

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2056591	(X3) Date Survey Completed 09/11/2025
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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following:</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interview with testing personnel (TP) #3; the laboratory failed to ensure patient testing records were documented and retained for five of five manual test methods including C-Reactive Protein (CRP) Latex, Anti-Streptolysin O (ASO) Latex, Heliobacter (H.) pylori Antibody (Ab) Latex, and Rheumatoid Factor (RF) Latex in the specialty of immunology and Erythrocyte Sedimentation Rate (ESR) in the specialty of hematology. Findings include: 1. Review of the patient log for the manual testing of CRP, ASO, H. pylori Ab, RF, and ESR revealed the log records began on 11/23/2024. 2. Review of patient records revealed manual testing was performed prior to 11/23/2024: Patient: Tests Performed: Date of Testing: 24070 CRP, ESR, H. Pylori 09/21/2023 3. Upon surveyor request on 09/11/2025, at 11:20 am, for patient logs of manual testing prior to 11/23/2024, it was confirmed by TP #3 the laboratory failed to ensure patient testing records were documented and retained for five of five manual test methods including CRP Latex, ASO Latex, H. pylori Ab Latex, and RF Latex in the specialty of immunology and ESR in the specialty of hematology prior to 11/23/2024.</p>
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing</p>

performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, American Proficiency Institute (API) and American Association of Bioanalysts-Medical Laboratory Evaluation (AAB-MLE) proficiency testing (PT) records, lack of documentation, and interview with the laboratory director (LD); the laboratory failed to ensure corrective action was taken for 12 of 49 unacceptable PT sample results from 2023 through the date of survey, 09/11/2025. Findings include: 1. Review of laboratory policies and procedures revealed the procedure titled "Proficiency Testing", which stated, under "Corrective Action:", "The evaluation of data of proficiency tests are critically reviewed by the supervisor and director. Those results that do not meet acceptable criteria of the laboratory or proficiency testing program are considered unsatisfactory. All unsatisfactory results must be evaluated to detect the error and correct Use proficiency testing corrective action form to document corrective action taken and file with proficiency testing manual." 2. Review of AAB-MLE PT records revealed the following 2 unsatisfactory PT results lacked corrective action documentation: PT Event: Analyte: Sample: 2023 Event 3 ESR* 12 2024 Event 1 CRP** 1 *ESR = Erythrocyte Sedimentation Rate **CRP = C-Reactive Protein 3. Review of API PT records revealed the following 10 unsatisfactory PT results lacked corrective action documentation: PT Event: Analyte: Sample: 2024 Event 1 ALT*** CH-04 2024 Event 1 Sodium CH-04 2024 Event 3 Triglyceride CH-11 2024 Event 3 Urea Nitrogen CH-11 2024 Event 3 Thyroxine CH-11 2024 Event 3 Thyroxine CH-12 2024 Event 3 Thyroxine CH-13 2024 Event 3 Thyroxine CH-14 2024 Event 3 Thyroxine CH-15 2025 Event 1 Monocyte ABT-02 ***ALT = Alanine Aminotransferase 4. Interview with the LD on 09/10/2025, at 10:59 am, confirmed the laboratory failed to ensure corrective action was taken for 12 of 49 unacceptable PT sample results from 2023 through the date of survey, 09/11/2025.

D5213

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(b)(1)

(b) The laboratory must verify the accuracy of the following: (b)(1) Any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.

This STANDARD is not met as evidenced by:

Based on review of American Proficiency Institute (API) proficiency testing (PT) records, laboratory records, lack of documentation, and interview with the laboratory director (LD); the laboratory failed to ensure accuracy of 12 of 12 analytes not evaluated by the PT provider from 2023 through the date of survey, 09/11/2025, in the specialties of hematology and chemistry. Findings include: 1. Review of API comparative evaluation summaries for PT events from 2023 through the date of testing, 09/11/2025, revealed the following un-graded PT samples: PT Event: Analyte: Sample: 2023 Event 2 Monocyte ABT-11 2024 Event 1 Bilirubin, Total CH-02 2024 Event 1 Bilirubin, Total CH-03 2024 Event 1 Bilirubin, Total CH-05 2024 Event 1 Monocyte ABT-05 2024 Event 3 Monocyte ABT-11 2024 Event 3 Monocyte ABT-13 2025 Event 2 Bilirubin, Total CH-07 2025 Event 2 Bilirubin, Total CH-09 2025 Event 2 Bilirubin, Total CH-10 2025 Event 2 Folate IA-07 2025 Event 2 Folate IA-09 2. Review of laboratory records revealed no documented review of the ungraded API PT analytes in the specialties of hematology and chemistry from 2023 through the date of

