Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D0320210	07/09/2024
Name of Provider or Supplier	**Street Address, City, State**	
Monroe Regional Hospital	400 S Chestnut St, Aberdeen, 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
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of the Medonic M Series hematology analyzer records including quality control, maintenance, and calibration records and confirmation with testing personnel (TP) #2 as listed on the Centers for Medicare and Medicaid Services 209 Personnel form, the laboratory failed to perform calibration on CBC (complete blood count) performed on the Medonic M Series every 6 months as required by the written laboratory procedure manual and instrument manufacturer for 1 of 4 calibrations due since the last survey.. Findings include: 1. Review of the Medonic M Series calibration records revealed calibration was performed on 1/6/2023, 7/11/2023 and 7/10/2024. 2. Review of the Medonic M Series calibration records revealed 1 of 4 calibrations from 12/6/2022 to 7/11/2023 was not performed every 6 months as required by the manufacturer. 3. Interview with the TP #2 on 7/11/2024 at 12:00 p.m confirmed CBC calibrations were not performed every 6 months for 1 of 4 calibrations required..
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 Stratus CS STAT analyzer records, to include calibration and QC (quality controls), lack of documentation and interview with testing personnel (TP) #2, the laboratory failed to perform calibration verification on the Stratus CS analyzer every 6 months for ProBNP, D-dimer and Troponin for three of three six-month calibration verifications. Findings include: 1. Review of the Stratus CS records from 12/7/2022 through 7/11/2024, revealed calibration verification had not been performed every 6 months according to manufacturer's instructions. The last documentation of calibration verification/linearity performed on the Stratus CS was on 1/27/2023. 2. Calibration verification is required every 6 months on any assay which is calibrated with less than 3 levels of calibration material. These 3 tests mentioned only have 1 or 2 calibrators provided by the manufacturer to use during calibration for ProBNP, D-dimer and Troponin. 3. The TP #2 confirmed in an interview on 7/11/2024 at 1:00 p.m. that calibration verification was not performed at the appropriate time frame or frequency during the period of 12/7/2022 through 7/11 /2024. Three of three six-month calibration verifications required were not performed and exceeded the 6-month time frame required by the manufacturer.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: A. Based on review of quality control (QC) records for the Sysmex CA 600 Coagulation analyzer and patient test logs, the laboratory failed to ensure at least 2 levels of QC (quality control) material met the laboratory and manufacturer's criteria

	for acceptability before reporting patient test results. Findings Include: 1. Review of the Sysmex CA 600 records (including QC patient logs and QC/patient analyzer printouts) from 1/1/2023 through 6/27/2024 revealed on the following days one or both levels (Level 1 and Level 3) of PT(prothrombin time) and PTT (partial prothrombin time) QC was outside of acceptable range: 3/17/2023, 3/20/2023, 3/21 /2023, 3/22/2023, 5/4/2023, 5/6/2023, 5/7/2023, 6/8/2023, 6/27/2023, 6/29/2023, 7/25 /2023, 7/27/2023, 10/5/2023, 10/13/2023, 10/21/2023, 10/23/2023, 11/9/2023, 12/12 /2023, 1/14/1024, 1/18/2024, 3/26/2024 2. Review of the retained