

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0878031	(X3) Date Survey Completed 10/24/2024
Name of Provider or Supplier Rapides Regional Cardiovascular Lab	Street Address, City, State 211 Fourth Street, Alexandria, 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 Validation survey was performed at Rapides Regional Cardiovascular Laboratory, CLIA ID 19D0878031, on October 24, 2024. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5785	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policy, temperature records and interview with personnel, the laboratory failed to document corrective actions performed when room temperature was not maintained within the acceptable range per laboratory policy for one hundred forty five (145) of six hundred fifty four (654) days reviewed in 2023 and 2024. Findings: 1. Review of the laboratory's policy "POC Temperature and Humidity" revealed "Each POCT area has specific temperature ranges due to the testing performed within it. Temperatures may be recorded in either in degrees Celsius or degrees Fahrenheit. Any out of control readings are reported to the supervisor and adjustments attempted. If the temperature remains out of range, maintenance or biomedical engineering is notified. On weekends or holidays, contact the Boiler room. Any materials which may be adversely affected are moved to another properly working instrument or storage area until the temperature has become regulated. Out of control readings must have documented corrective actions". 2. Review of the laboratory's temperature logs for the Cath Lab revealed the acceptable room temperature as 57 - 77 degrees fahrenheit. 3. Further review of the laboratory's temperature logs for 2023 and 2024 revealed the room temperature was documented as outside of the acceptable limits without documented corrective actions for the</p>

12, 2024: documented room temperature as 52 degrees fahrenheit July 13, 2024: documented room temperature as 53 degrees fahrenheit July 14, 2024: documented room temperature as 52 degrees fahrenheit July 15, 2024: documented room temperature as 52 degrees fahrenheit July 16, 2024: documented room temperature as 52 degrees fahrenheit July 17, 2024: documented room temperature as 52 degrees fahrenheit July 18, 2024: documented room temperature as 52 degrees fahrenheit July 19, 2024: documented room temperature as 52 degrees fahrenheit July 20, 2024: documented room temperature as 52 degrees fahrenheit July 21, 2024: documented room temperature as 52 degrees fahrenheit July 22, 2024: documented room temperature as 52 degrees fahrenheit July 23, 2024: documented room temperature as 52 degrees fahrenheit July 24, 2024: documented room temperature as 52 degrees fahrenheit July 25, 2024: documented room temperature as 52 degrees fahrenheit July 26, 2024: documented room temperature as 52 degrees fahrenheit July 27, 2024: documented room temperature as 52 degrees fahrenheit July 28, 2024: documented room temperature as 52 degrees fahrenheit July 29, 2024: documented room temperature as 52 degrees fahrenheit July 30, 2024: documented room temperature as 53 degrees fahrenheit July 31, 2024: documented room temperature as 53 degrees fahrenheit August 1, 2024: documented room temperature as 53 degrees fahrenheit August 8, 2024: documented room temperature as 56 degrees fahrenheit August 12, 2024: documented room temperature as 53 degrees fahrenheit August 13, 2024: documented room temperature as 52 degrees fahrenheit August 14, 2024: documented room temperature as 52 degrees fahrenheit August 15, 2024: documented room temperature as 53 degrees fahrenheit August 16, 2024: documented room temperature as 53 degrees fahrenheit August 17, 2024: documented room temperature as 54 degrees fahrenheit August 18, 2024: documented room temperature as 56 degrees fahrenheit August 19, 2024: documented room temperature as 52 degrees fahrenheit 4. In interview on October 24, 2024 at 3:40 am, Point of Care Coordinator confirmed the laboratory did not document corrective actions for unacceptable room temperatures for the identified days.

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 review of laboratory policy, temperature records and interview with personnel, the Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Refer to D5785.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's CMS-209 (Laboratory Personnel Report), personnel records and interview with personnel, the Laboratory Director failed to ensure testing personnel had appropriate training documentation prior to patient testing for two (2) of two (2) testing personnel in 2024. Findings: 1. Review of the laboratory's CMS-209 (Laboratory Personnel Report) revealed the following testing personnel performs moderate complexity testing in the specialty of Chemistry: * Personnel 6 * Personnel 7 2. Review of the personnel records from 2024 revealed the Laboratory Director did not review the initial training for the following two (2) of two (2) testing personnel: a) Personnel 6 - initial training performed 10/18/2024 b) Personnel 7 - initial training performed 06/10/2024 3. In interview on October 24, 2022 at 3:31 pm, Point of Care Coordinator confirmed the initial training for the above identified testing personnel was not reviewed by the Laboratory Director.

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 procedures for assessing personnel competency were maintained for seven (7) of ten (10) Testing Personnel reviewed. Refer to D6046.

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 CMS 209 form (Laboratory Personnel Report), personnel competency assessment forms, and interview with personnel, the technical consultant failed to perform competency assessments in 2023 and 2024 for seven (7)

of ten (10) testing personnel. Findings: 1. Review of the laboratory's CMS 209 form provided to surveyor revealed the Laboratory Director serves as Technical Consultant. 2. Review of personnel records from 2023 and 2024 revealed the technical consultant did not perform the competency assessments as required for the following seven (7) of ten (10) testing personnel: a) Testing Personnel 1: 2023 b) Testing Personnel 2: 2023 c) Testing Personnel 4: 2023 d) Testing Personnel 5: 2024 e) Testing Personnel 8: 2024 f) Testing Personnel 9: 2024 g) Testing Personnel 10: 2024 3. In interview on October 24, 2024 at 3:30 pm, Point of Care Coordinator confirmed the competency assessments for the identified personnel was not performed by the technical consultant in 2023 and 2024.