Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D0029772	12/10/2024
Name of Provider or Supplier	**Street Address, City, State**	
Magee General Hospital	300 3rd Ave Se, Magee, 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
D3025	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(d) Investigation of transfusion reactions. The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities. This STANDARD is not met as evidenced by: Based on review of the facility's Blood Administration Policy, review of six patients' medical records, and interview with the facility's Quality Management Nurse, the facility failed to ensure that the Blood Administration Policy, for preventing transfusion reactions, was followed in the transfusion of fourteen units of packed red blood cells to six, of six, patients reviewed. Findings include: 1. The facility's Blood Administration Policy states, "Total sets of vital signs will include pre-transfusion; 15 minutes after transfusion begun; Document vital signs every 30 minutes until transfusion complete and 1 hour after end time." The policy also states, "At the completion of the transfusion, record the time the transfusion ended." 2. Review of six patients' medical records revealed vital sign checks included temperature, respirations, blood pressure, and oxygen saturation. 3. Review of the following six patients' medical records revealed the Blood Administration Policy was not followed when a total of fourteen units of packed red blood cells were transfused to the following six patients: Patient #1593047 transfused on 5/2/2023 1st Unit--#W0691-23-12358--After the transfusion began at 1:10 a.m., vital signs were documented at 1:25 a.m., 2:10 a. m., 3:10 a.m., and 4:10 a.m. Two of four, 30-minute vital sign checks were not documented. The completion of the transfusion was not documented, and vital signs at one hour after completion were not documented. 2nd Unit--#W0691-23-123549--After the transfusion began at 5:56 a.m., vital signs were documented at 6:15 a.m., 6: 29 a.m., and 8:00 a.m. Two of three, 30-minute vital sign checks were not documented. Patient #1610718 transfused on 10/1/2023 1st Unit--#W0691-23-

	145992B--After the transfusion began at 12:15 p.m., vital signs were documented at 12:30 p.m., 1:34 p.m., and 2:38 p.m. Two of four, 30-minute vital sign checks were not documented. 2nd Unit--#W0691-23-145992A--After the transfusion began at 2:40 p.m., vital signs were documented at 3:00 p.m., 3:45 p.m., and 4:45 p.m. One of two, 30-minute vital sign check was not documented. Patient #1619244 transfused on 12/8 /2023 1st Unit--#W0691-23-151684--After the transfusion began at 8:10 p.m., vital signs were documented at 8:29 p.m., 9:10 p.m., and 10:10 p.m. One of three, 30-minute vital sign check was not documented. 2nd Unit--#W0691-23-162184--After the transfusion began at 11:20 p.m., vital signs were documented at 11:40 p.m., 12:20 a.m., and 1:15 a.m. on 12/9/2023. One of three, 30-minute vital sign check was not documented. Vital signs at one hour after completion were not documented. Patient #1631546 transfused on 4/16/2024 1st Unit--#W0691-24-114220--After the transfusion began at 11:44 a.m., vital signs were documented at 12:00 p.m., 12:45 p. m., and 2:08 p.m. Two of four, 30-minute vital sign checks were not documented. 2nd Unit--#W0691-24-114220--After the transfusion began at 2:26 p.m., vital signs were documented at 2:45 p.m., 3:31 p.m., and 4:39 p.m. One of three, 30-minute vital sign check was not documented. Patient #1644618 transfused on 7/20/2024 1st Unit--#W0691-24-139106--After the transfusion began at 7:59 p.m., vital signs were documented at 8:44 p.m. The 15-minute vital sign check was not documented. Vital signs were not documented again until 9:50 p.m. One of three, 30-minute vital sign check was not documented. 2nd Unit--#W0691-24-138995--After the transfusion began at 11:45 p.m., vital signs were documented at 12:08 a.m., 12:58 a.m., and 2:27 a.m. on 7/21/2024. Three of five, 30-minute vital sign checks were not documented. 3rd Unit--#W0691-24-139103--The transfusion began at 3:39 a.m. on 7/21/2024, but no pre-transfusion vital signs were documented. A vital sign check was documented at 4:29 a.m. The 15-minute vital sign check was not documented. The unit was completed at 6:29 a.m. with no documentation of a vital sign check. Four of five, 30-minute vital sign checks were not documented. The post-transfusion vital sign check was documented at 7:55 a.m. Patient #1657744 transfused on 11/8/2024 1st Unit--#W0691-24-122097--After the transfusion began at 8:22 p.m., vital signs were documented at 8:37 p.m., 9:22 p.m., and 10:22 p.m. Two of four, 30-minute vital sign checks were not documented. 2nd Unit--#W0691-24-123783--After the transfusion began at 11:45 p.m., vital signs were documented at 11:57 p.m., 12:45 a.m., 1:45 a.m., and 2:15 a.m. One of two, 30-minute vital sign check was not documented. There was no documentation of the time of completion of this unit. 3rd Unit--#W0691-24-151374--After the transfusion began at 2:40 a.m., vital signs were documented at 3:33 a.m., 4:33 a.m., 5:25 a.m., 6:20 a.m., and 7:46 a.m. The 15-minute vital sign check was not documented, and three of seven, 30-minute vital sign checks were not documented. There was no documentation of the time of completion of this unit. 4. In an interview on 12/10/2024 at 9:30 a.m., the Quality Management Nurse confirmed there was no documentation of the missing vital sign checks.
