Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D2070630	04/29/2022
Name of Provider or Supplier	**Street Address, City, State**	
Mercy Bella Vista	1 Mercy Way, Bella Vista, 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
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Through a review of the IQCP (Individualized Quality Control Plan) for Arterial Blood Gas (ABG) testing performed on the Istat analyzer it was determined the IQCP was missing the required element of frequency of external quality control performance. Survey findings include: A. The laboratory performs moderate complexity ABG analysis using the Istat analyzer . B. The laboratory developed an IQCP for the tests performed on the Istat analyzer in order to perform quality control at a less frequent interval than required by CLIA regulation. A review of the IQCP revealed that it was missing the frequency of external quality control testing. C. In an interview, at 09:15 a.m. on 4/29/22, laboratory employee #1 (as listed on the form CMS-209) confirmed the IQCP did not specify the frequency of external QC performance.
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: Through review of the Blood bank refrigerator and fresh frozen plasma freezer temperature recording charts, lack of documentation and interview it was determined that the laboratory could not document proper storage temperature requirements were maintained on 17 of 17 occasions when the storage temperature for blood and blood components could not be confirmed on the temperature recording charts. Findings follow: A) Review thirty-five (August 1, 2021 to April 1, 2022) weeks of the temperature recording charts for the blood storage refrigerator and the fresh frozen plasma storage freezer revealed that temperature records were not recorded on three occasions when the recording pen failed on the blood storage refrigerator and four occasions on the blood plasma storage freezer and that temperatures were recorded on ten occasions with unacceptable readings (reading 0 degrees C.) when the pen was inapropriately calibrated on the blood storage refrigerator . B) Upon request, the laboratory was unable to provide documentation of actual temperature readings on the occasions identified above. C) In an interview on 4/28/22 at 03:35 PM the laboratory staff members, identified as numbers one and two on the CMS 209 form , confirmed that the laboratory could not document proper storage temperatures for the blood storage refrigerator and the fresh frozen plasma freezer for the periods identified above.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: . Through review of quality control (QC) policy and procedure , QC results for September 2021, patient result reports, lack of documentation and interviews with laboratory staff it was determined that the laboratory failed to evaluate patient results back to the last successful performance of QC, on one of one occasions when QC failed criteria for acceptability for (ALT) analysis. Findings follow: A) Review of the laboratory policy and procedure revealed that action is to be taken when QC fails criteria for acceptability and stated when any control is outside the acceptable range do not report patient results. B) Review of QC records for (ALT) test for September 2021 revealed that on 9/29/21 at 11:30 PM Biorad Level 1 Control lot # 45890 with acceptable limits of 25.16 to 28.09 was resulted as 25.01 which was greater than minus 2 standard deviations (SD) from the target value and Biorad level 3 Control with acceptable limits of 175.91 to 186.91 was resulted as 175.0 which was greater than minus 2 SD from the target value. C) Review of documentation of corrective action for the event identified above revealed that the test system had been

	recalibrated which indicated a change in the test system operation. D) Review of QC results revealed the previous acceptable QC results for ALT testing was performed on 9/28/21 at 11:30 PM. E) Review of patient result reports revealed that a ALT tests were performed and reported on 11 patients between 9/28/21 after 11:30 PM and 9/29 /21 before 11:30 PM. F) Upon request, the laboratory was unable to provide documentation that the patients identified above with ALT results performed and resulted had been evaluated. G) In an interview on 4/29/22 at 09:15 AM the laboratory staff member, identified as number one on the CMS 209 form, confirmed that the ALT tests performed on 9/29/21 had not been evaluated and should have been.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Through a review of personnel records for ten testing personnel, a lack of documentation, an interview with laboratory staff, it was determined the laboratory director failed to give written authorization for four of ten testing personnel to perform testing without direct supervision. Survey findings follow: A) A review of personnel records for ten testing personnel reviewed revealed that four of ten (# 3, # 13, # 15, and # 18) as listed on the CMS-209) failed to have the laboratory director's written authorization to perform testing in their records. B) Upon request, the laboratory was unable to provide written authorization to perform testing for testing personnel, identified as numbers 3, 13, 15, and 18 on the CMS 209 form, signed by the laboratory director. C) In an interview, at 2:12 p.m. on 4/28/2022, laboratory employee # 1 (as listed on theCMS-209 form) confirmed the lack of written authorizations for employees # 3, # 13, # 15 and # 18.