Department of Health & Human Services
Centers for Medicare & Medicaid Services

Form Approved
OMB No. 0938-0391

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0464915	(X3) Date Survey Completed 04/13/2018
Name of Provider or Supplier Avoyelles Hospital Blood Gas Laboratory	**Street Address, City, State** 4231 Highway 1192, Marksville, 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 conducted on April 9-13, 2018 at Avoyelles Hospital-Blood Gas Laboratory-CLIA ID # 19D0464915. The laboratory was found in compliance with 42 CFR 493 Requirement for Laboratories; however, standard deficiencies were cited.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to establish written policies that would ensure positive identification of patient samples for blood gas testing performed on the Opti-CCA analyzer. Findings: 1. Observation by surveyors on April 9, 2018 revealed the laboratory utilized the Opti-CCA analyzer for blood gas testing. 2. Review of the laboratory's policy and procedure manual revealed the laboratory did not have a written policy for specimen labeling/identification in the blood gas instrument. 3. In interview on April 10, 2018 at 10:00 am, Personnel 4 stated the laboratory did not have a written policy indicating the patient identification information to be entered into the blood gas instrument.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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.

	This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to ensure written policies and procedures to assess competency for the Technical Consultants were complete. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed Personnel 2 and Personnel 3 serve as the Technical Consultants. 2. Review of the laboratory's policies and procedures revealed the laboratory did not have a policy for competency assessment of the Technical Consultant. 3. Review of personnel records revealed competency assessments for the duties of Technical Consultant were not performed. 4. In interview on April 9, 2018 at 3:45 pm, Personnel 4 stated the laboratory competency assessments for the identified personnel were not performed.
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 laboratory's documents and records revealed the laboratory did not have written polices and procedures that included: a) Description of action to take if test system becomes inoperable b) Individualized Quality Control Plan (IQCP) 2. In interview on April 9, 2018 at 3:40 pm, Personnel 4 confirmed the laboratory did not have the identified policies.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) 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 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 ensure the procedure manual contained complete policies and procedures. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not have written policies that included the following: a) Step-by-step performance of the procedure, to include collection. 2. In interview on April 9, 2018 at 3:40 pm, Personnel 4 stated the laboratory's current policy did not include the laboratory's current collection process.
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: Based on observation, record review, and interview with personnel, the laboratory failed to monitor the humidity where blood gas testing is performed per manufacturer requirements. Findings: 1. Observation by surveyors during laboratory tour on April 9, 2018 revealed the laboratory utilizes the Opti-CCA blood gas analyzer. 2. Review of the Opti-CCA's operator manual revealed the following physical requirement: "maximum relative humidity 95 %." 3. Further observation by surveyors during laboratory tour on April 9, 2018 revealed the laboratory did not have a humidity monitor where the blood gas analyzer was located. 4. In interview on April 10, 2018 at 9:30 am, Personnel 4 stated she was unaware of the instrument's humidity requirement. In further interview Personnel 4 stated the laboratory monitors the room temperature only.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to ensure quarterly maintenance for the Opti-CCA was performed and documented as required. Findings: 1. Review of the "Opti-CCA Maintenance Logs" indicated the following quarterly maintenance task: Quarterly: "Perform tHb-Calibration" 2. Further review of the 2017 Opti-CCA maintenance logs revealed the laboratory did not document quarterly maintenance for the following one (1) of four (4) quarters: 3rd Quarter, due August 2017 3. In interview on April 10, 2018 at 9:35 am, Personnel 4 stated she was unaware quarterly maintenance was missed for one (1) quarter.

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 April 9, 2018 revealed the laboratory utilized the Opti-CCA for blood gas testing. 2. Review of the laboratory's IQCP documents revealed the following components were not included: a) In-house data to support the reduction in frequency of external (liquid) QC to monthly b) Quality Assessment Plan 3. In interview on April 9, 2018 at 2:29 pm, Personnel 4 stated the laboratory's IQCP did not have a Quality Assessment Plan. 4. In interview on April 9, 2018 at 2:39 pm, Personnel 4 stated liquid controls for the Opti-CCA are run the first of every month. 5. In further interview on April 9. 2018 at 2:50 pm, Personnel 4 stated the laboratory did not have in-house QC data to support the QC reduction to monthly. Personnel 4 further stated the laboratory had ten (10) days of QC data, not thirty (30). 6. Review of the laboratory's Task 1 and 3 forms revealed the laboratory performs 840 blood gas tests (to include pH, pCO2, and PO2) annually.
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 laboratory personnel performed testing as required. Refer to D5413.
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.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) 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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the Laboratory Director failed to ensure that the laboratory performed the required maintenance to ensure acceptable levels of analytical performance. Refer to D5429.
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 ensure written policies and procedures to assess competency for the Technical Consultants were complete. Refer to D5209. 2. The Technical Consultant(s) failed to ensure the procedures to assess personnel competency were complete. Refer to D6046. 3. the Technical Consultant(s) failed to ensure all testing personnel were assessed through testing previously analyzed specimens, internal blind samples, or external proficiency samples. Refer to D6051.
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 to all personnel responsible for any aspect of the testing process. Findings: 1. The laboratory failed to establish written policies that would ensure positive identification of patient samples for blood gas testing performed on the Opti-CCA analyzer. Refer to D5203. 2. The laboratory failed to have a complete policies and procedure manual. Refer to D5401. 3. The laboratory failed to ensure the procedure manual contained complete policies and procedures. Refer to D5403.
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 record review and interview with personnel, the Technical Consultant(s) failed to ensure the procedures to assess personnel competency were complete. Findings: 1. Review of personnel records revealed the laboratory utilized a "Competency Based Performance Evaluation for ABG's" form; however, this form did not include the following six (6) procedures as a minimal requirement for assessing the competency of all personnel performing laboratory 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 or 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. Review of the annual personnel competency assessments for 2017 revealed the Technical Consultant(s) did not perform the assessments. 3. Further review of the laboratory's competency assessment forms revealed Personnel 4, listed as a Testing Personnel on the CMS-209 (Laboratory Personnel Report), performed the annual competency for testing personnel. 4. In interview on April 9, 2018 at 3:45 pm, Personnel 4 stated the laboratory utilizes the identified competency evaluation form and two quizzes to assess personnel competency. Personnel 4 confirmed the laboratory's evaluation form did not include at a minimum the six (6) procedures listed. In additional interview, Personnel 4 stated she was aware the evaluation form needed to be updated and was in the process of updating. 5. In further interview on April 9, 2018 at 3:45 pm, Personnel 4 stated she

	performs the competency assessments for testing personnel. Personnel 4 further stated the Laboratory Director performs her competency assessment for testing personnel duties.
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(s) 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 4 Personnel 5 Personnel 6 Personnel 7 Personnel 8 Personnel 9 Personnel 10 Personnel 11 Personnel 12 Personnel 13 2. Review of the laboratory's 2017 College of American Pathologists (CAP) Proficiency Testing (PT) and personnel competency assessment records revealed the following personnel did not did not perform previously analyzed specimens, internal blind samples, or external proficiency samples testing: Personnel 5 Personnel 6 Personnel 8 Personnel 10 Personnel 11 Personnel 12 Personnel 13 3. In interview on April 9, 2018 at 2:37 pm, Personnel 4 stated not all testing personnel perform PT testing. Personnel 4 confirmed the identified testing personnel were not assessed through testing previously analyzed specimens, internal blind samples, or external proficiency samples.