

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D0960705	<b>(X3) Date Survey Completed</b>  12/15/2025
<b>Name of Provider or Supplier</b>  T I M M A Diagnostic Laboratory	<b>Street Address, City, State</b>  5620 Wilbur Ave Ste 330, Tarzana, 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>D0000</b>	A proficiency testing desk review survey was performed on December 15, 2025, the laboratory was found not in compliance with the following CONDITION LEVEL DEFICIENCIES D2016 - 42 C.F.R. 493.803 Condition: Successful proficiency testing participation; and D6076 - 42 C.F.R. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director.
<b>D2016</b>	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) - 0155D and American Association of Bioanalysts - Medical Laboratory Evaluation (AAB-MLE) records (2023-M2, 2023-M3, and 2024-M2), the laboratory</p>

	<p>failed to successfully participate in a proficiency testing program approved by HHS for each specialty, subspecialty and analyte or test in which the laboratory is certified under CLIA, the laboratory failed to successfully participate in the analyte Gram stain resulting in unsuccessful performances. See D2026.</p>
<p><b>D2026</b></p>	<p><b>BACTERIOLOGY</b> CFR(s): 493.823(d)</p> <p>(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile and American Association of Bioanalysts - Medical Laboratory Evaluation (AAB-MLE) report, the laboratory failed to achieve satisfactory performance for three events (2023-M2, 2023-M3, and 2024-M2) for the analyte Gram stain (specialty Microbiology): The finding include: Gram stain 0% - 2023 second testing event (M2); 0% - 2023 third testing event (M3); 0% - 2024 second testing event (M2); A review of the 2023 &amp; 2024 scores from AAB-MLE reports confirmed the above subsequent proficiency testing failures.</p>
<p><b>D6076</b></p>	<p><b>LABORATORY DIRECTOR</b> CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on a proficiency testing desk review of the CASPER 0155D report and American Association of Bioanalysts - Medical Laboratory Evaluation records for 2023-M2, 2023-M3, and 2024-M2 events, the laboratory director failed to provide overall management and direction of the laboratory services. Refer to D6089.</p>
<p><b>D6089</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(4)(i)</p> <p>(e)(4)(i) The proficiency testing samples are tested as required under subpart H of this part;</p> <p>This STANDARD is not met as evidenced by: Based on a proficiency testing desk review of the CASPER 0155D report and American Association of Bioanalysts - Medical Laboratory Evaluation records for 2023-M2, 2023-M3 and 2024-M2 events, the laboratory director failed to ensure successful participation in an HHS proficiency testing program. Refer to D2026.</p>