

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2056591	(X3) Date Survey Completed 12/05/2023
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
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 desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile and the American Association of Bioanalysts - Medical Laboratory Evaluation (AAB-MLE) Proficiency Testing (PT) records the laboratory failed to successfully participate in PT for the routine chemistry analyte chloride (Cl) for two of three events in 2023, resulting in the initial unsuccessful PT performance for chloride. See D2096.</p>
D2096	<p>ROUTINE CHEMISTRY CFR(s): 493.841(f)</p>

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.

This STANDARD is not met as evidenced by:

Based on desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile and the American Association of Bioanalysts - Medical Laboratory Evaluation (AAB-MLE) Proficiency Testing (PT) records the laboratory failed to successfully participate in PT for the routine chemistry analyte chloride (Cl) for two of three events in 2023, resulting in the initial unsuccessful performance for Cl. Findings include: 1. Review of the CASPER Report 0155D ran on 12-1-2023, found the laboratory received the following unsatisfactory PT scores for the analyte Cl. Chloride (Cl) AAB EVENT-1, 2023 = 60% - Unsatisfactory AAB EVENT-3, 2023 = 40% - Unsatisfactory 2. Review of the AAB PT records confirmed the initial unsuccessful PT performance for Cl for two of three PT events in 2023. Chloride (Cl) AAB EVENT-1, 2023 = 60% - Unsatisfactory AAB EVENT-3, 2023 = 40% - Unsatisfactory

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

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 desk 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) Proficiency Testing (PT) records the laboratory director failed to ensure successful participation in a Health and Human Services (HHS) approved PT program for the chemistry analyte chloride in 2023. See 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 desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile and American Association of Bioanalysts (AAB) Proficiency Testing (PT) records the laboratory director failed to ensure successful participation in a Health and Human Services (HHS) approved PT program for the chemistry analyte chloride (Cl). See D2096.