Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0469307	05/01/2025
Name of Provider or Supplier	**Street Address, City, State**	
Mercy Hospital Booneville	880 West Main Street, Booneville, AR	

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
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: Based upon a review of the laboratory's policy and procedure manual, lack of documentation, and interview with laboratory staff, it was determined that the laboratory failed to follow written policy and procedure for specimen collection, specimen labeling, and specimen storage and processing. Findings follow: A) During review of the laboratory's policy and procedure manual the surveyor found a policy named "MW LABQ Mercy Lab Quality Management System" which stated: "Each area in which specimens are collected and or processed has written procedures for: Specimen collection, labelling and preservation; Ensuring patient identification at the time of specimen collection; Specimen packaging and transport; Registration/order rejection; Specimen rejection and suboptimal specimens; Acceptance from authorized source; Variance and/or SAFE reporting; Add on functions." B) Upon request, the laboratory was unable to show policies at each draw station. C) In an interview on 4/29 /25 at 2:03pm, when asked if their were written policies governing specimen collection, labeling, storage and processing, at each collection point; the General Supervisor confirmed there were not.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a)

	(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of laboratory policies and procedures for chemistry, a review of the chemistry lot changeover records, and interviews with laboratory staff, the laboratory failed to follow written procedures for Chemistry standard deviation (SD) range calculation. Survey findings include: A) The laboratory chemistry QC policy named "BNVAR LABQ Quality Control for Chemistry Policy" states: "Unassayed Material is run to accumulate a minimum of 20 data points to establish our inhouse mean and standard deviation. This study is performed before the supply of the previous lot number is exhausted." B) A review of the chemistry lot changeover records from May of 2024 showed data for 20 samples of a new lot being ran prior to use. The documentation included a note stating "Keep your current SD. As far as range - after your run your samples, find the mean of each one. From your mean, use your current SD to find your range for each." This note was initialled by the previous lab director. C) Upon request, there was no documentation provided of ranges being calculated for the new lot. D) In an interview, at 3:01pm on 4/30/25, the General Supervisor confirmed that SD ranges weren't calculated during the May 2024 lot changeover.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 upon observation, review of temperature and humidity records, lack of documentation and interview; the laboratory failed to monitor the temperature and humidity of freezers, refigerators, and rooms on each day of operation in which supplies and instruments with storage temperature requirements were located. Findings follow: A) During a tour of the laboratory on 4/29/25 at 9:32am., the surveyor observed a main laboratory room containing laboratory items with temperature and humidity storage/operation requirements (examples include a Sysmex xn430 and cobas 311 along with their reagents), as well as freezers and refigerators containing reagents with temperature requirements. B) A review of the laboratory's complete 2024 temperature and humidity records revealed that temperatures were not recorded for the "Summit Freezer" on January 28, July 20, December 1, 7, 8, and 13. Temperatures were not recorded for the "Dandy Freezer" on July 20. Temperatures were not recorded for the "Reagent Refrigerator" on July 20, September 19, and December 1. Laboratory Humidity was not recorded on December 1. C) In an

	interview on 5/1/25 at 09:20 a.m, the laboratory general supervisor confirmed that temperature humidity records for the above dates were not recorded, and there was no quality assurance remediation.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. This STANDARD is not met as evidenced by: Based on a review of the laboratory policy and procedure "Hematology Analyzer Quality Control Policy", Levey-Jennings (LJ) Reports for October 2024, December of 2024, January 2025, and February of 2025 for Mean Corpuscular Volume (MCV) hematology analysis, and through interviews with laboratory staff; the laboratory failed to monitor, over time, the accuracy of hematology test results. Survey findings include: A) A review of the "Hematology Analyzer Quality Control Policy" revealed a policy stating " Quality Control is printed off monthly and reviewed by the lab director to determine if any shifts or trends are identified." B) A review of the 10/8/24 through 11/5/24 Sysmex XN-L Levey-Jennings charts for QC-42651401 XN-L Control level 1, QC-42651402 XN-L Control level 2, and QC-42651403 XN-L Control level 3, showed MCV values above the mean for each day. A review of the 12 /1/24 through 12/31/24 Sysmex XN-L Levey-Jennings charts for QC-42651401 XN-L Control level 1, QC-42651402 XN-L Control level 2, and QC-42651403 XN-L Control level 3, showed MCV values above the mean for each day. A review of the 1/1 /25 through 2/28/25 Sysmex XN-L Levey-Jennings charts for QC-43491401 XN-L Control level 1, QC-43491402 XN-L Control level 2, and QC-43491403 XN-L Control level 3, showed MCV values above the mean for each day. C) A review of the quality assurance records for 2024 and 2025 found no mention of shifts in MCV analysis. D) Upon request, the laboratory was unable to provide documentation of corrective action taken to address shifts in MCV analysis. E) In an interview, at 5/1/25 at 9:48am, the general supervisor confirmed the shifts were present without documented corrective actions.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control