survey, 09/11/2025. 3. Interview with the LD on 09/10/2025, at 10:59 am, confirmed the laboratory failed to ensure accuracy of 12 of 12 analytes not evaluated by the PT provider from 2023 through the date of survey, 09/11/2025, in the specialties of hematology and chemistry.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:
Based on direct observation, review of manufacturer's operating instructions, laboratory records, lack of documentation, and interview with testing personnel (TP) #3; the laboratory failed to monitor and document the laboratory environment for accurate and reliable test system operation for one of six testing dates reviewed from 2023 through the date of survey, 09/11/2025. Findings include: 1. Upon a tour of the laboratory on 09/10/2025, at 9:52 am, surveyors observed routine chemistry testing performed on the Envoy 500+ analyzer (Serial Number: 43100527), immunoassay testing performed on the Beckman Coulter Access 2 analyzer (Serial Number: 509993), and hematology testing performed on the Diatron Abacus 5 analyzer (Serial Number: 510698). 2. Review of manufacturer's operating instructions revealed the following environmental requirements for ambient temperature to ensure accurate and reliable analyzer operation: i. Envoy 500+: Under "Environmental Conditions", "Temperature 18 - 32 [degrees Celsius]" ii. Beckman Coulter Access 2: "The standard Beckman Coulter Access 2 operating ambient temperature range is 18 [degrees Celsius] to 28 [degrees Celsius]. iii. Diatron Abacus 5: Under "Environmental Factors", "Operate the 'Abacus 5' analyzer within the ambient temperature range of 15-30 [degrees Celsius]" 3. Review of laboratory records revealed a lack of ambient temperature monitoring on one of six dates of patient testing on the above three analyzers reviewed from 2023 through the date of survey, 09/11/2025. Patient: Date of Testing: 16029 12/17/2023 4. Interview with TP #3 on 09/11/2025, at 9:54 am, confirmed the laboratory failed to monitor and document the laboratory environment for accurate and reliable test system operation for one of six testing dates reviewed from 2023 through the date of survey, 09/11/2025.

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:
Based on direct observation, review of laboratory preventative maintenance records, lack of documentation, and interview with testing personnel (TP) #3; the laboratory

failed to document preventative maintenance for three of three analyzers on one of six testing dates reviewed from 2023 through the date of survey, 09/11/2025. Findings include: 1. Upon a tour of the laboratory on 09/10/2025, at 9:52 am, surveyors observed routine chemistry testing performed on the Envoy 500+ analyzer (Serial Number: 43100527), immunoassay testing performed on the Beckman Coulter Access 2 analyzer (Serial Number: 509993), and hematology testing performed on the Diatron Abacus 5 analyzer (Serial Number: 510698). 2. Review of laboratory preventative maintenance logs revealed a lack of documentation of preventative maintenance performance for one of six dates of patient testing on the above three analyzers reviewed from 2023 through the date of survey, 09/11/2025. Patient: Date of Testing: 16029 12/17/2023 3. Interview with TP #3 on 09/11/2025, at 9:54 am, confirmed the laboratory failed to document preventative maintenance for three of three analyzers on one of six testing dates reviewed from 2023 through the date of survey, 09/11/2025.

D5787

TEST RECORDS
CFR(s): 493.1283(a)

(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:
Based on review of laboratory patient test records, lack of documentation, and interview with testing personnel (TP) #2; the laboratory failed to maintain records and dates of all specimen testing, including the identity of the testing personnel who performed the testing for six of six patients reviewed in the specialty of hematology. Findings include: 1. Review of patient testing records revealed the laboratory failed to document the testing date and testing personnel who performed the complete blood count and automated differential for six of six reviewed testing dates in the specialty of hematology. Patient: Date Specimen Received: 24070 09/21/2023 16029 12/16 /2023 8981 04/05/2024 27768 10/24/2024 17692 03/19/2025 24088 07/10/2025 2. Interview with TP #3 on 09/11/2025, at 10:50 am, confirmed the laboratory failed to maintain records and dates of all specimen testing, including the identity of the testing personnel who performed the testing for six of six patients reviewed in the specialty of hematology.

D6168

TESTING PERSONNEL
CFR(s): 493.1487

The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed.

This CONDITION is not met as evidenced by:
Based on direct observation, review of laboratory personnel records, and interview

with the laboratory director (LD); the laboratory failed to ensure three of five testing personnel (TP) were qualified for high complexity C-Reactive Protein (CRP) Latex testing in the specialty of diagnostic immunology (See D6171).

D6171

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1489(b)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; or (b)(2)(i) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(2)(ii) Be qualified under the requirements of 493.1443(b)(3) or 493.1449(c)(4) or (5); or (b)(3)(i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution or (b)(3)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes (b)(3)(ii)(A) (A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either (b)(3)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(3)(ii)(A)(2) 24 semester hours of science courses that include (b)(3)(ii)(A)(2)(i) 6 semester hours of chemistry; (b)(3)(ii)(A)(2)(ii) 6 semester hours of biology; and (b)(3)(ii)(A)(2)(iii) 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(3)(ii)(B) Have laboratory training that includes: (b)(3)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or (b)(3)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or (b)(4) Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(5) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(6) For blood gas analysis (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section; or (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution. (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (f) to perform tissue examinations.

This STANDARD is not met as evidenced by:

Based on direct observation, review of laboratory personnel records, and interview with the laboratory director (LD); the laboratory failed to ensure three of five testing personnel (TP) were qualified for high complexity C-Reactive Protein (CRP) Latex testing in the specialty of diagnostic immunology. Findings include: 1. Upon a survey of the laboratory on 09/10/2025, at 9:52 am, surveyors observed CRP Latex testing being performed utilizing Germaine Laboratories Aim CRP Test Kit. 2. Review of personnel educational documentation revealed three of five TP (TP #2, #3, and #5) failed to have qualifying documentation for high complexity CRP Latex testing in the

specialty of diagnostic immunology. 3. Interview with the LD on 09/11/2025, at 10:46 am, confirmed the laboratory failed to ensure three of five TP were qualified for high complexity CRP Latex testing in the specialty of diagnostic immunology.