

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  19D2055846	<b>(X3) Date Survey Completed</b>  05/23/2023
<b>Name of Provider or Supplier</b>  Baton Rouge Clinic Industriplex	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A Recertification survey was performed on May 23, 2023 at Baton Rouge Clinic Industriplex, CLIA ID # 19D2055846. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual as well as interview with personnel, the laboratory failed to establish written policies and procedures to assess competency for testing personnel. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not have a competency assessment policy for testing personnel to include but not limited to frequency of performance and the following six (6) procedures as a minimal requirement for assessing the competency of all personnel performing moderate complexity testing: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting of test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. f) Assessment of problem solving skills. 2. In interview on May 23, 2023 at 2:30 p.m., Technical Consultant 3 confirmed the laboratory did not have a competency assessment policy.</p>

<b>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on observation, review of temperature records, and interview with laboratory personnel, the laboratory failed to perform daily monitoring of the room temperature in the phlebotomy room where blood collection supplies are stored. Findings: 1. Observation by surveyors during the laboratory tour on May 23, 2023 at 10:16 a.m. revealed blood collection supplies stored in the phlebotomy room. 2. Review of temperature records for the phlebotomy room revealed the room temperature was monitored weekly and not daily as required by the manufacturer. 3. In interview on May 23, 2023 at 2 p.m., Technical Consultant 3 confirmed the room temperature was not monitored daily for the phlebotomy room.</p>
<b>D5415</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on observation, review of the laboratory's policy and procedure manual and quality control records, as well as interview with laboratory personnel, the laboratory failed to document when new lots of Hematology quality control material were put into use for two (2) of two (2) lots reviewed. Findings: 1. Observation by surveyors during the laboratory tour on May 23, 2023 at 10:16 a.m. revealed the laboratory utilized Coulter 4C Plus Cell Control for Hematology quality control testing on the Beckman Coulter AcT analyzer. 2. Review of quality control records for the following lots of Coulter 4C Plus Cell Control revealed the laboratory did not document the date the laboratory put the new quality control lots into use: -Lot 067900, 077900, 087900 expiration date August 29, 2022 -Lot 068600, 078600, 088600 expiration date December 2, 2022 3. In interview on May 23, 2023 at 11:33 a.m., Testing Personnel 1 confirmed the in use dates of the quality control lots identified above was not documented.</p>
<b>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have</p>

deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on observation and interview with laboratory personnel, the laboratory failed to ensure that test kits were not used beyond their expiration dates. Findings: 1.

Observation by surveyors during the laboratory tour on May 23, 2023 at 10:16 a.m. revealed one (1) expired test kit: - Quidel Sofia Influenza A + B FIA, Lot 706820, Expiration date: May 8, 2023 2. In interview on May 23, 2023 at 10:37 a.m., Testing Personnel 1 confirmed the item identified above was expired.

**D5779**

**CORRECTIVE ACTIONS**

CFR(s): 493.1282(a)

Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policies, quality control and corrective action records; as well as interview with laboratory personnel, the laboratory failed to follow their corrective action policy for Hematology quality control. Findings: 1. Review of the laboratory's policy "Beckman Coulter AcT 2 Procedure" under "Quality Control" revealed "Document steps taken to bring controls within the acceptable range." 2. Review of quality control (QC) records from February 27, 2023 to March 25, 2023 revealed the laboratory repeated quality control results outside the laboratory's acceptable range on the following dates, but did not document the corrective actions taken: a) March 20, 2023 Lot 079900: QC tested two (2) times b) April 10, 2023 Lot 079900: QC tested four (4) times c) April 11, 2023 Lot 079900: QC tested six (6) times d) April 12, 2023 Lot 079900: QC tested two (2) times 3. Review of the laboratory's "Hematology Corrective Action Log" revealed no documentation of corrective actions for quality control on the dates identified above. 4. In interview on May 23, 2023 at 1:15 p.m., Testing Personnel 1 confirmed the laboratory did not follow their corrective action policy for the dates identified above.

**D5785**

**CORRECTIVE ACTIONS**

CFR(s): 493.1282(b)(3)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.

This STANDARD is not met as evidenced by:

I. Based on review of the laboratory's temperature records and interview with laboratory personnel, the laboratory failed to perform corrective actions for humidity outside of the laboratory's acceptable range for two (2) of eighty-seven (87) days reviewed in October, November and December 2022. Findings: 1. Review of the laboratory's temperature logs for October, November, and December 2022 revealed the humidity was outside of the laboratory's acceptable range of 20-80% with no corrective action performed on the following two (2) days: December 24, 2022 - Humidity 16% December 27, 2022 - Humidity 16% 2. In interview on May 23, 2023

