Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0464876	06/01/2018
Name of Provider or Supplier	**Street Address, City, State**	
Lasalle General Hospital	187 9th Street, Jena, 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 Certification Survey was conducted May 30, 2018 through June 1, 2018 at LaSalle General Hospital - CLIA ID # 19D0464876. The laboratory was found in compliance with 42 CFR 493 Requirement for Laboratories; however, standard deficiencies were cited.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) 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. This STANDARD is not met as evidenced by: Based on the record review and interview with personnel, the laboratory failed to have a complete policies and procedure manual. Findings: 1. Review of the respiratory's records revealed the laboratory did not have written polices and procedures that included: a) Specimen collection: to include the steps in collection of Arterial Blood Gas samples and the testing of samples on the instrument b) Identification of instrument tapes 2. In interview on May 30, 2018 at 3:35 pm, Personnel 10 confirmed the laboratory did not the above policies in place. 3. Review of the laboratory's records revealed the laboratory did not have written policy for the manual checks of the Internationalized Normallized Ratio (INR) calculation. 4. In interview on May 31, 2018 at 11:10 am, Personnel 3 confirmed there was not a policy for manual INR checks.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed

	following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to perform manual checks of the International Normalized Ratio (INR) calculation. Findings: 1. Review of the policy and procedure manual revealed the laboratory did not have a policy for manual INR checks. 2. Further review of records revealed the laboratory did not have any documentation of manual INR checks being performed. 3. In interview on May 31, 2018 at 11:10 am, Personnel 3 stated the laboratory does not perform manual INR checks.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to have a complete Individualized Quality Control Plan (IQCP) to support the reduction in frequency of quality control (QC). Findings: 1. Observation by surveyors during the laboratory tour on May 30, 2018 revealed the laboratory utilized the Opti-Medical CCA-TS2 for blood gas testing. 2. Review of the laboratory's IQCP documents revealed the laboratory did not include the in-house data to support the reduction in frequency of external (liquid) QC to monthly. 3. In interview on May 30, 2018 at 3:45 pm, Personnel 2 and 10 stated the in-house QC data was not included. 4. Review of the laboratory's Task 1 and 3 forms revealed the laboratory performs 147 blood gas tests (to include pH, pCO2, and PO2) annually.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to document temperature changes recorded on the circular temperature charts. Findings:

	1. Review of the laboratory's "Blood Bank Storage" policy revealed "The refrigerator has a temperature graph that records the temperatures for 7 days. The graphs are changed weekly on Monday morning. They are reviewed each week as well." 2. Review of the Blood Bank's Circular Temperature Charts for 2017 and 2018 revealed the following charts without documentation for temperature changes: a) Date On: 12-26-16; Date Off: 1-2-17; Temperature recorded on form as 3.6 degrees: The circular chart temperature recorded as -1 degrees for the week. b) Date On: 1-2-17; Date Off: 1-9-17; Temperature recorded on form as 3.5 degrees: The circular chart temperature recorded as 0 degrees for the week. c) Date On: 3-5-18; Date Off: 3-12-18; Temperature recorded on form as 3.5 degrees: The circular chart temperature recorded as -1 degrees for the week. d) Date On: 3-26-18; Date Off: 4-2-18; Temperature recorded on form as 3.6 degrees: The circular chart temperature recorded as 1 degrees for the week. e) Date On: 4-9-18; Date Off: 4-16-18; Temperature recorded on form as 3.6 degrees: The circular chart temperature recorded as -1 degrees for the week. 3. Review of the Quality Assurance log book revealed the laboratory did not document any circular chart temperatures issues. 4. In interview on June 1, 2018 at 9:32 am, Personnel 3 stated she was unaware the pin that records the temperature on the circular charts was at a different temperature. Personnel 3 further stated she checks for variations in temperature but does not check the actual temperature on the circular chart. 5. In further interview on June 1, 2018, Personnel 3 confirmed the laboratory did not document the temperature changes recorded on the circular charts.
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 record review, and interview with personnel, the laboratory's Quality Assurance (QA) monitors failed to identify and correct quality issues. Findings: 1. Review of the laboratory's "Quality Assurance Plan" revealed under "Quality Assurance Log Book" the following monitors: A. A monthly log book is kept and the following are documented: 1. Quality Control 2. Instrument Maintenance 3. Calibration 4. Miscellaneous Logs 5. Physician or Department complaints B. Problems are noted and the action taken is documented 2. Review of the laboratory's records revealed the laboratory did not identify the following issues: a) Ensure all patients included in the Normal Mean Prothrombin Time Patient Study meet the "normal" requirements and if any further questioning of patients is needed, to include all documentation. b) The laboratory failed to have a complete policies and procedure manual. Refer to D5401. c) The laboratory failed to perform manual checks of the International Normalized Ratio (INR) calculation. Refer to D5411. d) The laboratory failed to have a complete Individualized Quality Control Plan (IQCP) to support the reduction in frequency of quality control (QC). Refer to D5445. e) The laboratory failed to document temperature changes recorded on the circular temperature charts. Refer to D5555. 3. In interview on June 1, 2018, Personnel 3 confirmed the laboratory's Quality Assessment monitors did not identify the identified issues.
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 record review and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required for accurate and reliable results. Refer to D5411.
D6020	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 program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that the quality control was maintained to assure quality laboratory services were provided. Refer to D5445.
D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on observation, record review and interview with laboratory personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was established and maintained to assure the quality of laboratory services provided. Refer to D5793.
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed

	specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultant failed to ensure all testing personnel were assessed through testing previously analyzed specimens, internal blind samples, or external proficiency samples. Findings: 1. Review of the laboratory's CMS-209 (Laboratory Personnel Report) form revealed the following testing personnel: Personnel 3 Personnel 4 Personnel 5 Personnel 6 Personnel 7 Personnel 8 Personnel 9 2. Review of the laboratory's 2017 American Proficiency Institute (API) Proficiency Testing (PT) and personnel competency assessment records revealed the following personnel did not perform previously analyzed specimens, internal blind samples, or external proficiency samples testing: Personnel 5 Personnel 8 Personnel 9 3. In interview on May 31, 2018, Personnel 2 confirmed the laboratory did not rotate PT or perform any type of blind sampling to cover all the specialties of testing performed as part of assessing competency
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 record review and interview with personnel, the Technical Consultant (Personnel 2) failed to evaluate and document the performance of individuals at least semiannually during the first year, for one (1) of seven (7) new personnel reviewed. Findings: 1. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory had written personnel policies and procedures for personnel competency that state the laboratory is to document competency/evaluation of new personnel for orientation (when hired), twice the first year (6 months and annual) then annually thereafter. 2. Review of Personnel Records revealed the laboratory failed to include documentation of competency/evaluation of new personnel at least semi annually for Personnel 15. Personnel 15 was hired on May 10, 2017. 3. In interview on May 30, 2017, Personnel 2 confirmed the six month evaluation for Personnel 15 was not completed as needed.
D6054	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 annually, after the first year. This STANDARD is not met as evidenced by: Based on record review and interview with personnel , the Technical Consultant failed to evaluate and document personnel competency annually for seven (7) of seven (7) testing personnel reviewed. Findings: 1. Review of personnel records revealed the personnel competencies for 2017 were performed; However, the Technical Consultant did not complete the assessments. 2. In interview on May 30, 2018 at 2:07 pm,

	Personnel 2 stated the personnel competencies were performed by other respiratory employees. Personnel 2 confirmed that she did not perform the 2017 competency assessements.