patient PT/ PTT and QC logs along with the analyzer patient results and QC printouts revealed approximately 25 patient PT and PTT tests reported on the days listed and QC was not in manufacturers and laboratory range. B. Based on review of QC records for the Stratus CS STAT fluorometric analyzer, QC assay sheets, patient test logs and analyzer printouts, the laboratory failed to ensure at least 2 levels of QC material met the laboratory and manufacturer's criteria for acceptability before reporting patient test results. Findings Include: 1. Review of the Stratus CS analyzer records (including QC and patient test logs, analyzer printouts, QC assay sheets) from 1/1/2023 through 6/30 /2024, revealed one or both levels (Level 1 and Level 2) of D dimer, ProBNP, and Troponin were out of acceptable range on thr following days: Troponin I---------- 04/04/2024 - 1 patient tested 04/06/2024 - 1 patient tested 04/08/2024 - 1 patient tested 04/11/2024 - 2 patients tested 04/12/2024 - 2 patients tested 04/25 /2024 - 2 patients tested 04/26/2024 - 3 patients tested 04/28/2024 - 3 patients tested 04/29/2024 - 3 patients tested 05/06/2024 - 4 patients tested 05/09/2024 - 5 patients tested 05/10/2024 - 4 patients tested 05/11/2024 - 4 patients tested 05/20/2024 - 5 patients tested 05/23/2024 - 1 patient tested 05/24/2024 - 2 patients tested 05/25/2024 - 2 patients tested 05/26/2024 - 4 patients tested 05/27/2024 - 2 patients tested 05/28 /2024 - 2 patients tested 05/29/2024 - 4 patients tested 05/31/2024 - 2 patients tested 06/01/2024 - 1 patient tested D dimer---------- 04/26/2024 - 1 patient tested 05/11/2024 - 1 patient tested 05/20/2024 - 2 patients tested 05/26/2024 - 2 patients tested 05/27/2024 - 2 patients tested 05/28/2024 - 1 patient tested 05/29/2024 - 1 patient tested 06/01/2024 - 1 patient tested ProBNP---------- 04/04/2024 - 3 patients tested 04/12/2024 - 2 patients tested 05/06/2024 - 1 patient tested 05/10/2024 - 5 patients tested 05/11/2024 - 2 patients tested 05/20/2024 - 1 patient tested 05/22 /2024 - 1 patient tested 05/23/2024 - 4 patients tested 05/28/2024 - 5 patients tested 05 /29/2024 - 3 patients tested 05/31/2024 - 3 patients tested 06/01/2024 - 2 patients tested
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (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. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of Immunohematology (blood bank) records and Jewett temperature graphs from 12/7/2022 through 7/11/2024, the laboratory failed to follow the manufacturer's instructions for equipment operation. Findings Include: 1. Review of the Immunohematology records and Jewett recorder graphs revealed the laboratory failed to change the temperature recorder graphs every seven days (according to

	manufacturer's instructions) as follows: 03/07/2023 through 03/20/2023 03/20/2023 through 03/30/2023 04/06/2023 through 04/14/2023 04/21/2023 through 05/01/2023 05/01/2023 through 05/10/2023 05/10/2023 through 05/18/2023 05/18/2023 through 05/30/2023 06/06/2023 through 06/14/2023 06/14/2023 through 06/22/2023 07/04 /2023 through 07/21/2023 07/12/2023 through 07/26/2023 07/26/2023 through 08/03 /2023 08/31/2023 through 09/09/2023 09/08/2023 through 09/19/2023 10/29/2023 through 10/27/2023 12/11/2023 through 12/20/2023 01/02/2024 through 01/10/2024 06/12/2024 through 06/20/2024 06/20/2024 through 06/28/2024 2. Review of blood bank Jewett refrigerator graphs revealed 19 of 80 weeks the refrigerator graphs were not removed at seven days required by the manufacturer's instructions.
