Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D0316753	03/21/2024
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
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: Based on review of the Sysmex CS-2500 coagulation system manufacturer's instructions, observation of coagulation reagents and controls in use on 3/21/2024 at 9: 30 a.m., interview with Technical Consultant #3 on 3/21/2024 at 1:45 p.m., and patient test counts, the laboratory failed to follow manufacturer's instructions for lot changes of reagents, put in use in October and November 2023. Findings include: 1. Sysmex CS-2500 coagulation system manufacturer's instructions stated when new lots of prothrombin time (PT) and activated partial thromboplastin time (APTT) reagents are put in use the patient reference intervals should be established or verified, a normal patient mean should be established for the new PT reagent, quality control ranges should be established with the new reagent lots, a lot-to-lot method correlation should be performed with the current reagent lots and the new reagent lots, and the heparin therapeutic range for APTT should be verified if monitoring unfractionated heparin therapy. 2. Manufacturer's instructions for Dade Ci-Trol Coagulation Control Level 1 and Level 3 stated each laboratory should establish its own level of performance. 3. Observation of PT and APTT reagents and coagulation controls in the laboratory refrigerator on 3/21/2024 at 9:30 a.m. and interview with Technical Consultant #3, listed on the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, on 3/21/2024 at 1:45 p.m. revealed the following lots of reagents and controls were in use: Dade Innovin PT reagent, Lot #564604, expiration date 9/9 /2024, was put in use on 11/13/2023 and used for patient PT testing for 4 of 21 months reviewed. Dade Actin FSL APTT reagent, Lot #562733, expiration date 11/22

	/2024, was put in use on 10/13/2023 and used for patient APTT testing for 5 of 21 months reviewed. Dade Ci-Trol Level 1 Control, Lot #564879, expiration date 3/5 /2026, was put in use on 9/28/2023. Dade Ci-Trol Level 3 Control, Lot #556579, expiration date 3/7/2026, was put in use on 8/27/2023. 4. On 3/21/2024 there was no documentation available of lot conversion studies performed, per manufacturer's instructions, on Dade Innovin PT reagent, Lot #564604, or Dade Actin FSL APTT reagent, Lot #562733, including establishment of acceptable ranges for Dade Ci-Trol Level 1 Control, Lot #564879, or Dade Ci-Trol Level 3 Control, Lot #556579. 5. In an interview on 3/21/2024 at 1:45 p.m., Technical Consultant #3 confirmed there was no documentation of lot conversion studies performed on Dade Innovin PT reagent, Lot #564604, or Dade Actin FSL APTT reagent, Lot #562733, or establishment of acceptable ranges for Dade Ci-Trol Level 1 Control, Lot #564879, or Dade Ci-Trol Level 3 Control, Lot #556579 with the new lots of reagent. 6. According to patient test counts provided by Technical Consultant #3, the following patient test results were reported during the tme frames listed below: Patient PT results reported from 11 /13/2023, when Innovin PT reagent Lot #564604 was put in use, through the day of the survey on 3/21/2024 were 1,970. Patient PTT results reported from 10/13/2023, when Actin FSL APTT reagent Lot #562733 was put in use, through 3/21/2024 were 3,226.
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 Gem Premier 4000 and 3500 blood gas analyzer records including quality control, maintenance, calibration verification (PVP-performance verification product) records from last survey on 6/23/2022 through 3/21/2024 and interview with the respiratory testing personnel (TP) #7 and technical consultant (TC) #2 as listed on the CMS (Centers for Medicare and Medicaid Services) 209 personnel form at 12:00 p.m. on 3/21/2024, the laboratory failed to document as performed, the PVP on the Gem Premier 4000 and 3500 blood gas analyzers every six months for pCO2, pH, pO2. Four of four calibration verifications (PVP) were not performed

	during the timeframe reviewed. Findings include: 1. Calibration verification (PVP) is required every six months on any assay which is calibrated with less than 3 levels of calibration material. This PVP material is provided by the manufacturer. The Gem Premier 4000 and 3500 blood gas analyzers use a single calibrator level to perform calibrations. 2. The Respiratory Department testing personnel utilize three Gem Premier blood gas analyzers. The Gem Premier 4000 is located in the ER (emergency room), one Gem Premier 3500 is located in the ICU (intensive care unit) and the second Gem Premier 3500 analyzer is in the Respiratory Department. Gem Premier blood gas analyzer records for all three revealed calibration verification (PVP) was not performed since the last survey on 6/23/2022. 3. Respiratory TP #7 and TC #2 confirmed in an interview at 12:00 p.m. on 3/21/2024 that a PVP on pH, pCO2 and pO2 was not performed at the appropriate timeframe or frequency during the period of 6/23/2022 through 3/21/2024. Four of four PVP verifications required were not performed and exceeded the six-month timeframe required by the manufacturer.