Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0707957	04/15/2021
Name of Provider or Supplier	**Street Address, City, State**	
St Helena Parish Hospital	16874 Highway 43 North, Greensburg, 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 Recertification survey was performed on April 12, 2021 through April 15, 2021 at St. Helena Parish Hospital, CLIA ID # 19D0707957. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records and interview with personnel, the laboratory failed to ensure the Laboratory Director and/or qualified designee signed the attestation forms for three (3) of six (6) proficiency testing (PT) events reviewed. Findings: 1. Review of the laboratory's American Proficiency Institute (API) PT records for 2019 and 2020 revealed the Laboratory Director and/or qualified designee did not sign the attestation statements for the following three (3) events: a) 2020: Hematology 3rd Event b) 2020: Immunology/Immunohematology 2nd Event; Laboratory Director did not sign c) 2019: Chemistry-Core 2nd Event 2. In

	interview on April 12, 2021 at 3:06 pm, the Technical Consultant 2 confirmed the Laboratory Director did not sign the attestation statements for the identified PT events.
D3021	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(c)(1) Blood and blood products storage and distribution. If a facility stores or maintains blood or blood products for transfusion outside of a monitored refrigerator, the facility must ensure the storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood product. This STANDARD is not met as evidenced by: Based on review of the laboratory's blood bank refrigerator temperature logs and interview with personnel, the laboratory failed to record the refrigerator temperature and checks for one (1) of thirty one (31) days in August 2020. Findings: 1. Review of the laboratory's blood bank refrigerator temperature logs for 2020 and 2019 revealed the laboratory did not document the refrigerator's "Rec. Chart" temperature, digital temperature, wall temperature, inside temperature, and alarm/battery checks for August 19, 2020. 2. In interview with personnel on April 14, 2021 at 3:58 pm, the Technical Consultant 2 confirmed the laboratory did not document the temperatures and alarm/ battery checks for August 19, 2020.
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 review of the laboratory's personnel records, and interview with personnel, the laboratory failed to ensure written policies and procedures to assess competency for one (1) of two (2) Technical Consultants and General Supervisors were followed. Findings: 1. Review of personnel records revealed no documentation of an annual competency assessment, per laboratory policy, for 2020 for Technical Consultant 1, who also serves as a General Supervisor, for her duties as Technical Consultant and General Supervisor. 2. In interview on April 12, 2021 at 2:15 pm, the Technical Consultant 2 confirmed the laboratory did not have documentation of performance of a competency assessment by the Laboratory Director for Technical Consultant 1 for 2020 for her duties as Technical Consultant and General Supervisor.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

	This STANDARD is not met as evidenced by: Based on observation by surveyor, review of patient test logs, manufacturer's package inserts, and interview with personnel, the laboratory failed to ensure patient samples for Lactic Acid testing were separated within fifteen (15) minutes of receipt per manufacturer requirements for three (3) of thirty four (34) patients reviewed. Findings: 1. Observation by surveyor during the laboratory tour on April 12, 2021 at 10:30 am revealed the laboratory utilizes the Vitros 5600 for Lactic Acid testing. 2. Review of the Ortho Vitros package insert under the "Special Precautions" section revealed "Centrifuge specimens and remove the plasma from the cellular material within 15 minutes of collection." 3. Review of patient test logs for Lactic Acid from October 2020 through March 2021 revealed the following three (3) patients: a) October 25, 2020: Patient 312063, collected 10:10 am, received 10:37 am b) February 21, 2021: Patient 315019, collected 3:10 am, received 3:35 am c) March 23, 2021: Patient 315814, collected 14:25, received 15:49 4. In interview on April 15, 2021 at 11:00 am the Technical Consultant 2 confirmed the identified patient samples were not separated per manufacturer requirements.
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 review of the laboratory's policies and procedures and interview with personnel, the laboratory failed to have a complete policy and procedure manual. Findings: 1. Review of the laboratory's policies and procedures revealed the laboratory did not include the following: a) Reporting of SARS COV-2 test results to state public health agency, to include but not limited to frequency and who is responsible b) Blood Culture Collection Kits: to include current manufacturer of kits for blood culture collection bottles 2. In interview on April 14, 2021 at 9:10 am, the Technical Consultant 2 confirmed the identified policies were not included.
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: I. Based on observation by surveyor, review of the manufacturer's instrument manual, quality control records, test menu, and interview with personnel, the laboratory failed to follow manufacturer's instructions for flags appearing on the Ortho Vitros analyzer for one (1) of eleven (11) patients reviewed for Lactate Dehydrogenase (LDH). Findings: 1. Observation by surveyor during the laboratory tour on April 12, 2021 at

