Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D0029634	03/13/2025
Name of Provider or Supplier	**Street Address, City, State**	
Ummc - Grenada	960 Jk Avent Drive, Grenada, 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) (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 observation of the Reference Time entered in the primary STA Compact MAX coagulation analyzer, Serial #CF79045261, and the back-up STA Compact MAX coagulation analyzer, Serial #0000008590, review of the establishment of the geometric mean of the normal patient reference range for the current lot of STA-Neoplastine C1 Plus prothrombin time (PT) reagent, Lot #265568, for the primary and back-up analyzers, manufacturer's instructions for the STA Compact MAX coagulation analyzer, and patient test counts, the laboratory failed to follow manufacturer's instructions for setting up the two STA Compact MAX coagulation systems to calculate the INR (international normalized ratio) for patient prothrombin time testing when PT reagent Lot #265568 was put in use for patient testing for seven of seven months. Findings include: 1. Manufacturer's instructions for the Stago STA Compact coagulation analyzer state to enter the geometric mean of the normal patient reference range as the Reference Time with each new lot of PT reagent for correct calculation of the INR. 2. Review of documentation of the establishment of the geometric mean of the normal patient reference range for STA-Neoplastine C1 Plus PT reagent Lot #265568, put in use on 8/1/2024, revealed the geometric mean was calculated as 13.9 for the primary STA Compact MAX analyzer, and the geometric mean was calculated as 13.6 for the back-up analyzer. 3. The Reference Time observed on 3/13/2025 at 11:00 a.m. in the primary and back-up STA Compact MAX analyzers was 13.5. 4. Review of patient test counts revealed 1,658 patient PT results were reported from 8/1/2024 until 3/13/2025.

D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) (d)(3)(ii) Each qualitative procedure, include a negative and positive control material; This STANDARD is not met as evidenced by: Based on review of quality control (QC) logs, patient testing logs, interview with the Laboratory Manager and testing personnel (TP) #3 as listed on the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, and lack of Individualized Quality Control Plan (IQCP), the laboratory failed to include a positive and negative control on each day of patient testing for the two Profile V-MedTox Scan Drug Screen Test readers. Findings Include: 1. Review of the MedTox Drug Screen patient test logs and QC log from 7/2/2023 through 1/27/2025 revealed that QC material was performed weekly on the MedTox Drug Screen reader instead of daily as required. The drug panel the laboratory tested consisted of twelve drugs performed on the MedTox Scan Drug Screen readers: reader #1 -serial number 2919M1847 and reader #2 serial number 1322M1909. 2. Interview with Laboratory Manager and TP #3 on 3/12/2025 at 1:00 p.m., confirmed that testing personnel were not performing two levels of QC (positive or negative) each day of patient testing with the Profile V-MedTox Scan Drug Screen Test readers. 3. There was no IQCP available for review on the day of the survey. An IQCP is required if two levels of quality control (QC) are not performed each day of use for moderate/high complexity testing. Approximately 3500 drug screen panels were performed on both Profile V-MedTox Scan Drug Screen systems since the last survey on 6/22/2023.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood shall be stored in a clean and orderly environment in a manner to prevent mix-ups. Expired blood must not be in the routine inventory. Unacceptable units must be segregated from routine inventory. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. This STANDARD is not met as evidenced by: A. Based on review of blood bank maintenance logs from 7/1/2023 through 1/31/2025 and continuous-monitoring temperature charts for Blood Bank Refrigerator #3, used for storage of packed red blood cells, and the Plasma Freezer from 7/3/2023 through 1 /28/2025, the laboratory failed to document, as performed, quarterly blood bank refrigerator and plasma freezer temperature alarm checks, according to the laboratory's policy, for six of seven quarters from July 2023 through January 2025. Findings include: 1. Review of the blood bank maintenance logs from 7/1/2023 through 1/31/2025 revealed the laboratory's policy included a quarterly temperature alarm check for Blood Bank Refrigerator #3 and the plasma freezer, to be performed in the months of January, April, July, and October. 