

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2152161	(X3) Date Survey Completed 10/12/2021
Name of Provider or Supplier Saddleback Medical Group	Street Address, City, State 24221 Calle De Louisa Ste 400, Laguna Hills, 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 the surveyor's review of the laboratory procedure manual and supporting temperature worksheets, and an interview with laboratory personnel (LP) on 10/12/2021 between 10 am and 11:30 am, it was determined that slide oven temperature logs were not consistent. Findings include: 1. On 10/12/2021, an inspection was conducted between 10 am and 11:30 am. 2. During a review of the procedure manual and the associated temperature log sheets for the slide oven, some temperatures were logged at 100 degree centigrade and some at 75 degrees centigrade. 3. The temperature log sheet was titled 'Slide oven temperatures 95-110 C'. 4. The values for Jan-June 2020 were mainly logged at 100 degrees Centigrade, while the values from July 2020 through October of 2021 were logged at 75 degrees Centigrade. 5. There was not a definitive temperature defined in the procedure manual. 6. The LP agreed at 11:00 am that the worksheets were inconsistent.</p>
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>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 establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result</p>

reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:

Based on the surveyor's review of the laboratory procedure manual and supporting maintenance record worksheets, and an interview with laboratory personnel (LP) on 10/12/2021 between 10 am and 11:30 am, it was determined that there was not a record of microscope maintenance in 2020. Findings include: 1. On 10/12/2021, an inspection was conducted between 10 am and 11:30 am. 2. During a review of the instrument maintenance records, it was noted that there was no indication of microscope maintenance during 2020. 3. The LP agreed at 11:15 am that the microscope maintenance records for 2020 were not present.