

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 19D0462236	<b>(X3) Date Survey Completed</b> 06/27/2024
<b>Name of Provider or Supplier</b> Pointe Coupee General Hospital	<b>Street Address, City, State</b> 2202 False River Drive, New Roads, 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 Validation survey was performed on June 24, 2024 through June 27, 2024 at Pointe Coupee, CLIA ID # 19D0462236. 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 policies and interview with laboratory personnel, the laboratory failed to establish a complete written competency assessment policy for Technical Consultant and General Supervisor. Findings: 1. Review of the laboratory's "Competency Testing" policy revealed the laboratory did not include performance of competency assessment for Technical Consultant and General Supervisor. 2. In interview on June 24, 2024 at 3:15 p.m., the Laboratory Manager confirmed the laboratory did not have a policy for assessing the competency of the Technical Consultant and General Supervisor.</p>
<b>D5407</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of the laboratory's procedures and interview with personnel, the laboratory failed to ensure policies and procedures were updated to current practices and signed by the current Laboratory Director. Findings: 1. Review of the laboratory's policies and procedures revealed the laboratory did not include the following: a) Current Method Validation procedure; laboratory had three (3) different procedures b) Proficiency Testing policy: approved/signed by the current Laboratory Director c) Competency Assessment policy: approved/signed by the current Laboratory Director d) Patient Grievance policy: approved/signed by the current Laboratory Director e) Hematology procedures: approved/signed by the current Laboratory Director 2. In interview on June 26, 2024 at 9:05 am, the Laboratory Manager stated she is in the process of updating the laboratory's policies and procedures. The Laboratory Manager confirmed the Laboratory Director had not approved all of the laboratory's policies and procedures.

**D5413**

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

This STANDARD is not met as evidenced by:

I. Based on observation by surveyors, review of manufacturers' storage requirements, and interview with personnel, the laboratory failed to monitor the room temperature of the hallway area where mobile phlebotomy carts were stored. Findings: 1. Observation by surveyors during laboratory tour on June 24, 2024 at 1:23 pm revealed the laboratory stored the following laboratory supplies on mobile phlebotomy carts in a hallway area near a door without monitoring the room temperature: a) FLOQ swabs b) Copan UTM -RT transport medium c) Vacuette blood transfer unit d) BD Vacutainer sodium fluoride blood collection tubes e) Vacuette serum blood collection tubes f) Vacuette lithium heparin blood collection tubes g) Vacuette K2EDTA blood collection tubes h) Remel Microtest M4RT tubes 2. Review of the manufacturers' storage requirements revealed the following: a) FLOQ swabs: 2-30 degrees Celsius b) Copan UTM-RT transport medium: 2-25 degrees Celsius c) Vacuette supplies: 4-25 degrees Celsius d) BD Vacutainer: 4-25 degrees Celsius e) Remel tubes: 2-30 degrees Celsius 3. In interview on June 24, 2024 at 2:02 pm, the Assistant Lab Manager confirmed the laboratory did not monitor the room temperature of the area where the mobile phlebotomy carts were stored. 47757 II. Based on observation, review of the laboratory's temperature records and manufacturers' instructions for use, and interview with personnel, the laboratory failed to define acceptable room temperature limits within the manufacturers' required ranges for one (1) of eight (8) areas where laboratory supplies are stored. Findings: 1. Observation by surveyors during the laboratory tour on June 24, 2024 at 1:22 p.m. revealed the laboratory stored the following laboratory supplies in the "Urinalysis" room: a) BD Vacutainer C&S Preservative - Manufacturer's storage requirement 4 - 25 degrees Celsius b) Remel Saline (0.85%) 1 ml - Manufacturer's storage requirement 2 - 25 degrees Celsius c) Copan Transystem Amies w/o ch plastic applicator rayon tipped - Manufacturer's storage requirement 5 - 25 degrees Celsius 2. Review of the laboratory's 2024

temperature and humidity logs for the area designated as "Urinalysis" revealed the laboratory defined the acceptable room temperature limits as 18 - 30 degrees Celsius which exceeded the manufacturers' acceptable upper limits. 3. In interview on June 25, 2024 at 3:30 p.m., the Quality Assurance Manager confirmed the room temperature limits defined by the laboratory exceeded the limits of the manufacturers as identified above. III. Based on observation, review of the laboratory's temperature records and manufacturer's instructions for use, and interview with personnel, the laboratory failed to define acceptable temperature limits within the manufacturer's required ranges for one (1) of two (2) refrigerators where laboratory supplies are stored in the Blood Bank. Findings: 1. Observation by surveyors during the laboratory tour on June 24, 2024 at 1:22 p.m. revealed the laboratory stored the following supplies in the Helmer refrigerator located in the Blood Bank: a) Ortho Blood Grouping Reagent Anti-D (Anti-RH1) - Manufacturer's storage requirement 2 - 8 degrees Celsius b) Ortho Rh-hr Control - Manufacturer's storage requirement 2 - 8 degrees Celsius c) Ortho Bovine Albumin Solution - Manufacturer's storage requirement 2 - 8 degrees Celsius d) Ortho Reagent Red Blood Cells Affirmagen - Manufacturer's storage requirement 2 - 8 degrees Celsius e) Ortho Reagent Red Blood Cells 0.8% Surgiscreen - Manufacturer's storage requirement 2 - 8 degrees Celsius f) Ortho Confidence System - Manufacturer's storage requirement 2 - 8 degrees Celsius g) Ortho Rho(D) Immune Globulin (Human) - Manufacturer's storage requirement 2 - 8 degrees Celsius 2. Review of the laboratory's 2024 Blood Bank temperature logs revealed the laboratory defined the acceptable temperature limits for the Helmer refrigerator as 1 - 6 degrees Celsius which exceeded the manufacturer's acceptable lower limits. 3. In interview on June 25, 2024 at 9:27 a.m., the Assistant Laboratory Manager confirmed the refrigerator temperature limits defined by the laboratory exceeded the limits of the manufacturer as identified above.

