Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D1047148	03/28/2018
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 survey was performed 3/26/18 through 3/28/18. The findings were reviewed with the director of laboratory services at the conclusion of the survey.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on a review of records and interview with the director of laboratory services, the laboratory failed to verify the accuracy of testing when the proficiency testing program did not evaluate submitted results. Findings include: (1) On the first day of the survey, the surveyor reviewed 2016 and 2017 proficiency testing records and identified the following had not been evaluated by the proficiency testing program: (a) Cardiac Markers (i) CAR-A 2016 Event (aa) 1 of 5 Troponin I, quant CR-05 (b) General Chemistry/Therapeutic Drugs (i) C-A 2017 Event (aa) 5 of 5 LDL Cholesterol, calc CHM-01, CHM-02, CHM-03, CHM-04, CHM-05 (bb) 5 of 5 Iron Saturation % CHM-01, CHM-02, CHM-03, CHM-04, CHM-05 (c) Ligand Assay - General (i) K-A 2017 Event (aa) 1 of 2 Vitamin B-12 K-02 (d) Diagnostic Immunology (i) S-B 2017 Event (aa) 1 of 2 CRP, quant CRP-03 (2) The surveyor further reviewed the records and could not locate documentation verifying the laboratory had performed a self-evaluation of the non-graded results; (3) The surveyor asked the director of laboratory services if the results had been documented as evaluated. The director of laboratory services reviewed the records and stated the non-graded results had not been documented as reviewed.

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: Based on a review of records, manufacturer's instructions, and interview with the director of laboratory services, the laboratory failed to ensure analyzers was stored as required by the manufacturer. Findings include: HEMATOLOGY (1) At the beginning of the survey, the director of laboratory services stated the following to the surveyor: (a) CBC (Complete Blood Count) testing was performed on the Sysmex XT 1800i analyzer; (b) Routine Chemistry testing was performed on the Ortho Vitros 5600 analyzer; (c) Coagulation testing was performed on the Sysmex CA-540 analyzer. (2) On the second day of the survey, the surveyor reviewed the manufacturer's environmental requirements for the analyzers. The manufacturer's required the relative humidity be maintained as follows: (a) Sysmex XT-1800i within the range of 45-85% (b) Ortho Vitros 5600 within the range of 15-60% (c) Sysmex CA-540 within the range of 30-80% (3) The surveyor reviewed laboratory humidity records from September 2017 through the second day of the survey, which verified the humidity readings were less than 45% (minimum to accommodate all analyzers) for 7 of 7 months as follows: (a) September 2017- 2 of 30 humidity readings were documented as less than 45% (days 6,7); (b) October 2017 - 17 of 31 humidity readings was documented as less than 45% (days 2,8,10,11,16,17,18,19,23,24,25,26,27,28,29,30,31); (c) November 2017 - 25 of 30 humidity readings were documented as less than 45% (days 1,2,3,4,6,7,8,9,10,11,13,16,18,19,20,21,22,23,24,25,26,27,28,29,30); (d) December 2017 - 30 of 31 humidity readings was documented as less than 45% (days 1,2,3,5,6,7,8,9,10,11,12,13,14,15,16,17,18,19,20,21,22,23,24,25,26,27,28,29,30,31); (g) January 2018 - 31 of 31 humidity readings were documented as less than 45% (h) February 2018 - 28 of 28 humidity readings was documented as less than 45% (i) March 2018 - 27 of 27 humidity readings was documented as less than 45% (4) The surveyor reviewed the records with the director of laboratory services who stated the humidity of the laboratory had been maintained below 45% as indicated above.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on a review of records and interview with the director of laboratory services, the laboratory failed to ensure reagents had not exceeded their expiration date. Findings include: (1) At the beginning of the survey, the immunohematology general

