

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2055846	(X3) Date Survey Completed 03/19/2019
Name of Provider or Supplier Baton Rouge Clinic Industriplex	Street Address, City, State 12351 Industriplex Blvd, Baton Rouge, LA	
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 Recertification survey was conducted at Baton Rouge Clinic - Industriplex-CLIA ID # 19D2055846 on March 19, 2019. The laboratory was found in compliance with 42 CFR 493 Requirement for Laboratories; however, standard deficiencies were cited.
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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to retain raw data for calibration for at least two (2) years for Hematology testing. Findings: 1. Record review of the laboratory's policy detailed the laboratory is to perform calibration every 6 months. 2. Review of the laboratory's calibration records revealed the laboratory performed a calibration for Complete Blood Count on the ACT Diff 2 on December 19, 2018; however, the raw data and calibration information was not available, only the summary report. 3. In interview on March 19, 2019 at 10:22 am, Personnel 2 confirmed the data to support the second annual calibration for 2018 was not in the calibration binder.</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step</p>

performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the laboratory failed to have a complete policy and procedure manual. Findings: 1. Review of the laboratory's policy and procedure manual revealed the manual did not include detailed instructions for the following: a) Quality Control - steps to take for troubleshooting failed quality control runs, actions to take for quality control programmed incorrectly, when patient assessment is necessary and steps to take to assess patients. b) Corrective Action - when corrective action should be taken and documentation process for corrective action. 2. Interview with Personnel 2 and 3 on March 19, 2018 confirmed the policy did not specifically address the above practices.

D5783

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the laboratory failed to take corrective action when quality control (QC) values were unacceptable for Complete Blood Count (CBC) testing. Findings: 1. Review of the laboratory's policy revealed the laboratory performs the following three (3) levels of QC each day of CBC testing which must be acceptable prior to patient testing. 3. Review of the laboratory's QC records revealed quality control was unacceptable prior to patient testing on the following five (5) days: a) May 12, 2018: Level (N) Normal b) June 29, 2018: Level (H) High c) September 23, 2018: Level (L) Low d) October 9, 2018: Level (L) Low e) June 19, 2018: Levels Low (L), Normal (N), High (H) 6. Further review of Quality Control records indicated QC on these days was programmed uncorrected and run in the wrong file for QC level or lot number. 7. In interview on March 19, 2019 Personnel 2 and 3 confirmed no documentation of corrective action was documented for the above QC runs.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT

	<p>CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to monitor, assess, and correct quality issues in the Analytic Systems. Findings: 1. The laboratory failed to have a complete policy and procedure manual. Refer to D5403 2. The laboratory failed to retain raw data for calibration for at least two (2) years for Hematology testing. Refer to D3031 3. The laboratory failed to take corrective action when quality control (QC) values were unacceptable for Complete Blood Count (CBC) testing. Refer to D5783</p>
<p>D6014</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii)</p> <p>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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.</p> <p>This STANDARD is not met as evidenced by: Based on record review, and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required. Refer to D3031</p>
<p>D6021</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided. Refer to D5791.</p>
<p>D6025</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform</p>

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)(7) Ensure that patient test results are reported only when the system is functioning properly.

This STANDARD is not met as evidenced by:
Based on record review and interview with personnel, the Laboratory Director failed to ensure patient test results were reported only when system functioning properly.
Refer to D5783

D6031

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(13)

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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:
Based on record review and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available for all aspects of the testing process. Refer to D5403.

D6036

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413

The technical consultant is responsible for the technical and scientific oversight of the laboratory.

This STANDARD is not met as evidenced by:
Based on observation, record review, and interview with personnel, the Technical Consultants failed to provide technical and scientific oversight to the laboratory. Findings: 1. The laboratory failed to have a complete policy and procedure manual. Refer to D5403 2. The laboratory failed to retain raw data for calibration for at least two (2) years for Hematology testing. Refer to D3031 3. The laboratory failed to monitor, assess, and correct quality issues in Analytic Systems. Refer to D5793

D6044

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(6)

(b) The technical consultant is responsible for-- (b)(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly;

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Technical Consultant failed to ensure corrective actions were taken and documented when deviations from the laboratory's policies occurred. Refer to D5783.