

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D0711439	<b>(X3) Date Survey Completed</b>  08/18/2021
<b>Name of Provider or Supplier</b>  Madera County Public Health Laboratory	<b>Street Address, City, State</b>  1604 Sunrise Ave, Madera, CA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2029</b>	<p><b>MYCOBACTERIOLOGY</b> CFR(s): 493.825(a)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on observation of Mycobacterial cultures, review of 2019 proficiency testing reports from CMS (report 155, Individual Laboratory Profile) and CAP (College of American Pathologists), laboratory proficiency testing records, and patients Mycobacterial Culture test records; and interview with the Laboratory Director, it was determined that the laboratory failed to attain an overall testing event score of at least 80% in Mycobacteriology, demonstrating unsatisfactory culture and identification of mycobacteria. Findings included: 1. CMS and CAP reported the unsatisfactory score of 66% for event B- 2019, Mycobacteriology based on the unacceptable results (*) reported for 2 of 5 samples, as follows: a. Specimen # E- 07 Lab result: Neg for Mycobacteria* [No growth] CAP intended response: M. tuberculosis complex b. Specimen # E- 09 Lab result: M. tuberculosis complex * CAP intended response: Mycobac/Not MTbCom 2. The Laboratory Director affirmed (8/18/21 @ 5pm) the aforementioned unacceptable culture results and stated that the root causes were two-fold: the samples were switched during numbering (preanalytical), and that specimen #E-07 missed being plated onto additional special media (or culture conditions) so there was no growth of the organism, yielding a false negative result. 3. The reliability and quality of Mycobacterial Cultures in 2019 could not be assured. Two selected at random for this survey were as follows: Date Number Reported ----- 12/18/19 MD19- 03020 No AFB found 12/26/19 MD19- 03062 No AFB found 4. The laboratory stated approximately 1,600 tests for mycobacteria were performed annually including cultures, Acid-Fast stains, and molecular methods. .</p>