D6049	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: Based on review of Respiratory department testing records, policy and procedure manual and interview with the blood gas testing personnel (TP) #8/Respiratory Supervisor, the Technical Consultant (TC) failed to document review of the Radiometer ABL 80 Co-Ox Flex Quality Controls(QC), calibration verification records and room temperature logs for 13 of 13 months. Findings Include: 1. Review of respiratory department records from 6/2/2023 through 7/8/2024 revealed no documentation of review by the TC for the following records: a. Respiratory department temperature logs (room) since 6/2/2023 (13 of 13 months) b. Radiometer ABL 80 Co-Ox Flex calibration verification (linearity) since the last survey. 4 of 4 not reviewed. c. Radiometer ABL 80 Co-Ox Flex QC from 6/2/2023 through 7/8/2024 (13 of 13 months) 2. Interview with TP #8/Respiratory Supervisor on 7/11/2024 at 3:00 p. m. confirmed there was no available documentation of review of these records by the Technical Consultant.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for 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: 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 Laboratory Manager and Respiratory Supervisor, the Technical Consultant (TC) failed to evaluate and document the performance of three of eleven blood gas testing personnel at least semiannually during the first year of moderate complexity testing. Findings include: 1. Review of the respiratory (blood gas) personnel records since the last survey on 12/7/2022 revealed no semiannual evaluation available for the performance of three of eleven testing personnel. a. TP #15 initial training-09/29 /2022, semiannual evaluation due-03/2023 b. TP #16 initial training-05/08/2023, semiannual evaluation due-11/2023 c. TP #17 initial training-07/16/2023, semiannual

	evaluation due-01/2024 2. The Laboratory Manager and Respiratory Supervisor confirmed in an interview on 7/11/2024 at 3:00 p.m., there was no 6-month evaluation /competency performed on TP #15, TP#16 and TP#17. 3. The TC failed to document 6-month competency evaluations on three of eleven blood gas testing personnel since the last survey.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of testing personnel (TP) as lsited on the Centers of Medicare and Medicaid Services (CMS) 209 personnel form, and interview with the Laboratory Manager and Respiratory Supervisor, the Technical Consultant failed to evaluate the performance for ten of eleven blood gas testing personnel, at least annually. Findings include: 1. Review of the Respiratory (blood gas) personnel records since the last survey on 12/7/2022 revealed no annual competency/evaluations of performance for ten of eleven blood gas testing personnel listed. a. TP #8 - competency /evaluation for 2023 and 2024 b. TP #9 - competency /evaluation for 2023 and 2024 c. TP #10 - competency /evaluation for 2023 and 2024 d. TP #11 - competency /evaluation for 2023 and 2024 e. TP #12 - competency /evaluation for 2023 f. TP #13 - competency /evaluation for 2023 and 2024 g. TP #14 - competency /evaluation for 2023 and 2024 h. TP #15 - competency /evaluation for 2023 i. TP #16 - competency /evaluation for 2024 j. TP #18 - competency /evaluation for 2023 and 2024
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for 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 testing personnel (TP#2), the Technical Supervisor (TS) failed to evaluate and document the performance of testing personnel # 4 responsible for performing high complexity (blood bank) testing at least semiannually during the first year of employment. Findings Include: 1. Based on the laboratory personnel records available for review on 7/11/2024, there was no semiannual competency on high complexity testing performed by the Technical Supervisor for TP #4 since the last survey. One of one new laboratory testing personnel had not had a semiannual evaluation/competency. 2. Interview with the GS and TP#2 confirmed the semiannual competency/evaluation for moderate and high complexity had not been documented as perfomed by the TS. 3. According to the personnel records for TP #4 the initial laboratory training was 6/20/2022. The semiannual competency should have been performed on 12/2022.

D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of laboratory testing personnel (TP) as listed on the Centers for Medicare and Medicaid Services (CMS) 209 personnel form and interviews with the General Supervisor/TP#1 and TP#2, the evaluations for high complexity were either not signed by the Technical Supervisor(TS) or not performed for seven of seven testing personnel. Findings include: 1. Review of the laboratory personnel records available on 7/11/2024 revealed no annual evaluations/competencies for Immunohematology were performed by the TS for the following individuals listed on the CMS 209 form: TP #1- for the years 2023 and 2024 TP #2- for the year 2024 TP #3- for the year 2024 TP #4- for the year 2023 TP #5- for the year 2023 TP #6- for the years 2023 and 2024 TP #7- for the years 2023 and 2024 2. Interview with both General Supervisor/TP#1 and TP#2 on 7/11/2024 at 3:00 p.m. confirmed the annual evaluation/competencies for moderate/high complexity testing (one form) had not been documented as performed by the Technical Supervisor listed on the CMS 209 form. Seven of seven laboratory testing personnel did not have annual evaluations /competencies. THIS IS A REPEAT DEFICIENCY