Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 19D0464876	**(X3) Date Survey Completed** 01/21/2021
Name of Provider or Supplier Lasalle General Hospital	**Street Address, City, State** 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 performed on January 19, 2021 through January 21, 2021 at LaSalle General Hospital, CLIA ID # 19D0464876. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
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 observation, maintenance record review and interview with personnel, the laboratory failed to ensure maintenance for the Siemens Sysmex CA 660 Coagulation analyzer was documented per manufacturer requirements. Findings: 1. Observation by surveyor during laboratory tour on January 19, 2021 at 1:32 pm revealed the laboratory utilizes a Siemens Sysmex CA 660 Coagulation analyzer for Prothrombin Time (PT), International Normalized Ratio (INR), Activated Partial Thromboplastin Time (APTT), and D-Dimer testing. 2. Review of the laboratory's "Sysmex CA-600 Operator Maintenance Checklist" revealed the laboratory performs the following maintenance as required by the manufacturer: a) Quarterly: Perform LED Calibration; Clean DI Water Rinse Bottle with Alcohol b) Yearly: Replace Rinse Filter 3. Review of the laboratory's maintenance logs from January 2019 through December 2020 revealed the laboratory did not document quarterly maintenance for the following three (3) of twenty four (24) months reviewed: a) Clean DI Water Rinse Bottle with Alcohol - June 2019, August 2019, February 2020 4. Further review of the laboratory's maintenance logs from January 2019 through December 2020 revealed the laboratory did not document yearly maintenance for 2019 and 2020. 5. In interview on January 21, 2021 at 10:37 am, the Laboratory Supervisor stated the

	quarterly maintenance not documented was moved to weekly maintenance but the maintenance logs were not updated to state this change. 6. In further interview on January 21, 2021 at 10:37 am, the Laboratory Supervisor stated that she was unaware that the yearly maintenance was not performed due to thinking the maintenance was performed upon preventive maintenance by the Siemens Field Service Representative.
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 observation, record review, and interview with personnel, the Laboratory Director failed to ensure that the laboratory performed required maintenance and calibration to ensure acceptable levels of analytical performance. Refer to D5429.
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, record review, and interview with personnel, the Technical Consultants failed to provide technical and scientific oversight to the laboratory. Refer to D5429.