

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  14D2056591	<b>(X3) Date Survey Completed</b>  10/09/2019
<b>Name of Provider or Supplier</b>  Citilabs, Inc	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on record review and an interview with the technical consultant (TC); the laboratory failed to follow quality control procedures for the General Immunology tests performed for the years of 2018 and 2019. Findings include: 1. The laboratory quality control (QC) logs for Rheumatoid Factor (RF), C-reactive protein (CRP), and Systemic Lupus Erythematosus (SLE) test kits and laboratory manuals were reviewed. 2. The QC logs from October, November, and December of 2018 and January, June and July of 2019 revealed the following: *The laboratory failed to record the controls' lot numbers and expiration dates of each kit used for testing, as required; *The laboratory failed to perform and document the parallel testing for each new kit lot received, prior to testing patients' samples. 3. The laboratory failed to complete QC procedures for the RF, CRP and SLE tests performed in the laboratory. 4. On a Recertification survey conducted on 10/09/2019 at 2:15 PM, the TC confirmed the above findings.</p>
<b>D5419</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(e)</p> <p>Components of reagent kits of different lot numbers must not be interchanged unless otherwise specified by the manufacturer.</p>

This STANDARD is not met as evidenced by:  
 Based on direct observation, record review, and an interview with the technical consultant (TC); the laboratory failed to ensure components of reagent kits of different lot numbers are not interchanged, during the years of 2018 and 2019. Findings: 1. On 10/09/2019 at 12:15 PM during a tour of the laboratory; the surveyor observed the following Arlington Scientific Inc (ASI) Systemic Lupus erythematosus (SLE) slide test kits: \*One kit A1, Lot #8B28S3 expiration date 12/31/2019; Marked - opened 06/27/2018 \*One kit A2, Lot #9A08S3 expiration date 12/31/2019; Marked - opened 04/11/2019 \*One kit A3, Lot #8L31S3 expiration date 08/31/2020; Not opened; and \*One kit A4, Lot #8J24S3 expiration date 08/31/2020; Not opened. The controls of both kits A1 and A2 were opened; however, kit A1 did not contain SLE slide test cards. 2. The laboratory failed to discard the controls from kit A1 prior to opening kit A2. 3. The laboratory manual failed to include an established method to ensure that all components of a test that are packaged together in a kit are not interchanged. 4. On a Recertification survey conducted on 10/09/2019 at 2:15 PM, the TC confirmed the above findings.

**D5481**

**CONTROL PROCEDURES**  
 CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:  
 Based on direct observation, record review, and an interview with the technical consultant (TC); the laboratory failed to ensure results of control materials meet the manufacturer's test system criteria for acceptability before reporting patient test results for 2 out of 4 days of patient testing for Cell Blood Count (CBC) analysis. Findings Include: 1. On 10/09/2019 at 11:55 AM during a tour of the laboratory, the surveyor observed the following Hematology controls in-use: \*Low - Lot #KK091L; \*Normal - Lot #KK091N; and \*High - Lot #KK091H. 2. The manufacturer's "Assay Values and Expected Ranges"; the hematology quality controls (QC) data sheets from 09/09/2019; 09/23/2019; 09/27/2019; and 10/08/2019, patient records, and procedures manual were reviewed. 3. The CBC controls failed to meet the acceptable criteria of the manufacturer on 09/09/2019 and 10/08/2019. 4. Review of patient records revealed 11 CBC results were reported on the above dates. 5. The laboratory failed to ensure hematology QCs were within expected ranges prior to reporting the patients' results. 6. On a Recertification survey conducted on 10/09/2019 at 2:15 PM, the TC and testing personnel confirmed the above findings.

**D5805**

**TEST REPORT**  
 CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:  
 Based on record review and an interview with the technical consultant (TC); the laboratory failed to ensure test reports indicate \*the name and address of the laboratory where the tests were performed; and \*the test report date from the referred laboratory. Findings include: 1. The patients' requisitions and final reports, and the laboratory's test menu were reviewed. 2. The 3 patients' (patients D1, D2, and D3) requisitions reviewed were from the following dates: 03/16/2018; 10/29/2018; and 05/23/2019. 3. Review of the final reports for patients D1, D2, and D3 and the laboratory's test menu revealed the following: \*The test results for Hepatitis-B surface antigen (HBSag); Hepatitis-C antibody (HCV-AB); and Prostate Specific Antigen (PSA) were included in the final reports. \*The laboratory does not perform the above tests. \*The final reports failed to indicate the date tested and the name and location of the laboratory that performed the above tests. 4. On a Recertification survey conducted on 10/09/2019 at 2:15 PM, the laboratory director and the TC confirmed the above findings.

**D6026**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
 CFR(s): 493.1407(e)(8)

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)(8) Ensure that reports of test results include pertinent information required for interpretation.

This STANDARD is not met as evidenced by:  
 Based on record review, manufacturer's instructions, and an interview with the technical consultant (TC); the laboratory director (LD) failed to ensure that reports of test results include pertinent information required for interpretation of tests performed in the subspecialty of General Immunology testing, affecting 3 out of 3 patients. Findings: 1. The procedures manual, the Arlington Scientific package inserts for the Rheumatoid Factor (RF), the C-reactive protein (CRP), Systemic Lupus Erythematosus (SLE) slide tests, and patients' test results from 03/16/2018; 10/29/2018; and 05/23/2019 were reviewed. 2. The manufacturer's instructions revealed the following reporting requirements: \*RF - Agglutination indicates an RF concentration of greater than or equal to 8 IU/ml in the serum sample; shown as > or = 8 IU/ml. \*CRP -Agglutination indicates a CRP concentration of greater than or equal to 6 mg/L in the serum sample; shown as > or = 6 mg/L; and \*SLE - Agglutination indicates a "reactive" SLE sample. 3. The patients' X1, X2, and X3 final reports showed the above analytes reported as follows: \*RF result was reported without the cut-off statement of " > or = 8 UI/ml " \*CRP result was reported without the cut-off statement of " > or = 6 mg/L"; \*Systemic Lupus Erythematosus (SLE) results were reported as Antinuclear Antibody (ANA) test results. 4. The LD failed to ensure the manufacturer's cut-off statements were reported with the patients' results to the authorizing providers from 03/16/2018 to the date of survey (10/09/2019). 5. On a recertification survey conducted 10/09/2019 at 1:30PM, the TC and testing personnel (TP) confirmed the above findings.