2. There was no documentation of a quarterly temperature alarm check for Blood Bank Refrigerator #3 or the plasma freezer for July and October 2023; April, July, and October 2024; and January 2025, according to laboratory policy. 3. Review of continuous-monitoring temperature charts for Blood Bank Refrigerator #3 and the plasma freezer revealed no temperature fluctuations on the temperature charts for these months, to indicate that alarm checks were performed. B. Based on review of Blood Bank Refrigerator #3 continuous-

	monitoring temperature charts from 7/3/2023 through 1/28/2025, Blood Bank Refrigerator #3 temperature logs, and blood bank transfusion records, the laboratory failed to ensure blood was stored under appropriate conditions for the weeks of 12/24 /2024 through 12/30/2024 and 1/13/2025 through 1/20/2025, when units of packed red blood cells (PRBC) were stored for transfusion. Findings include: 1. Review of Blood Bank Refrigerator #3 continuous-monitoring temperature charts from 7/3/2023 through 1/28/2025 revealed no temperature recorder graphs for the weeks of 12/24 /2024 through 12/30/2024 and 1/13/2025 through 1/20/2025. 2. Review of Blood Bank Refrigerator #3 temperature logs from 7/1/2023 through 1/31/2025 revealed the temperature of Blood Bank Refrigerator #3 was manually recorded on the logs only once per day, which did not ensure continuous storage under appropriate conditions. 3. Review of blood bank transfusion records for the weeks of 12/24/2024 through 12 /30/2024 and 1/13/2025 through 1/20/2025 revealed units of PRBC were stored for transfusion during this time frame.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. This STANDARD is not met as evidenced by: A. Based on review of Gem Premier 5000 Blood Gas analyzers (SN #22041624) and (SN #22041621) quality control and calibration records, confirmation by Respiratory Supervisor and Technical Consultant #2, listed on the CMS 209 personnel form and lack of documentation of comparison of results for blood gases (pH, pO2, pCO2) testing between both Gem Premier 5000 analyzers, the laboratory failed to evaluate the relationship between the results of blood gases performed using different methods, at least twice a year. Findings include: 1. Review of the Gem Premier 5000 Blood Gas analyzers (SN #22041624) and (SN#22041621) records from 7/10/2023 through 3/13 /2025, revealed no documentation of comparison of results for pH, pCO2 and pO2 testing between the two analyzers. 2. The Respiratory Supervisor and Technical Consultant #2 both confirmed that a comparison between both Gem Premier 5000 Blood Gas analyzers was not performed twice annually. Four of four evaluations were not performed since 6/22/2023. B. Based on review of the Profile V-Med Tox Scan DOA (drugs of abuse) system (SN #2919M1847) and (SN #1322M1909) quality control and records, confirmation by Technical Consultant #2 listed on the CMS 209 form and laboratory manager, and lack of documentation of comparison of results for drugs of abuse testing between both Med Tox DOA systems, the laboratory failed to evaluate the relationship between the results of DOA testing performed using different methods, at least twice a year. Findings include: 1. Review of the Med Tox DOA systems (SN #2919M1847) and (SN #1322M1909) records from 7/2/2023 through 1 /27/2025, revealed no documentation of comparison of results for amphetamine, barbiturates, benzodiazepine, cannabinoids, cocaine, methamphetamine, methadone, opiates, oxycodone, phencyclidine, propoxyphene and tricyclic antidepressants testing between the two analyzers since 8/3/2023. 2. The Technical Consultant #2 and laboratory manager both confirmed that a comparison between both MedTox DOA systems was not performed twice annually. Three of four evaluations were not performed since 6/22/2023. C. Based on review of verification of performance specifications for the Stago STA Compact MAX back-up coagulation analyzer (Serial

