Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0707957	07/24/2024
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	Recertification Survey was conducted on July 22, 2024 through July 24, 2024 at St Helena Parish Hospital - CLIA ID # 19D0707957. The laboratory was found in compliance with 42 CFR 493 Requirement for Laboratories; however, standard deficiencies were cited.
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; review of manufacturers' storage requirements, package inserts, and the laboratory's temperature records; as well as interview with personnel, the laboratory failed to define acceptable room temperature limits within the manufacturers' required ranges for laboratory supplies and reagents for two (2) of three (3) rooms. Findings: 1. Observation by surveyor during the laboratory tour on July 22, 2024 at 10:31 a.m. revealed supplies stored in the laboratory to include, but not limited to, the following: a) Main Lab - MEDTOX Scan - Manufacturer's storage requirements 64 - 77 degrees Fahrenheit or 18 - 25 degrees Celsius - HemosIL Cleaning solution - Manufacturer's storage requirements 15 - 25 degrees Celsius b) Blood Bank - DxH 500 Series cleaner - Manufacturer's storage requirements 2 - 25 degrees Celsius - DxH 500 Series Lyse - Manufacturer's storage requirements 4 - 25 degrees Celsius 2. Further observation revealed the laboratory utilized the following reagents for coagulation testing: - HemosIL SynthASil - HemosIL RecombiPlasTin

	2G - HemosIL Normal Control 1 - HemosIL Abnormal Control 3 3. Review of the HemosIL package inserts revealed the following preparation requirements: - HemosIL SynthASil - "Each vial of APTT Reagent must be equilibrated at 15 - 25 degrees Celsius for at least 15 minutes and mixed thoroughly before use." - HemosIL RecombiPlasTin - "Allow each vial of RecombiPlasTin 2G Diluent to equilibrate at 15 - 25 degrees Celsius for at least 15 minutes before reconstituting the lyophilized reagent with the diluent...Following reconstitution...Keep the reagent at 15 - 25 degrees Celsius for 15 - 20 minutes and invert to mix before use." - HemosIL Normal Control 1 - "...Make sure of the complete reconstitution of the product. Keep the control at 15 - 25 degrees Celsius for 30 minutes..." - HemosIL Abnormal Control 3 - "...Make sure of the complete reconstitution of the product. Keep the control at 15 - 25 degrees Celsius for 30 minutes..." 4. Review of the laboratory's temperature logs from January 2023 through June 2024 revealed the laboratory defined the room temperature acceptable upper limit for both the Main Lab and Blood Bank as 84.6 degrees Fahrenheit (29.2 degrees Celsius) which exceeded the manufacturers' acceptable upper limits. 5. In interview on July 23, 2024 at 2:45 p.m., the General Supervisor confirmed the laboratory's room temperature upper limit exceeded the manufacturers' acceptable upper limit for the Main Lab and Blood Bank.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's validation records, policies, and test menu; as well as interview with personnel, the laboratory failed to ensure the patient final test reports included the laboratory's validated reference range for cell blood count (CBC) testing. Findings: 1. Review of the laboratory's validation study for the DxH 560 revealed validated reference ranges based on gender to include the following analytes: a) Male - Red Blood Cell Count - 4.06 - 5.63 m/uL - Mean Corpuscular Hemoglobin Concentration - 32.5 - 36.3 g/dL b) Female - Red Blood Cell Count - 3.63 - 4.92 m/uL - Lymphocyte number - 1.1 - 3.1 K/uL 2. Review of a random selection of two (2) patient final reports from May 2024 revealed the following reference ranges included on the patient final reports: a) May 15, 2024: Patient 349926 - Male - Red Blood Cell Count - 4.06 - 4.92 m/uL - Mean Corpuscular Hemoglobin Concentration - 32.3 - 36.3 g/dL b) May 6, 2024: Patient 349673 - Female - Red Blood Cell Count - 3.63 - 5.63 m /uL - Lymphocyte number - 1.1 - 3.2 K/uL 3. In interview on July 23, 2024 at 1:52 p. m., the General Supervisor confirmed the reference ranges on the final patient test report for the analytes identified above were incorrect. 4. Review of the laboratory's test menu revealed the laboratory performs 4, 074 tests annually.
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) 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)(8) Ensure that reports of test results include pertinent information

	required for interpretation. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure final reports for hematology testing included pertinent information. Refer to D5807.
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 surveyors, record review, and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory. Refer to D5413.
D6151	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463(b)(3)(4) (3) The director or technical supervisor may delegate to the general supervisor the responsiblity for providing orientation to all testing personnel; and (4) Annually evaluating and documenting the performance of all testing personnel. This STANDARD is not met as evidenced by: Based on review of laboratory policies and personnel records and interview with personnel, the General Supervisor failed to perform an annual competency assessment for one (1) of six (6) testing personnel reviewed. Findings: 1. Review of the laboratory policy "Performance Evaluations and Competency Assessments" revealed "All new laboratory testing personnel shall have an evaluation/competency assessment at initial hire/6 months, one year, and then annually thereafter from the original date of hire." 2. Review of personnel records revealed Testing Personnel 4 was hired April 2023 and had a semi-annual competency performed in October 2023. 3. Further review of personnel records for Testing Personnel 4 revealed an annual competency was not performed when due in April 2024. 4. In interview on July 23, 2024 at 9:30 a.m., the General Supervisor confirmed the annual competency for Testing Personnel 4 was not performed one year after the hire date.