	10:30 am revealed the laboratory utilizes the Ortho Vitros 5600 for LDH testing. 2. Review of the manufacturer's instrument manual revealed the following codes and actions: a) "Incubator Temperature (IT): The incubator temperature is outside of specifications. Actions: Once the analyzer displays 'READY' repeat the test." 3. Review the laboratory's quality control records for LDH testing from October 2020 through February 2021 revealed the following instrument flags and patients reported: a) January 5, 2021: Level 1: flag "IT": Patient 313725 4. In interview on April 13, 2021 at 3:26 pm, Testing Personnel 6 stated the temperature may have been out when QC was run. Testing Personnel 6 stated for the identified flag the laboratory does not repeat the the quality control. 5. Review of the laboratory's test menu reveals the laboratory performs thirty two (32) LDH tests annually. II. Based on observation by surveyor, review of the manufacturer's package insert, laboratory records, and interview with personnel, the laboratory failed to document visual inspection of blood culture bottles prior to use per manufacturer requirements. Findings: 1. Observation by surveyor during the laboratory tour on April 12, 2021 at 10:30 am revealed the laboratory utilizes the BioMerieux Adult and Pediatric Blood Culture Collection kits that contain BacT/ALERT FA Plus Aerobic, Anaerobic ad PF Plus Pediatric bottles. 2. Review of the manufacturer's package insert revealed "Inspect each blood culture bottle before use to ensure integrity of bottle and sensor on bottom of bottle is intact. The sensor is normally a uniform grayish-green color and a yellow color would indicate contamination of the broth. Discard any bottle found to be damaged or with a sensor that is yellow." 3. Review of the laboratory's records revealed the laboratory does not document visual inspections of the blood culture bottles prior to use. 4. In interview on April 13, 2021 at 3:00 pm the Technical Consultant 2 confirmed the laboratory does not document visual inspections of the blood culture bottles received in the collection kits prior to use.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of the laboratory's policies, and interview by personnel, the laboratory failed to ensure supplies had not exceeded their expiration dates. Findings: 1. Observation by surveyor during laboratory tour on April 12, 2021 at 10:30 am revealed the following expired supplies: a) BACT/ALERT FN Plus blood culture collection bottles, Lot 0004055286, Expiration date: 2021-02-20, Quantity: ten (10) bottles b) Remel Microtest M4RT Transport tubes, Lot 422133, Expiration date: 2020-04-15, Quantity: one (1) tube; Lot 474803, Expiration date: 2020-07-28, Quantity: one (1) tube; Lot 504639, Expiration date: 2020-09-24, Quantity: three (3) tubes; Lot 496250, Expiration date: 2020-09-03, Quantity: four (4) tubes; Lot 474061, Expiration date: 2020-07-27, Quantity: one (1) tube 2. Review of the laboratory's "Inventory/Inspection of Reagents, Calibrators, Solutions, Controls, Other Supplies, Etc" policy revealed "The Laboratory shall conduct a MONTHLY inventory/inspection of reagents, calibrators, solutions, controls, other supplies, etc to ensure that they are not expired." 3. In interview on April 14, 2021 at 11:28 am, Testing Personnel 4 confirmed the identified items were expired.
D5447	CONTROL PROCEDURES

	CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of the laboratory's quality control (QC) records, policies, patient test logs, test menu, and interview with personnel, the laboratory failed to perform two (2) levels of controls prior to patient testing for Alcohol testing for one (1) of 182 days reviewed. Findings: 1. Observation by surveyor during the laboratory tour on April 12, 2021 at 10:30 am revealed the laboratory utilizes the Vitros 5600 for Alcohol testing. 2. Review of the laboratory's "Quality Control Program (Overview)" policy revealed "Patient testing will not occur until all levels of known control material have been analyzed according to procedural guidelines are within the established acceptable range. Control specimens are to be run in the same manner as patient specimens to verify that the entire test system is working properly." 3. Review of the laboratory's quality control records for alcohol testing and patient logs from October 2020 through March 2021 revealed the laboratory did not perform two (2) levels of QC prior to patient testing for the following patient: November 6, 2020: Patient 312412 4. In interview on April 13, 2021 at 4:47 pm, the Technical Consultant 2 stated she was unable to find documentation of QC performance for the identified date. 5. Review of the laboratory's test menu reveals the laboratory performs 119 alcohol tests annually.
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 by surveyor, record review, and interview with personnel, the laboratory's quality assessment monitors failed to correct issues identified with the analytic system. Findings: 1. Review of the laboratory's "Quality Assurance Indicators"policy revealed the following monitors: a) "Evaluation of Testing Personnel" b) "Test Management/QC Assessment" c) "Quality Control" d) "Proficiency Testing" e) "Communications/Complaints" f)"Staff Review" g) "QA records are maintained in an orderly manner and retained for at least two years" 2. Observation by surveyor, review of laboratory records, and interview with personnel revealed the following issues within the analytic system: a)The laboratory failed to have a complete policy and procedure manual. Refer to D5401. b) The laboratory failed to follow manufacturer's instructions for flags appearing on the Ortho Vitros analyzer for one (1) of eleven (11) patients reviewed for Lactate Dehydrogenase (LDH). Refer to D5411 I. c) The laboratory failed to document visual inspection of blood culture bottles prior to use per manufacturer requirements. Refer to D5411 II. d)

	The laboratory failed to ensure supplies had not exceeded their expiration dates. Refer to D5417. e) The laboratory failed to perform two (2) levels of controls prior to patient testing for Alcohol testing for one (1) of 182 days reviewed. Refer to D5447.
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 surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel were performing test methods as required. Findings: 1. The laboratory failed to ensure patient samples for Lactic Acid testing were separated within fifteen (15) minutes of receipt per manufacturer requirements for three (3) of thirty four (34) patients reviewed. Refer to D5311. 2. The laboratory failed to follow manufacturer's instructions for flags appearing on the Ortho Vitros analyzer for one (1) of eleven (11) patients reviewed for Lactate Dehydrogenase (LDH). Refer to D5411 I. 3. The laboratory failed to document visual inspection of blood culture bottles prior to use per manufacturer requirements. Refer to D5411 II. 4. The laboratory failed to ensure supplies had not exceeded their expiration dates. Refer to D5417.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure all proficiency testing reports are reviewed by the appropriate staff. Refer to D2015.
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 record review and interview with personnel, the Laboratory Director failed to ensure that a quality control program was maintained to assure quality laboratory services were provided. Refer to D5447.
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 by surveyor, 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.
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 laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D5401.
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 observation by surveyor, record review, and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory. Findings: 1. The laboratory failed to ensure patient samples for Lactic Acid testing were separated within fifteen (15) minutes of receipt per manufacturer requirements for three (3) of thirty four (34) patients reviewed. Refer to D5311. 2. The laboratory failed to follow manufacturer's instructions for flags appearing on the Ortho Vitros analyzer for one (1) of eleven (11) patients reviewed for Lactate Dehydrogenase (LDH). Refer to D5411 I. 3. The laboratory failed to document visual inspection of blood culture bottles prior to use per manufacturer requirements. Refer to D5411 II. 4. The laboratory failed to ensure supplies had not exceeded their expiration dates. Refer to D5417.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Technical Consultant failed to ensure the quality control program was maintained to assure the quality of laboratory testing. Refer to D5447.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that 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 test methods as required. Refer to D3021.

D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must 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 maintained for assessing personnel competency. Refer to D5209.