| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 05D2048849 | 06/27/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Sunrise Clinical Laboratories Inc | 2654 Honolulu Ave, Montrose, 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 |
|---|---|
| **D5435** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(b)(2)<br><br>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of equipment function check documentation for 2017, 2018 and 2019, ten (10) randomly selected patient test results from 06/30/2017 to 05/29/2019 and interviews with laboratory personnel, it was determined that the laboratory failed to ensure function checks were performed and documented as specified in paragraph (b)(2)(i) of this section. No documentation could be retrieved for the rotator's rotation per minute (RPM) accuracy checks performed by ASI Rapid Plasma Reagin (RPR) for Treponema Pallidum patient testing for the period cited. The findings included: a. On 06/27/2019 (survey date) review of the laboratory's "RPR Daily QC" showed that no documentation for the rotator's RPM was recorded on the testing log sheet. The laboratory's policy entitled "ASI PRP Slide Test" under the section Reagents and Materials Item 7: Rotator (100+/-rpm). b. Laboratory staff confirmed on 06/27/2019 13:00 the lack of documentation cited above during the interview for the ASI RPR patient testing performed, yet patient tests were resulted and reported. c. The laboratory's testing declaration of 06/25/2019 estimated the 8,000 immunology patient tests were performed which included the ASI RPR serology annually. |