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:
A. Based on direct observation, lack of documentation, and an interview with Technical Consultant (TC) #1 and TC #2 as listed on the Centers for Medicare and Medicaid Services (CMS) 209 form, the laboratory failed to monitor room temperature and define criteria for proper storage of blood collection tubes in an outpatient exam phlebotomy room. Findings include: 1. In direct observation on 12/9 /2024 at 10:30 a.m., the following blood collection tubes were stored in the outpatient phlebotomy room without temperature monitoring according to the manufacturer's instructions: a. 32 Red top clot activator tubes - lot #B240350 expiration date 10/31 /2025 b. 6 Purple top (EDTA) tubes - B2408347 expiration date 12/1/2025 c. 10 Green top (lithium heparin) tubes - B2405345 expiration date 8/31/2025 d. 18 Blue top (sodium citrate) tubes - B2402346 expiration date 4/1/2025 e. 7 flats Gold top (clot activator/gel separator) B4173403 expiration 5/31/2025 2. The Vacuette Tube manufacturer required storage temperature is 4-25 degrees Celsius(C) 3. The laboratory did not provide documentation that they monitored room temperature for proper storage of collection tubes. There was no thermometer in the outpatient collection room on the day of the survey. 4. TC #1 and TC #2 confirmed in an interview on 12/9/2024 at 10:30 a.m., the outpatient collection room temperature was not being documented and monitored. B. Based on direct observation, lack of documentation, and an interview with Technical Consultant (TC) #1 and TC #2 as listed on the Centers for Medicare and Medicaid Services (CMS) 209 form, the laboratory failed to monitor room temperature and define criteria for proper storage of blood collection tubes and Hematology reagents in the laboratory storage room. Findings Include: 1. In direct observation on 12/9/2024 at 10:30 a.m., the following blood collection tubes and Hematology reagents were stored in the laboratory storage room without temperature monitoring according to the manufacturer's instructions: a. 3 flats Blue top tubes - B2404346 expiration date 4/1/2025 b. 20 flats Red top tubes - B240733K expiration date 10/31/2025 c. 22 flats Green top tubes - B240433 expiration date 8/1/2025 d. 11 flats Purple top tubes - B240939 expiration date 1/1 /2026 e. 17 flats Red top tubes - B24073 EL expiration date 1/1/2026 f. 3 - Beckman Coulter DxH 690 Diluent lot# 3552820 expiration 3/20/2026 g. 1 - Beckman Coulter DxH 690 Cleaner lot# 3911595 expiration 9/25/2025 h. 6 - Beckman Coulter DxH 690 lyse lot# 4705006 expiration 11/28/2025 2. The Vacuette Tube manufacturer required storage temperature is 4-25 degrees C. 3. The DxH manufacturer's instructions require the rinse, diluent and lyse be stored at 2-25 degrees C. 4. The laboratory did not provide documentation that they monitored room temperature for proper storage of the Vacuette collection tubes and Beckman Coulter DxH Hematology reagents. There was no thermometer in the storage room to monitor temperatures on the day of the survey. 5. TC #2 confirmed in an interview on 12/9 /2024 at 10:30 a.m., the laboratory storage room temperature was not being documented and monitored. C. Based on direct observation, lack of documentation, and an interview with Technical Consultant (TC) #2 and General Supervisor (GS) #2 as listed on the Centers for Medicare and Medicaid Services (CMS) 209 form, the laboratory failed to monitor room temperature and define criteria for the Chemistry testing room/department. Findings Include: 1. In direct observation on 12/9/2024 at 10: 35 a.m., the following require room temperatures to be monitored: a. Vitros 7600 chemistry analyzer manufacturer's instructions requires an operating room temperature of 15-30 degrees C and relative humidity of 15-75 % b. Vitros 7600 cartridges/slides require room temperature of 18-28 degrees C before loading on the analyzer. c. BioRad Multiqual quality control (QC) material, liquid assay QC, diabetic QC, and calibration material all require a room temperature of 18-28 degrees C before use. d. Desiccant packs and Humidity packs both are to be stored at room

	temperatures of 15-30 degrees C with a relative humidity of 15-75 % according to the manufacturer's instructions. 2. The laboratory did not provide documentation that they monitored room temperature for the Chemistry room where the Vitros 7600 is stored and testing is performed. There was no thermometer in the Chemistry room to monitor temperatures on the day of the survey. 3. TC #2 and GS #2 confirmed in an interview on 12/9/2024 at 10:45 a.m., the Chemistry testing room temperature was not being documented and monitored.