Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D1047148	05/31/2024
Name of Provider or Supplier	**Street Address, City, State**	
Mcbride Orthopedic Hospital	9600 Broadway Ext, Oklahoma City, OK	

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
D0000	The recertification survey was performed on 05/28, 29, 30, 31/2024. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with technical consultant #2 and technical consultant #5 at the conclusion of the survey.
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 a review of records, the general nursing policy and interview with general supervisor #1, the facility failed to ensure written policies were followed for preventing transfusion reactions for one of nine units reviewed. Findings include: (1) On 05/29/2024 at 2:30 pm, general supervisor #1 stated that the laboratory performed Crossmatch Testing, which consisted of ABO/Rh, Antibody Screen, and Compatibility testing (performed between the patient and red blood cell donor unit (s)); (2) The policy "Administration of Blood Products" defined the parameters for ensuring blood products are transfused safely; (3) The surveyor reviewed the policy which stated, "The blood must be transfused within four hours of check-out from the lab"; (4) A review of transfusion records for nine units of blood transfused with general supervisor #1 identified for one of nine units transfused, the policy was not followed by nursing personnel: (a) Unit #W091024151058 - The unit was checked out from the blood bank at 09:25 am and was completed at 1:30 pm, exceeding the four hour window. (5) Interview with general supervisor #1 on 05/29/2024 at 02:30 pm confirmed the facility failed to ensure the policy was being followed as written.

D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of records, written policies, and interview with technical consultant #2 and technical consultant #5, the laboratory failed to establish a written technical consultant, technical supervisor, and general supervisor competency assessment policy, based on the position responsibilities as listed in the Subpart M. Findings include: (1) A review of the policy titled, "Laboratory Personnel Competency Assessment" and interview with technical consultant #2 and technical consultant #5 on 05/29/2024 at 09:25 am identified the policy did not define the specific responsibilities based on each position for the technical consultant, technical supervisor, and general supervisor; (2) A review of Form CMS-209 (Laboratory Personnel Report) and personnel records for competency assessments performed during the review period of May 2022 through the current date identified no documentation competency assessments had been performed based on position responsibilities for four of four technical consultants, four of four general supervisors, and one of one technical supervisor; (3) The findings were reviewed with technical consultant #1 and technical consultant #5 on 05/29/2024 at 09:30 am, who confirmed the laboratory failed to define and perform assessments based on the specific position responsibilities.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(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 policies and procedures and interview with technical consultant #2, technical consultant #4, and technical consultant #5, the laboratory failed to have a written procedure that explained the current practices and procedures for one of four procedure reviewed. Findings include: (1) On 05/30/2024 at 02:57 pm, technical consultant #4 stated the laboratory began testing arterial and venous blood gas (pH, pO2, and pCO2) on the i-STAT analyzer (Serial Number 406592) using the CG4+ cartridges on 07/10/2023; (2) A review of the policy titled, "I-STAT PROCEDURE" stated the G3+ cartridge was used for blood gas testing instead of the CG4+ cartridge; (3) The findings were reviewed with technical consultant #2, technical consultant #4, and technical consultant #5, who stated on 05/30/2024 at 03:00 pm, the I-STAT procedure had not been revised to include the CG4+ cartridge.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system

	must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #2, technical consultant #4, and technical consultant #5, the laboratory failed to utilize the demonstrated reportable range for one of one new test method. Findings include: (1) On 05/30/2024 at 02:57 pm, technical consultant #2, technical consultant #4, and technical consultant #5 stated the laboratory began performing pH, pCO2 and pO2 using the CG4+ cartridge and i-STAT1 analyzer (Serial Number 406952) on July 10, 2023; (2) A review of the performance specification records identified the laboratory had demonstrated the following reportable range: (a) pCO2 - 20.0-103.1 mm/Hg (3) Interview with technical consultant #2 and technical consultant #5 on 05/30/2024 at 03:33 pm confirmed the laboratory was using the previous test method's reportable range for the analyzer instead of the reportable ranges that had been demonstrated by the laboratory: (a) pCO2 - 5-130 mm/Hg
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 a review of records and interview with technical consultant #2, technical consultant #4, and technical consultant #5, the laboratory failed to perform calibration verification procedures at least once every six months for one of four i-STAT1 test system during the review period of 04/15/2022 through the current date. Findings include: (1) On 05/30/2024 at 01:45 pm, technical consultant #2, technical consultant #4, and technical consultant #5 stated the laboratory performed Troponin I testing

	using the cTnI cartridge on the i-STAT 1 analyzer: (2) A review of records from 04/15 /2022 through the current date identified no evidence the calibration verification procedures had been performed between 04/15/2022 and 07/05/2023 for the cTnI test system; (3) The findings were reviewed with technical consultant #2, technical consultant #4, and technical consultant #5 who stated on 05/30/2024 at 02:00 pm, the calibration verification procedures had not been performed every six months as stated above.