	supervisor verified to the surveyor Crossmatch testing was performed in the laboratory which included: (a) ABO Typing and Antibody Screen using the Ortho ID-MTS gel system (2) On the second day of the survey, the surveyor reviewed quality control (QC) and patient testing records for 6 months (September 2017 through February 2018). It was identified that expired Affirmagen (used for reverse ABO typing) and Surgiscreen (used for Antibody Screen testing) had been used during 1 of 6 months reviewed: (a) Affirmagen lot #8A689, expiration date of 10-10-17 and Surgiscreen lot #V55939, expiration date of 10/10/17 had been used to perform QC and patient testing on 10/11/17 and 10/12/17; (3) The surveyor reviewed the records with the director of laboratory services and immunohematology general supervisor who stated expired reagents had been used as indicated above;
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the director of laboratory services and hematology supervisor/technical consultant #2, the laboratory failed to ensure equipment maintenance was performed as required by the manufacturer. Findings include: (1) At the beginning of the survey, the director of laboratory services stated to the surveyor CBC (Complete Blood Count) testing was performed on the Sysmex XT-1800i analyzer; (2) The surveyor reviewed records from June 2017 through February 2018 (9 months) of manufacturer's maintenance logs for the analyzer with the following identified: (a) Daily - Execute Shutdown (i) The daily maintenance procedures had not been documented as performed: (aa) June 2017 - Days 2,9,11,16,23,28,29 (bb) September 2017 - Days 4,28 (cc) November 2017 - Day 27 (b) Monthly - Clean sampler right rack pool, left rack pool, analysis line, and sample rack (i) The monthly maintenance procedure had not been documented as performed between the following: (aa) 11/03/17 and 01/5/18 (3) The surveyor reviewed the records with the director of laboratory services and hematology supervisor/technical consultant #2 who stated there was no evidence the above maintenance had been documented as performed.
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: Based on a review of records and interview with the director of laboratory services, the laboratory failed to ensure corrective actions were taken when quality control was

	not performed; and failed to evaluate patient test results obtained when quality control was not performed to determine if the results had been adversely affected. Findings include: (1) On the first day of the survey, the director of laboratory services stated the following to the surveyor: (a) BNP (B-Type Natriuretic Peptide) testing was performed in the Abbott iSTAT analyzer utilizing the BNP cartridge; (b) Two levels of quality control materials were tested monthly, according to the laboratory IQCP (Individualized Quality Control Plan); (c) The results for two levels of control materials must be acceptable in order to report patient results. (2) On the second day of the survey, the surveyor then reviewed BNP quality control records for testing performed from December 2017 through March 2018. For the review period, the following was identified for lot #B17270: (a) Level 1 control results could not be located for January 2018; (b) Level 3 control results could not be located for January 2018; (3) The surveyor asked the director of laboratory services for Lot# B17270 level 1 and Level 3 control results. The director of laboratory services stated BNP monthly quality controls for level 1 and level were not performed in January 2018; (4) The surveyor obtained examples of patient BNP testing performed from 01/08/18 - 01 /27/18, with BNP results reported when there was no evidence that two levels of controls were performed. They were: (a) Patient testing performed on 01/08/18 (b) Patient testing performed on 01/15/18 (c) Patient testing performed on 01/23/18 (d) Patient testing performed on 01/24/18 (e) Patient testing performed on 01/27/18 (5) The surveyor asked the director of laboratory services if results had been evaluated to determine if they had been adversely affected. The director of laboratory services stated there was no evidence which would support that the results had been evaluated.
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. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of records and interview with the director of laboratory services, the laboratory failed to have a policy for monitoring the effectiveness of their IQCP. Findings include: (1) At the beginning of the survey, the director of laboratory services stated the following to the surveyor: (a) The laboratory performed BNP (Brain Natriuretic Peptide), Troponin I, pH, pCO2, PO2 (G3+ cartridge) testing on the Abbott iSTAT analyzer; (b) IQCP's (Individualized Quality Control Plans) had been developed for the test systems. (2) The surveyor reviewed the IQCP (dated as effective 12/11/15). The QA (Quality Assessment) portion of the IQCP did not include a schedule for evaluating the QCP to ensure it continues to provide accurate and reliable test results. There was no evidence of QA reviews for the IQCP's since the effective date; (3) The surveyor reviewed the records with the director of laboratory services and asked if there was a policy to address how the laboratory will monitor the IQCP, including the frequency of the reviews and if a QA review had been performed since 12/11/15. The laboratory director/technical consultant stated a policy had not been written and a QA review had not been performed.