	materials having previously determined statistical parameters. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure for Quality Control (QC) program, Levey-Jennings Chemistry Quality Control (QC) reports for November 2024 and February 2025, and interview with laboratory staff; the laboratory did not establish acceptable ranges by the use of appropriate statistical methods. This is a repeated deficiency cited at the last CLIA survey conducted on 7/31/23. Survey findings follow: A) Review of the laboratory's procedure for Chemistry QC revealed that acceptable QC is based upon Standard Deviations (SD) from the established mean with unacceptable QC results being any value greater than 2 or 3 SD from the mean /target value. B) Review of the November 2024 and February 2025 "Levey-Jennings Reports" for clinical chemistry assays using Biorad Multi-Qual QC material Lot # 92971 revealed that all values showed a distribution from the target value with all points less than one SD, and SD's utilized for QC being greater than the actual SD's experienced. For example: For February 2025 Creatinine Level 1, the SD Utilized for acceptable range is 0.4, Actual SD Calculated during that month is 0.04 For November 2024 Creatinine Level 1, the SD Utilized for acceptable range is 0.4, Actual SD Calculated during that month is 0.03 For February 2025 Direct Bilirubin Level 1, the SD Utilized for acceptable range is 0.7, Actual SD Calculated during that month is 0.025. For Novemeber 2024 Direct Bilirubin Level 1, the SD Utilized for acceptable range is 0.7, Actual SD Calculated during that month is 0.012. For February 2025 Magnesium Level 2, the SD Utilized for acceptable range is 1.9, Actual SD Calculated during that month is 0.12. For November 2024 Magnesium Level 2, the SD Utilized for acceptable range is 1.9, Actual SD Calculated during that month is 0.14. C) In an interview on 4/30/25 at 1:35 pm the general supervisor confirmed the above ranges were in use.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure, review of selected quality control Levy-Jennings charts from October 2024 through February 2025, review of QA review notes, lack of documentation, and interview it was determined that the laboratory failed to follow written policy when the QC control data met the labs definition of a shift. Findings follow: A) Review of the laboratory's policy and procedure for "BNVAR LAB Quality control - Shifts and Trends" revealed that "A shift occurs when all quality control results are on one side of the mean consecutively for 5 to 7 days. A trend occurs when quality control results increase or decrease consistently for 5 to 7 days." " Shifts and trends must be documented by noting in the corrective action whether there have been reagent lot or instrument changes or whether scheduled or unscheduled maintenance has been done." B) Review of Sysmex XN-L Levey-Jennings charts for 10/8/24 through 11/5/24 showed MCV values above the mean for each day. A review of the Sysmex XN-L Levey-Jennings charts for showed 12/1/24 through 12/31/24 showed MCV values above the mean for each day. A review of the Sysmex XN-L Levey-Jennings charts for 1/1/25 through 2

	/28/25 showed MCV values above the mean for each day. C) Upon request, the laboratory was unable to provide documentation that the shift identified above had been documented according to laboratory policy. D) In an interview, at 5/1/25 at 9: 48am, the general supervisor confirmed the shift was present without documented corrective actions.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on a review of facility records and staff interviews, it was revealed the laboratory director failed to provide overall management for the laboratory (refer to citations at D6093, and D6095).
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interviews it was determined that the Laboratory Director failed to ensure that quality control programs were maintained to assure the quality of testing and identify failures in quality as they occur. Cross refer to D5401, D5413, D5441, D5469, and D5791 Findings include: A) The laboratory director failed to ensure temperature and humidity were recorded for areas housing temperature and humidity sensitive reagents and instruments. B) The laboratory director failed to ensure trends in quality control were addressed in a manner consistent with laboratory policy. C) Calculation of SD ranges for all chemistry controls did not follow established written procedure. D) SD ranges for Magnesium, Creatinine, and Direct Bilirubin were too large to ensure accurate function of the intrumentation from October 2024 through February 2025.