**D5781**

**CORRECTIVE ACTIONS**  
CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:  
Based on observation, review of the laboratory's procedure manual, manufacturer's package insert, laboratory temperature logs, patient records, and interview with personnel, the laboratory failed to perform corrective actions when the room temperature exceeded the manufacturer's acceptable temperature limits for performing Rapid Plasma Reagin (RPR) testing for seven (7) of twenty-nine (29) days reviewed. Findings: 1. Observation by surveyors during the laboratory tour on June 24, 2024 at 1:22 p.m. revealed the laboratory performed the Sure-Vue Rapid Plasma Reagin (RPR) test in the room designated as "Urinalysis." 2. Review of the laboratory's policy "RPR Quality Control Protocol" revealed "Record Room Temperature on the RPR Worksheet at the time of each Patient run. (Acceptable: 20 - 30 Degrees Centigrade)." 3. Review of the manufacturer's package insert section "Preparation for the Assay"

revealed "Allow all reagents and samples to warm to room temperature (20-30 degrees Celsius) before use." 4. Review of the laboratory's room temperature logs for "Urinalysis" and patient test records revealed the laboratory failed to maintain the room temperature between 20 - 30 degrees Celsius in the room RPR testing is performed on the following days: a) March 20, 2024 - 19.1 degrees Celsius - Patient K75925 b) March 25, 2024 - 19.7 degrees Celsius - Patient K76452 - Patient 76454 - Patient 76466 c) March 27, 20224 - 19.7 degrees Celsius - Patient 76634 - Patient 76647 d) March 28, 2024 - 19.6 degrees Celsius - Patient 76723 e) March 29, 2024 - 19.0 degrees Celsius - Patient 76911 f) April 15, 2024 - 18 degrees Celsius - Patient K78270 - Patient K78279 - Patient K78296 g) April 29, 2024 - 18.6 degrees Celsius - Patient K79491 - Patient K79552 5. In interview on June 25, 2024 at 4:45 p.m., the Quality Assurance Manager confirmed the laboratory did not perform corrective actions when the temperatures exceeded the manufacturer's requirements as identified above.

**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 by surveyors, record review and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5413 I.

**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 for assessing personnel competency were maintained. Refer to D5209.

**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 personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D5407.

**D6032**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(14)

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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's CMS 209 form (Laboratory Personnel Report) and personnel records and interview with personnel, the Laboratory Director failed to delegate, in writing, the responsibilities of Technical Consultant to three (3) of three (3) personnel serving as Technical Consultants. Findings: 1. Review of the laboratory's CMS 209 form (Laboratory Personnel Report) revealed the following personnel were listed as Technical Consultants: Personnel 2 Personnel 3 Personnel 5  
2. Review of personnel records revealed the laboratory did not have documentation of the Laboratory Director delegating the tasks and responsibilities of Technical Consultant for the personnel identified above. 3. In interview on June 24, 2024 at 3:12 p.m., the Laboratory Manager confirmed the laboratory did not have documentation of the Laboratory Director delegating the tasks and responsibilities of Technical Consultant to the personnel identified above.

**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 record review and interview with personnel, the Technical Consultants failed to provide technical and scientific oversight to the laboratory. Findings: 1. The

	<p>laboratory failed to monitor the room temperature of the hallway area where mobile phlebotomy carts were stored. Refer to D5413 I. 2. The laboratory failed to define acceptable room temperature limits within the manufacturers' required ranges for one (1) of eight (8) areas where laboratory supplies are stored. Refer to D5413 II.</p>
<p><b>D6044</b></p>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b>  CFR(s): 493.1413(b)(6)</p> <p>(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;</p> <p>This STANDARD is not met as evidenced by:  Based on observation, record review, and interview with personnel, the Technical Consultants failed to ensure corrective actions were taken and documented when deviations from the laboratory's policies occurred. Refer to D5781.</p>
<p><b>D6106</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b>  CFR(s): 493.1445(e)(14)</p> <p>The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.</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 an approved procedure manual was available to all personnel. Refer to D5407.</p>
<p><b>D6107</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b>  CFR(s): 493.1445(e)(15)</p> <p>The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.</p> <p>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 Laboratory Director failed to delegate, in writing, the responsibilities of General Supervisor to one (1) of four (4) personnel serving as General Supervisors. Findings: 1. Review of the laboratory's CMS 209 form revealed Personnel 5 served as a General Supervisor. 2. Review of personnel records for Personnel 5 revealed the laboratory did not have documentation of the Laboratory Director delegating the tasks and responsibilities of General Supervisor to her. 3. In interview on June 24, 2024 at 3:12 p.m., the Laboratory</p>

Manager confirmed the laboratory did not have documentation of the Laboratory Director delegating the tasks and responsibilities of General Supervisor to Personnel 5 as identified above.

**D6144**

**GENERAL SUPERVISOR RESPONSIBILITIES**

CFR(s): 493.1463

The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the General Supervisors failed to provide day-to-day supervision to testing personnel to ensure accurate and reliable test performance of laboratory testing. Refer to D5413 III.