

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0477839	(X3) Date Survey Completed 06/16/2023
Name of Provider or Supplier Lab Of Drs Mathieu, Daniel, Poole	Street Address, City, State 3601 North Star, Richardson, TX	
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
D0000	The following deficiencies are a result of a desk review of proficiency testing scores obtained from the CMS (Centers for Medicare and Medicaid Services) national database and verified with the proficiency testing company, American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE). The facility was found to be out of compliance with the conditions of participation of the CLIA program. The following CONDITION LEVEL DEFICIENCIES were found to be out of compliance: 493.803 Successful participation in a proficiency testing program 493.1403 Laboratory Director, Moderate Complexity
D2016	<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:</p>

	<p>Based on a proficiency testing desk review of Center for Medicare and Medicaid Services (CMS) form 0155 and American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) records, it was determined the laboratory had not successfully participated 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 did not successfully participate in the specialty of Bacteriology. Refer to D2020 and D2028.</p>
D2020	<p>BACTERIOLOGY CFR(s): 493.823(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 a proficiency testing desk review of Center for Medicare and Medicaid Services (CMS) form 0155 and American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) 2022 (2nd Event) and 2023 (1st Event) records, it was revealed the laboratory failed to achieve an overall testing event score of satisfactory performance (80% or greater) for two out of three consecutive testing events for the specialty of Bacteriology. Two of three consecutive unsatisfactory scores result in unsuccessful PT performance. Findings included: 1. Review of the CMS 0155 report revealed the following results: Bacteriology 2022 - 2nd Event laboratory received an unsatisfactory score of 50% for Bacteriology specialty. Bacteriology 2023 - 1st Event laboratory received an unsatisfactory score of 67% for Bacteriology specialty. 2. A proficiency desk review from AAB-MLE 2022 and 2023 proficiency testing records confirmed the above scores.</p>
D2028	<p>BACTERIOLOGY CFR(s): 493.823(e)</p> <p>Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on a proficiency testing desk review of Center for Medicare and Medicaid Services (CMS) form 0155 and American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) 2022 (2nd Event) and 2023 (1st Event) records, it was revealed that the laboratory failed to achieve satisfactory performance (80% or greater) for the same analyte in two out of three consecutive testing events in the specialty of Bacteriology. Two of three consecutive unsatisfactory scores result in unsuccessful PT performance. Findings included: 1. Review of the CMS 0155 report revealed the following results: Bacteriology 2022 - 2nd Event laboratory received an unsatisfactory score of 50% for bacteriology. Bacteriology 2023 - 1st Event laboratory received an unsatisfactory score of 67% for bacteriology. 2. A proficiency desk review from AAB-MLE 2022 and 2023 proficiency testing records confirmed the above scores.</p>
D6000	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p>

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:
Based on a proficiency testing desk review of Center for Medicare and Medicaid Services (CMS) form 0155 and American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) records, the Laboratory Director failed to fulfill their responsibilities. The Laboratory Director failed to ensure proficiency testing was tested as required under subpart H. Refer to D6016.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(i)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:
Based on a proficiency testing desk review of Center for Medicare and Medicaid Services (CMS) form 0155 and American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) records, the Laboratory Director failed to ensure proficiency testing was tested as required. The laboratory director failed to ensure successful participation in an HHS approved proficiency testing program. Refer to D2020 and 2028.