	#0000008590) performed at installation, interview with the laboratory manager, and lack of documentation of comparison of results for prothrombin time (PT), activated partial thromboplastin time (APTT), D-dimer, and fibrinogen testing between the Stago STA Compact MAX back-up coagulation analyzer and the Stago STA Compact MAX primary coagulation analyzer (Serial #CF79045261), the laboratory failed to evaluate the relationship between the results of PT, APTT, D-dimer, and fibrinogen testing using different methods, at least twice a year. Findings include: 1. Review of verification of performance specifications for the Stago STA Compact MAX back-up coagulation analyzer revealed a comparison of PT, APTT, D-dimer, and fibrinogen testing with the Stago STA Compact MAX primary coagulation analyzer was performed on 11/15/2023. 2. Review of records for the primary and back-up Stago STA Compact MAX coagulation analyzers from 11/15/2023 through 3/13/2025 revealed no documentation of comparison of results for PT, APTT, D-dimer, and fibrinogen testing between the two analyzers. Two of the two evaluations due in 2024 were not performed. 3. In an interview on 3/13/2025 at 3:20 p.m., the Laboratory Manager confirmed that there was no documentation of a comparison between the two Stago STA Compact MAX coagulation analyzers since 11/15/2023.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: A. Based on review of respiratory testing personnel (TP) as listed on the Centers for Medicare and Medicaid Services (CMS) 209 personnel form and interview with the General Supervisor (GS) and Respiratory Supervisor, the Technical Consultant (TC) failed to evaluate and document the performance of four of fourteen blood gas testing personnel at least semiannually during the first year of moderate complexity (blood gas) testing. Findings include: 1. Review of the respiratory (blood gas) personnel records since the last survey on 6/22/2023 revealed no semiannual competency evaluations were available for the performance of four of fourteen respiratory testing personnel. a. TP #15 initial training-07/19/2024, semiannual evaluation due-01/2025 b. TP #18 initial training-05/26/2023, semiannual evaluation due-08/2023 c. TP #19 initial training-06/26/2023, semiannual evaluation due-12/2023 d. TP #20 initial training-09/18/2023, semiannual evaluation due-03/2024 2. The General Supervisor and Respiratory Supervisor confirmed in an interview on 3/12/2025 at 3:00 p.m., there was no semiannual competency evaluations performed on TP #15, TP #18, TP #19 and TP #20 by the TC. B. Based on review of laboratory personnel records including the Centers for Medicare and Medicaid Services (CMS) 209 personnel form and interviews with the General Supervisor (GS) and Laboratory Manager, the Technical Consultant (TC) failed to evaluate and document the performance of two of nine testing personnel responsible for performing moderate complexity laboratory testing at least semiannually during the first year of employment. Findings Include: 1. Review of the laboratory personnel records since the last survey on 6/22/2023, revealed no semiannual competency evaluations were available for the performance of two of nine laboratory testing personnel. a. TP #11-initial training-5/17/2023; semiannual evaluation due-11/2023 b. TP #13-hire date 6/18/2024; semiannual

	evaluation due 12/2024 2. The General Supervisor and Laboratory Manager confirmed in an interview on 3/11/2025 at 2:30 p.m., there was no semiannual competency evaluations performed on TP #11 and TP #13 by the TC.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) (b)(9) Evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of laboratory personnel records including the Centers for Medicare and Medicaid Services (CMS) 209 personnel form and interviews with the General Supervisor (GS) and the Laboratory Manager, the Technical Supervisor (TS) failed to evaluate and document the performance of two of nine testing personnel responsible for performing high complexity laboratory testing at least semiannually during the first year of employment. Findings Include: 1. Review of the laboratory personnel records since the last survey on 6/22/2023, revealed no semiannual competency evaluations were available for the performance of two of nine laboratory testing personnel. a. TP #11-initial training-5/17/2023; semiannual evaluation due-11/2023 b. TP #13-hire date 6/18/2024; semiannual evaluation due 12/2024 2. The General Supervisor and Laboratory Manager confirmed in an interview on 3/11/2025 at 2:30 p. m., there was no semiannual competency evaluations performed on TP #11 and TP #13 by the TS.