

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D1065292	(X3) Date Survey Completed 07/24/2024
Name of Provider or Supplier Del Mar M E D	Street Address, City, State 12395 El Camino Real, Ste 200, San Diego, 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
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review of ten (10) randomly chosen patient records, a review of the laboratory's policies and procedures, and interviews with the technical supervisor (TS) and laboratory assistant (LA), it was determined that the laboratory failed to perform and document preventive maintenance (PM) as defined by the manufacturer and with at least the frequency specified by the manufacturer for the laboratory's small equipment. The findings included: 1. Based on the laboratory's policies and procedures, PM for the microscope will be performed annually by the service company. However, upon review of the template for the microscope daily maintenance log, it stated that PM will be performed with each day of use. 2. Based on the review of 10 randomly chosen patient records, four out of 10 had no record of preventive maintenance for the microscope on the days testing was performed. 3. The TS and LA affirmed on July 24, 2024, at approximately 12:00 p.m. that maintenance performed for the microscope only recorded the scheduled days when Mohs testing was performed and does not reflect the other dates when the microscope was used for KOH testing. 4. According to the test volume declared by the laboratory on July 24, 2024, the laboratory performed approximately 70 tests for KOH and 150 Mohs tests annually.</p>
D6082	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1)</p> <p>The laboratory director must ensure that testing systems developed and used for each</p>

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 the surveyor's review of the laboratory's policies and procedures, ten randomly selected patients' test records and preventive maintenance documentation, and interviews with the laboratory 's teschnical supervisor and testing personnel on July 24, 2024; it was determined that the laboratory director is cited herein due to failure to ensure that aspects of the analytic phase of the laboratory testing was monitored. See D5429.