at 1:30 p.m., Testing Personnel 1 confirmed the laboratory did not take corrective actions for the humidity on the days identified above. II. Based on review of the laboratory's temperature records and interview with laboratory personnel, the laboratory failed to perform corrective actions for refrigerator temperatures outside of the laboratory's acceptable range for sixty-one (61) of eighty-seven (87) days reviewed in October, November and December 2022. Findings: 1. Review of the laboratory's refrigerator temperature logs for October, November, and December 2022 revealed the following: a) The laboratory defined the acceptable range as 2-8 degrees Celsius. b) The laboratory documented the current temperature reading as well as the minimum and maximum readings. c) The laboratory did not perform corrective actions for temperature readings that were outside of the laboratory's acceptable range on the following sixty-one (61) days: October 5, 2022 minimum temperature 1.9 October 6, 2022 minimum temperature 1.0 October 7, 2022 minimum temperature 0.5 October 8, 2022 minimum temperature 0.3, current temperature 1.2 October 9, 2022 minimum temperature 0.6 October 10, 2022 minimum temperature 0.8 October 11, 2022 minimum temperature 1.0 October 12, 2022 minimum temperature 1.3 October 13, 2022 minimum temperature 0.9 October 14, 2022 minimum temperature 0.3, current temperature 1.8 October 22, 2022 minimum temperature 1.3 October 23, 2022 minimum temperature 1.9 October 24, 2022 minimum temperature 1.5 October 25, 2022 minimum temperature 1.8 October 26, 2022 minimum temperature 1.4, current temperature 1.8 October 27, 2022 minimum temperature 1.8 October 29, 2022 minimum temperature 1.3 October 30, 2022 minimum temperature 1.1 November 1, 2022 minimum temperature 1.4 November 2, 2022 minimum temperature 1.1 November 3, 2022 minimum temperature 0.8 November 4, 2022 minimum temperature 1.0 November 5, 2022 minimum temperature 1.3 November 6, 2022 minimum temperature 0.9 November 7, 2022 minimum temperature 0.7 November 8, 2022 minimum temperature 0.8 November 9, 2022 minimum temperature 1.8 November 10, 2022 minimum temperature 0.9 November 11, 2022 minimum temperature 1.3 November 13, 2022 minimum temperature 1.1 November 15, 2022 minimum temperature 0.1 November 17, 2022 minimum temperature 0.2 November 18, 2022 minimum temperature 0.3 November 19, 2022 minimum temperature 0.1 November 21, 2022 minimum temperature 0.3 November 22, 2022 minimum temperature 0.5 November 23, 2022 minimum temperature 0.9 November 25, 2022 minimum temperature 0.1 November 29, 2022 minimum temperature 1.4 November 30, 2022 minimum temperature 1.3 December 1, 2022 minimum temperature 1.5 December 2, 2022 minimum temperature 1.3 December 3, 2022 minimum temperature 1.8 December 4, 2022 minimum temperature 1.9 December 6, 2022 minimum temperature 1.1 December 7, 2022 minimum temperature 1.8 December 8, 2022 minimum temperature 0.5, current temperature 1.5 December 9, 2022 minimum temperature 0.8 December 10, 2022 minimum temperature 0.9 December 11, 2022 minimum temperature 0.1 December 12, 2022 minimum temperature 0.9 December 13, 2022 minimum temperature 0.2 December 14, 2022 minimum temperature 1.0 December 15, 2022 minimum temperature 0.5 December 16, 2022 minimum temperature 1.1 December 17, 2022 minimum temperature 1.8 December 18, 2022 minimum temperature 1.3 December 19, 2022 minimum temperature 1.0 December 21, 2022 minimum temperature -0.8 December 22, 2022 minimum temperature 0.1 December 27, 2022 minimum temperature -1.1 2. In interview on May 23, 2023 at 1:30 p.m., Testing Personnel 1 confirmed the laboratory did not perform corrective actions for the unacceptable temperature readings identified above. III. Based on review of the laboratory's temperature records and interview with laboratory personnel, the laboratory failed to document all corrective actions performed for refrigerator temperatures outside of the laboratory's acceptable range for twelve (12) of eighty-seven (87) days reviewed in October, November and December 2022.

