

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 48D0699866	<b>(X3) Date Survey Completed</b> 12/05/2025
<b>Name of Provider or Supplier</b> Clinical Laboratory Inc	<b>Street Address, City, State</b> Island Med Ctr Suite 6, Sunny Isle, St Croix, VI	
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>	The following deficiencies are a result of a desk review of proficiency testing scores obtained from the national database and verified with the proficiency testing company. The facility was found to be out of compliance with the conditions of the CLIA program. The following CONDITION LEVEL DEFICIENCIES were found to be out of compliance: D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing] D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director
<b>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> 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: This CONDITION is not met as evidenced by: Based on a proficiency testing desk</p>

	<p>review of the Certification and Survey Provider Enhanced Reporting (CASPER) 0155 report and American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) 2025 records, the laboratory failed to successfully participate in a proficiency testing program approved by HHS, for each specialty, subspecialty, and analyte in which the laboratory is certified under CLIA. The laboratory failed to successfully participate in the sub-specialty of Routine Chemistry for the Follicle Stimulating Hormone (FSH) analyte, in the sub-specialty of Hematology for the Prothrombin Time (PT) analyte and in the sub-specialty of Immunohematology for the Antibody Detection (Ab-detection) analyte. Refer to D2096, D2130, and D2164.</p>
<p><b>D2096</b></p>	<p><b>ROUTINE CHEMISTRY</b> CFR(s): 493.841(f)</p> <p>(f) Failure to achieve satisfactory performance for the same analyte or test in 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 the CASPER 0155 report and AAB-MLE 2025 proficiency testing records, the laboratory failed to achieve satisfactory performance (80% or greater) for the same analyte in two of two consecutive testing events (2025 Events 2 and 3) in the sub-specialty of Routine Chemistry for the FSH analyte. Findings: 1. A review of the CASPER 0155 report revealed the following results: AAB-MLE 2025- 2nd Event The laboratory received an unsatisfactory score of 60% for FSH. AAB-MLE 2025- 3rd Event The laboratory received an unsatisfactory score of 40% for FSH. 2. A review of AAB-MLE 2025 proficiency testing records confirmed the laboratory received the above results.</p>
<p><b>D2130</b></p>	<p><b>HEMATOLOGY</b> CFR(s): 493.851(f)</p> <p>(f) Failure to achieve satisfactory performance for the same analyte in two consecutive 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 the CASPER 0155 report and AAB-MLE 2025 proficiency testing records, the laboratory failed to achieve satisfactory performance (80% or greater) for the same analyte in two of three testing events (2025 Events 1 and 3) in the sub-specialty of hematology for the Prothrombin Time (PT) analyte. Findings: 1. A review of the CASPER 0155 report revealed the following results: AAB-MLE 2025- 1st Event The laboratory received an unsatisfactory score of 60% for PT. AAB-MLE 2025- 3rd Event The laboratory received an unsatisfactory score of 60% for PT. 2. A review of AAB-MLE 2025 proficiency testing records confirmed the laboratory received the above results.</p>
<p><b>D2164</b></p>	<p><b>UNEXPECTED ANTIBODY DETECTION</b> CFR(s): 493.861(a)</p> <p>(a) Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance.</p>

	<p>This STANDARD is not met as evidenced by:  Based on a proficiency testing desk review of the CASPER 0155 report and AAB-MLE 2025 proficiency testing records, the laboratory failed to achieve satisfactory performance (100% or greater) for the same analyte in two of three testing events (2025 Events 1 and 3) in the sub-specialty of Immunohematology for the Antibody Detection (Ab-detection) analyte. Findings: 1. A review of the CASPER 0155 report revealed the following results: AAB-MLE 2025- 1st Event The laboratory received an unsatisfactory score of 80% for Ab-detection. AAB-MLE 2025- 3rd Event The laboratory received an unsatisfactory score of 80% for Ab-detection. 2. A review of AAB-MLE 2025 proficiency testing records confirmed the laboratory received the above results.</p>
<b>D6000</b>	<p><b>MODERATE COMPLEXITY LABORATORY DIRECTOR</b>  CFR(s): 493.1403</p> <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.</p> <p>This CONDITION is not met as evidenced by:  Based on a proficiency testing desk review of the CASPER 0155 report and AAB-MLE 2025 proficiency testing records, the laboratory director failed to provide overall management and direction of the laboratory services. Refer to D6016.</p>
<b>D6016</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b>  CFR(s): 493.1407(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 0155 report and AAB-MLE 2025 proficiency testing records, the laboratory director failed to ensure the overall quality of the laboratory services provided. The laboratory director failed to ensure successful participation in an HHS approved proficiency testing program. Refer to D2096, D2130, and D2164.</p>