

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2056591	(X3) Date Survey Completed 08/15/2025
Name of Provider or Supplier Citilabs, Inc	Street Address, City, State 6201 N California Ave, Suite 111, Chicago, IL	
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	A Proficiency Testing (PT) desk review was performed on August 15, 2025. The laboratory was found to be out of compliance with the 42 CFR Part 493 CLIA requirements for the following CONDITION level deficiencies: 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
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: Based on a desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile, American Proficiency</p>

	<p>Institute (API) Proficiency Testing (PT) records, and American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) PT records, the laboratory failed to successfully participate in and achieve satisfactory performance for the analyte, Chloride in the subspecialty of Routine Chemistry for two of three PT events in 2023 (event 1 of 2023 and event 3 of 2023) and two of three PT events in 2024 and 2025 (event 3 of 2024 and event 2 of 2025) resulting in the laboratory's subsequent unsuccessful PT performance. Refer to D2096.</p>
<p>D2096</p>	<p>ROUTINE CHEMISTRY 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 desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile, American Proficiency Institute (API) Proficiency Testing (PT) records, and American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) PT records, the laboratory failed to achieve satisfactory performance for the analyte, Chloride in the subspecialty of Routine Chemistry for two of three PT events in 2023 (event 1 of 2023 and event 3 of 2023) and two of three events in 2024 and 2025 (event 3 of 2024 and event 2 of 2025) resulting in the laboratory's subsequent unsuccessful PT performance. Findings include: 1. Review of the CASPER Report 0155D, generated on 08-01-2025, the laboratory received the following unsatisfactory scores for the analyte, Chloride. Chloride Initial Unsuccessful PT Performance EVENT 1, 2023 - 60% Unsatisfactory EVENT 3, 2023 - 40% Unsatisfactory Subsequent Unsuccessful PT Performance EVENT 3, 2024 - 0% Unsatisfactory EVENT 2, 2025 - 20% Unsatisfactory 2. Review of API PT evaluation reports (Chemistry - Core) and AAB-MLE PT evaluation reports (Chemistry M1 & M3, 2023) confirmed the above unsatisfactory scores that resulted in the laboratory's subsequent unsuccessful PT performance for the analyte, Chloride.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR 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 desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile, American Proficiency Institute (API) Proficiency Testing (PT) records, and American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) PT records, the laboratory director failed to ensure successful participation in their PT program for the analyte, Chloride in the subspecialty of Routine Chemistry resulting in the laboratory's subsequent unsuccessful PT performance. Refer to D6016.</p>
<p>D6016</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES</p>

CFR(s): 493.1407(e)(4)(i)

(e)(4)(i) 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 desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile, American Proficiency Institute (API) Proficiency Testing (PT) records, and American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) PT records, the laboratory director failed to ensure successful participation in their PT program for the analyte, Chloride in the subspecialty of Routine Chemistry resulting in the laboratory's subsequent unsuccessful PT performance. Refer to D2096.