Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D1047148	01/16/2020
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 01/13/20-01/16/20. The findings were reviewed with the director of laboratory services at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
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 the director of laboratory services, the laboratory failed to perform calibration verification procedures at least once every

	6 months. Findings include: (1) At the beginning of the survey, the director of laboratory services, stated to the surveyor the laboratory put a new Ortho Vitros chemistry analyzer into use for patient testing on 05/06/19. The testing included the analyte B12; (2) On the third day of the survey, the surveyor reviewed calibration verification records for testing performed in 2019 and to date in 2020 (since routine calibration procedures were performed using less than three calibrators for B12, calibration verification procedures, using three or more levels of calibration materials, were required every 6 months). The surveyor identified calibration verification procedures had not been performed since 05/03/19 when the manufacturer's specifications for the new analyzer had been demonstrated; (3) The surveyor reviewed the findings with the director of laboratory services, who stated to the surveyor, the laboratory had not performed calibration verification procedures for B12 at least once every 6 months in 2019.
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. (g) The laboratory must document all control procedures performed. 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 control procedures that monitored the accuracy and precision of the complete analytic process. Findings include: PT/INR AND PTT (1) On the first day of the survey, the director of laboratory services stated to the surveyor: (a) PT/INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin) testing were performed using the Sysmex CA660 analyzer, which was put into use on 01/16/19; (b) The laboratory analyzed two levels of QC (Quality Control) materials (Normal Control Level 1 and Abnormal Control Level 3) each 8 hours of patient testing; (c) The acceptable QC limits were established during lot rollover studies before new lot numbers of PT and PTT reagents, and/or new lot numbers of QC materials were put into use. (2) The surveyor reviewed QC records from 2019 and identified the laboratory had not utilized the QC ranges that had been established during the reagent rollover, but used ranges which were wider. The specific findings follow: (a) Normal Control Level 1, Lot #54805 was put into use on 02/21/2019: (i) PTT: (aa) A 2SD range of 26.2-26.9 had been established; (bb) A range of 25.4-27.8 was utilized from 02/21/19 through 12/31/19. (b) Abnormal Control Level 3, Lot #556511 was put into use on 02/21/19: (i) PT: (aa) A 2SD range of 41.1-46.5 had been established; (bb) A range of was 38.9-48.7 utilized from 02/21 /19 through 12/31/19. (3) The surveyor reviewed the findings with the director of laboratory services and asked why the laboratory had not utilized the QC ranges established by the laboratory. The director of laboratory services stated to the surveyor, the laboratory used the mean obtained during the lot rollover but used historic SD's instead of the SD's determined during the lot rollover; (4) The surveyor

	explained to the director of laboratory services, the manufacturer's instructions required the use of SD's determined during the lot rollover. In addition, the ranges utilized by the laboratory from 03/01/19 through 12/31/19 were wider than the QC ranges established by the laboratory. D-DIMER (1) The director of laboratory services stated to the surveyor: (a) D-Dimer testing was performed using the Sysmex CA660 analyzer, which was put into use on 01/16/19; (b) The laboratory analyzed two levels of QC materials (Level 1 and Level 2) each 8 hours of patient testing; (c) The acceptable QC limits were established during the implementation studies performed between 12/06/18-12/10/18. (2) The surveyor reviewed QC records from 2019 and identified the laboratory had not utilized the QC ranges established during the implementation study but used ranges which were wider. The specific findings follow: (a) Control Level 1, Lot #562240: (i) A 2SD range of 0.34-0.38 had been established; (ii) A range of 0.22-0.50 was utilized from 03/01/19 through 12/31/19. (b) Control Level 2, Lot #562140: (i) A 2SD range of 2.70-2.89 had been established; (ii) A range of 1.61-3.73 was utilized from 03/01/19 through 12/31/19. (3) The surveyor reviewed the findings with the director of laboratory services and asked why the laboratory did not utilize the QC ranges established by the laboratory. The director of laboratory services stated to the surveyor, the laboratory used the mean obtained during the implementation study but used historic SD's instead of the SD's determined during the implementation study; (4) The surveyor explained to the director of laboratory services the manufacturer's instructions required the use of SD's determined by the laboratory for the QC materials being used. In addition, the ranges utilized by the laboratory from 03/01/19 through 12/31/19 were wider than the QC ranges established by the laboratory
D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed. 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 the hematology technical consultant, the laboratory failed to follow the manufacturer's specifications for control materials. Findings include: (1) On the first day of the survey, the the director of laboratory services stated to the surveyor the laboratory used the two Sysmex XT-1800i analyzers to perform CBC testing (i.e. WBC (White Blood Count), RBC (Red Blood Count), Hemoglobin, Hematocrit, Platelet count, etc). The analyzer designated as #1 (SN#14237) was the primary analyzer and analyzer #2 (SN#1234) served as the backup analyzer; (2) The director of laboratory services also stated to the surveyor, the laboratory tested three levels (Level 1, Level 2, and Level 3) of Sysmex e-CHECK control materials on the primary and back up analyzers each day of testing, and tested three levels again on the primary analyzer during the evening shift; (3) On the second day of the survey, the surveyor asked the hematology technical consultant how the laboratory implemented a new lot number of QC materials. The hematology technical consultant stated to the surveyor, before the old QC lot numbers wer retired, and before the new lot numbers were put into use, the three levels of the new QC lot number were tested two times per day on both analyzers (morning and evening shifts) for 5 days. From those 10 values, the laboratory calculated the mean and SD

	(Standard Deviation) for each analyte of each level. The laboratory then utilized the mean and 2SD for the acceptable limits when the new lot numbers of QC materials were put into use; (4) The surveyor then reviewed the assay values (package insert) for the QC materials. The assay value sheet included an expected range of means for each analyte. The manufacturer's instructions for the QC materials stated, "The mean assay values for each parameter of e-CHECK are derived from replicate analyses on whole blood calibrated instrumentation. The mean values obtained on e-CHECK should be within the expected ranges. The expected ranges should not be used as QC file limits. Inter-laboratory variation is usually accounted for by analyzer calibration, maintenance and operating technique;" (5) The surveyor reviewed QC records from both analyzers of 21 lot numbers used from 11/28/18 through 01/14/20. The surveyor identified the laboratory began using a new lot number of QC materials at the same time the mean and SD's were being established. In addition, the documentation showed the laboratory utilized the manufacturer's mean and expected ranges from the package insert for its acceptable QC limits on 2 days (08/06/20-08/07/20) and did not follow the manufacturer's specifications to establish its own mean and limits of acceptability, for 3 of the 21 QC lot numbers used during the review period: (a) Used from 08/06/19-09/30/19: (i) Level 1, Lot #91910801 (ii) Level 2, Lot #91910802 (iii) Level 3, Lot #91910803 (6) The surveyor reviewed the findings with the director of laboratory services and the hematology technical consultant, who stated to the surveyor, the laboratory used the package insert means and expected ranges as its acceptable QC limits on both analyzers for the 3 lot numbers of QC materials listed above, and failed to follow the manufacturer's specifications for the QC materials.