Findings: 1. Review of the laboratory's refrigerator temperature logs for October, November, and December 2022 revealed the following: a) The laboratory documented the current temperature as well as the minimum and maximum temperature. b) The log had an up arrow symbol with "adjust temperature up" stated next to it and a down arrow symbol with "adjust temperature down" stated next to it. c) The laboratory documented temperatures that exceeded the acceptable range stated on the log as 2-8 degrees Celsius and did not document all corrective actions on the following twelve (12) days: November 12, 2022 minimum temperature 0.2, temperature at time of reading 1.1 (with an up arrow) November 16, 2022 minimum temperature 0.1, temperature at time of reading 0.4 (with an up arrow) November 20, 2022 minimum temperature 0.2, temperature at time of reading 1.9 (with an up arrow) November 26, 2022 minimum temperature 0.2, temperature at time of reading 1.1, (with an up arrow) November 27, 2022 minimum temperature 0.4, temperature at time of reading 1.3, (with an up arrow) November 28, 2022 minimum temperature 1.1, temperature at time of reading 1.5, (with an up arrow) December 5, 2022 minimum temperature 1.2, temperature at time of reading 1.5, (with an up arrow) December 20, 2022 minimum temperature 0.7, temperature at time of reading 1.2, (with an up arrow) December 23, 2022 minimum temperature -0.5, temperature at time of reading 1.2, (with an up arrow) December 24, 2022 minimum temperature 1.1, temperature at time of reading 0.4, (with an up arrow) December 29, 2022 minimum temperature 1.1, temperature at time of reading 1.8, (with an up arrow) December 30, 2022 minimum temperature -0.1, temperature at time of reading 1.1, (with an up arrow) d) The laboratory did not have documentation of temperature readings after the adjustments and did not have documentation of any further corrective actions. 2. In interview on May 23, 2023 at 1: 30 p.m., Testing Personnel 1 confirmed the laboratory did not document the corrected temperature and any further corrective actions for the dates identified above.

**D5793**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1289(b)(c)

(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:  
Based on observation, record review, and interview with personnel, the laboratory's quality assessment monitors failed to identify and correct quality issues in Analytic Systems. Findings: 1. The laboratory failed to perform daily monitoring of the room temperature in the phlebotomy room where blood collection supplies are stored. Refer to D5413. 2. The laboratory failed to document when new lots of Hematology quality control material were put into use for two (2) of two (2) lots reviewed. Refer to D5415. 3. The laboratory failed to ensure that test kits were not used beyond their expiration dates. Refer to D5417. 4. The laboratory failed to follow their corrective action policy for Hematology quality control. Refer to D5779. 5. The laboratory failed to perform corrective actions for humidity outside of the laboratory's acceptable range for two (2) of eighty-seven (87) days reviewed in October, November and December 2022. Refer to D5785 I. 6. The laboratory failed to perform corrective actions for refrigerator temperatures outside of the laboratory's acceptable range for sixty-one (61) of eighty-seven (87) days reviewed in October, November and December 2022. Refer to D5785 II. 7. The laboratory failed to document all corrective actions

performed for refrigerator temperatures outside of the laboratory's acceptable range for twelve (12) of eighty-seven (87) days reviewed in October, November and December 2022. Refer to D5785 III.

**D6014**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(3)(iii)

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.

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to monitor the room temperature daily for a room where blood collection supplies are stored. Refer to D5413. 2. The laboratory failed to document when new lots of Hematology quality control material were put into use for two (2) of two (2) lots reviewed. Refer to D5415. 3. The laboratory failed to ensure that test kits were not used beyond their expiration dates. Refer to D5417.

**D6022**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(5)

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 the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on observation, 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 and to identify failures as they occur. Refer to D5793.

**D6024**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(7)

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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified,

This STANDARD is not met as evidenced by:  
 Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Findings: 1. The laboratory failed to follow their corrective action policy for Hematology quality control. Refer to D5779. 2. The laboratory failed to perform corrective actions for humidity outside of the laboratory's acceptable range for two (2) of eighty-seven (87) days reviewed in October, November and December 2022. Refer to 5785 I. 3. The laboratory failed to perform corrective actions for refrigerator temperatures outside of the laboratory's acceptable range for sixty-one (61) of eight-seven (87) days reviewed in October, November and December 2022. Refer to 5785 II. 4. The laboratory failed to document complete corrective actions performed for refrigerator temperatures outside of the laboratory's acceptable range for twelve (12) of eighty-seven (87) days reviewed in October, November and December 2022. Refer to 5785 III.

**D6030**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
 CFR(s): 493.1407(e)(12)

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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:  
 Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures were established for assessing personnel competency, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Findings: 1. The laboratory failed to establish written policies and procedures to assess competency for testing personnel. Refer to D5209. 2. The Technical Consultant failed to perform a competency semi-annually during the first year for one (1) of seven (7) hematology testing personnel reviewed. Refer to D6053.

**D6046**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
 CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:  
 Based on review of the laboratory's policy and procedure manual and personnel records as well as interview with personnel, the Technical Consultant failed to ensure the procedures to assess competency were complete. Refer to D5209.

**D6053**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's CMS 209 (Laboratory Personnel Report) form and personnel records and interview with personnel, the Technical Consultant failed to perform a competency semi-annually during the first year for one (1) of seven (7) hematology testing personnel reviewed. Findings: 1. Review of the laboratory's CMS 209 form revealed the laboratory had eight (8) testing personnel. 2. Review of personnel records revealed Testing Personnel 7 had an initial training performed December 2021 and an annual competency assessment performed December 2022, but a semi-annual competency assessment due in June 2022 was not performed. 3. In interview on May 23, 2023 at 2:30 p.m., Technical Consultant 1 confirmed the semi-annual competency assessment for Testing Personnel 7 was not performed.