Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0707957	10/27/2022
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 Certification survey was performed on October 25, 2022 through October 27, 2022 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.
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 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) "Therapeutic Phlebotomy Weight Scale" including procedure for quarterly checks and corrective action for weight not within acceptable limits b) Verification procedures for antibody screen cells to include, but not limited to, screen cells utilized by the laboratory, acceptability criteria, and corrective actions 2. In interview on October 25, 2022 at 2:40 pm, the Technical Consultant confirmed the laboratory did not have a written procedure for verification of antibody screen cells. 3. In interview on October 27, 2022 at 2:30 pm, the Technical Consultant confirmed the laboratory did not have a written policy/procedure for therapeutic phlebotomy weight checks.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)

	Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of the laboratory's performance verification studies, and interview with personnel, the laboratory failed to perform complete performance verification studies for SARS COV-2 antigen testing. Findings: 1. Observation by surveyor during the laboratory tour on October 25, 2022 at 10:30 am revealed the laboratory utilizes the Vitros 5600 for SARS COV-2 antigen testing. 2. Review of the laboratory's performance verification studies for the SARS COV-2 antigen test revealed the laboratory did not include the following: a) Summary to include how studies were performed and acceptability criteria b) Operator variance for precision studies c) Laboratory Director's approval 3. In interview on October 25, 2022 at 2:56 pm, the Technical Consultant confirmed the identified information was not included in the SARS COV-2 performance verification studies.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of the laboratory's performance specification studies, and interview with personnel, the laboratory failed to have complete verification of antibody screen cells for immunohematology testing. Findings: 1. Observation by surveyor during the laboratory tour on October 25, 2022 at 10:30 am revealed the laboratory utilizes the Ortho Workstation with Gel cards for immunohematology testing. 2. Review of the laboratory's performance specification studies for their OrthoWorkstation revealed the laboratory did not include the following: a) Summary of the laboratory's procedure b) Identification of Antibody Screen I cells c) Acceptability Criteria d) Laboratory Director's approval 3. In interview on October 25, 2022 at 2:40 pm, the Technical Consultant confirmed the laboratory did not include the identified items.
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 review of maintenance logs and interview with personnel, the laboratory failed to perform daily maintenance as required by the manufacturer for one (1) of thirty days reviewed in September 2022 for Chemistry testing. Findings: 1. Review of the maintenance logs for the Vitros 5600 revealed the following daily tasks: a) Maintain ERF b) Maintain IWF c) Perform metering maintenance d) Empty waste containers e) Load supplies and remove empty/outdated reagents f) Inspect/Clean universal sample trays and adaptors g) Clean SR dispense probe h) Perform quality control i) Clean cap retainers j) Clean VersaTip supply registration rails 2. Review of the Vitros 5600 maintenance log for September 2022 revealed the laboratory did not perform the metering maintenance on September 11, 2022. 3. In interview on October 28, 2022 at 2:28 pm, the Technical Consultant confirmed the identified maintenance was not performed.
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 personnel, the Laboratory Director failed to ensure that the laboratory performed required maintenance. Refer to D5429.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to establish complete performance specifications for testing. Refer to D5423.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must 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 records, personnel records, and interview with personnel, the Laboratory Director failed to ensure six (6) of six (6) Testing Personnel reviewed had documentation of training and approval to perform testing on the immunohematology workstation. Findings: 1. Review of the laboratory's personnel and laboratory records revealed the laboratory did not have training documents for the immunohematology workstation that was put into use July 2022 for six (6) testing personnel. 2. In interview on October 25, 2022 at 2:40 pm, the Technical Consultant stated the training on the blood bank workstation was quality control and patients during the validation of the equipment. 3. In further interview on October 25, 2022 at 2:40 pm, the Technical Consultant confirmed the laboratory did not indicate the validation was a part of the training for Testing Personnel. The Technical Consultant confirmed documentation of the Laboratory Director approving the Testing Personnel for testing was not included.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must 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.