Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D0316753	02/21/2020
Name of Provider or Supplier	**Street Address, City, State**	
Delta Health System - The Medical Center	1400 East Union St - Laboratory, Greenville, MS	

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
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 review of laboratory temperature records since the last survey 3/22/18 and confirmation with a laboratory technical consultant (TC) at 3:00 PM on 2/20/20, the laboratory failed to monitor and document the temperatures of the Beckman Coulter Power Processor Stockyard Refrigeration Unit where patient samples are stored after testing. Findings include: 1. Observation of the laboratory "Stockyard" refrigerator where samples (serology, immunology, chemistry, endocrinology, toxicology, hematology and immunohematology) are refrigerated and stored for at least 6 days revealed that there was no mechanism to monitor the internal temperature. There was no attached thermometer control panel nor was there a calibrated thermometer inside the refrigerator. 2. Beckman Coulter Power Processor Stockyard Refrigeration manufacturer's instructions read that if the laboratory's Stockyard refrigerator does not have a Refrigeration Control Panel Display on the outside of the "Stockyard", the laboratory is to use a calibrated thermometer to check the temperature. The temperature should be read and recorded daily. 3. Beckman Coulter Stockyard manufacturer's instructions require optimal temperature range for sample storage to be between 2 and 8 degrees centigrade. This refrigeration unit houses thousands of post-test samples. These samples have the potential to be used for add-on testing at a later date and must be maintained at the appropriate temperature. 4. Interview with the

	laboratory TC at 3:00 PM on the day of survey confirmed there was no external Refrigeration Control Panel Display on the "Stockyard" nor was there a calibrated thermometer in the refrigerator unit.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on review of maintenance logs for the two Stago STA Compact MAX coagulation systems (Serial #5031212 and Serial #5031214) from 4-1-18 through 1-31-20 and confirmation by General Supervisor #2, listed on the Centers for Medicare and Medicaid Services (CMS) 209 Laboratory Personnel Form, the laboratory failed to document daily function checks, as defined by the manufacturer, for the coagulation system in use for eleven days during this time frame. Findings include: Review of maintenance logs for the two Stago STA Compact MAX coagulation systems (Serial #5031212 and Serial #5031214) from 4-1-18 through 1-31-20 revealed the following daily function checks were not documented, as performed, for either of the coagulation systems on 5-2-19, 5-3-19, 5-23-19, 5-24-19, 7-25-19, 9-14-19, 9-15-19, 10-17-19, 10-18-19, 10-26-19, and 10-27-19: Needle temperature Measuring Block temperature Reagent Drawer temperature Syringe percentage General Supervisor #2 confirmed that one of the two coagulation systems is used every day for patient testing.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

	This STANDARD is not met as evidenced by: Based on review of the Laboratory Coagulation Procedure Manual, lack of calibration verification records for the two Stago STA-Compact MAX coagulation systems, interview on 2-20-20 at 4:30 p.m. with General Supervisor #2, listed on the CMS Laboratory 209 personnel form, and confirmation by Technical Consultant #2, the laboratory failed to document, as performed, calibration verification for D-dimer and fibrinogen testing at least once every six months since 3-22-18. Findings include: Review of the Laboratory Coagulation Procedure Manual revealed the Calibration Verification policy for the D-dimer and fibrinogen tests state, "Since a pre-calibrated test cannot be calibrated every six months, calibration verification must be performed in lieu of the calibration." On the day of the survey, 2-20-20, there was no documentation of performance of calibration verification for D-dimer and fibrinogen testing on the Stago STA-Compact MAX coagulation systems (Serial #5031212 and Serial #5031214) since the last survey on 3-22-18. In an interview on 2-20-20 at 4:30 p.m., General Supervisor #2 stated calibration verification for D-dimer and fibrinogen testing was not performed since the last survey on 3-22-18. Technical Consultant #2 confirmed calibration verification was not performed for D-dimer and fibrinogen testing since 3-22-18.