readings. 3. Based on the laboratory's submitted testing declaration volume, the laboratory tested and reported approximately 8,710,830 samples annually.

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1299(a)

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.

This STANDARD is not met as evidenced by:
Based on review of patient test results records, laboratory's policy and procedure manual, and interviews with the technical supervisors (TS) and technical consultant (TC); it was determined that the laboratory failed to establish written policies and procedures for turn-around-times of each test results as part of 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 turn-around-times for all the test performed in the laboratory. 2. Based on the laboratory's annual test declaration submitted and signed by the laboratory director on May 15, 2023; the laboratory analyzed and reported 8,710,830 test results for which there were no-turn-around times established policy to monitor timely test results reporting during the postanalytic phase of testing. 3. The TS affirmed on May 30, 2023, and May 31, 2023, at approximately 2:30 p.m. that the laboratory did not have a written policy or procedure for monitoring turn-around-times for each test performed in the laboratory.

D6082

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(1)

The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's records for policies and procedures, patient review records, proficiency testing reports, direct observation by the surveyors during the lab tour, and interviews with the technical supervisors, technical consultant, and testing personnel on May 30 and May 31, 2023; it was determined that the laboratory director failed to ensure that several aspects of the preanalytic, analytic, and postanalytic phases of laboratory testing were monitored. See D2109, D5413, and D5891.