Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D1047148	05/01/2026
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 04/29/2026 through 05/01/2026. The laboratory was found out of compliance with the following CLIA Condition: 493.1213; D5022 : Toxicology, High Complexity
D5022	TOXICOLOGY CFR(s): 493.1213 If the laboratory provides services in the subspecialty of Toxicology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on a review of records, urine drug screen package insert and test kit box, FDA database, email correspondence with an FDA representative, and interview with general supervisor #1, the laboratory failed to ensure the requirements were met for the subspecialty of Toxicology for 18 of 18 months of patient testing. Findings include: (1) The laboratory failed to establish the performance specifications for the McKesson Drugs of abuse test cups 12-drug panel with adulterants test not categorized by the FDA. Refer to D5423; (2) The laboratory failed to perform a negative and positive control material 18 of 18 days of patient urine drug screen testing. Refer to D5449.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by:

	Based on a review of records and interview with technical consultant #2, the laboratory failed to verify the accuracy of Reticulocyte testing at least twice annually during the review period of January 2025 through the current date. Findings include: (1) On 04/29/2026 at 11:00 am, technical consultant #2 stated the laboratory performed Reticulocyte testing using two Sysmex XN-1000 analyzers denoted by the laboratory as "Boomer" and "Sooner"; (2) A review of 2025 and 2026 CAP (College of American Pathology) proficiency testing records identified the laboratory had not enrolled and participated in proficiency testing; (3) Interview with technical consultant #2 on 04/30/2026 at 09:30 am confirmed the laboratory had not enrolled and participated in proficiency testing and did not have a method in place to verify the accuracy of Reticulocyte testing at least twice annually.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) (b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #2, the laboratory failed to utilize the demonstrated reportable ranges for three of six analytes reviewed on the QuidelOrtho Vitros 5600 analyzer. Findings include: (1) On 04/30/2026 at 11:30 am, technical consultant #2 stated the laboratory began performing ALP (Alkaline Phosphatase), CK (Creatine Kinase), and Amylase testing using the QuidelOrtho Vitros 5600 analyzer on 03/13/2026; (2) A review of the performance specification records identified the laboratory had demonstrated the following reportable ranges: (a) ALP - 12.9-1337 U/L (b) CK - 36.6-1470.6 U/L (c) Amylase - 32.1-1017.6 U/L (3) Interview with technical consultant #2 on 04/30/2026 at 02:35 pm confirmed the laboratory was using the following manufacturer's reportable ranges instead of the reportable ranges that had been demonstrated by the laboratory: (a) ALP - 20-1500 U/L (b) CK - 20-1600 U/L (c) Amylase - 30-1200 U/L 48517 Based on a review of records, urine drug screen package inserts, FDA database, email correspondence with FDA representative, and interview with general supervisor #1, the laboratory failed to establish the performance specifications for the McKesson 12 Drug Panel With Adulterants test not categorized by the FDA. Findings include: (1) On 04/30/2026 at 02:45 pm, general supervisor #1 stated the laboratory performed patient urine drug screen using the McKesson 12 Drug Panel With Adulterants test; (2) A review of the FDA (Food and Drug Administration) test categorization database did not include a categorization for the test kit, which defaults the categorization of the test as high complexity. This was also confirmed during email correspondence with an FDA representative on 04/30/2026; (3) Interview with general supervisor #1 on 04/30/2026 at 02:45 pm confirmed the test kit had been put into use for patient testing on or around December 1, 2024; (4) A review of records for the test system revealed no evidence the performance specifications of accuracy, precision, analytical

	sensitivity, analytical specificity, reportable range, and reference intervals as applicable, had been established prior to putting the test into use for patient testing; (5) The findings were reviewed with general supervisor #1, who stated on 04/30/2026 at 02:45 pm the laboratory did not establish the performance specifications prior to putting the test kit into use because it was believed the test kit was categorized as waived; (6) Refer to D5449 for examples of patient urine drug screen testing performed.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) (b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, and interview general supervisor #1, the laboratory failed to follow their written protocol for ensuring the Ortho MTS 5150-60 centrifuge was functioning properly for two of four annual function checks performed during the review period of December 2024 through the current date. Finding include: (1) On 04/01/2026 at 11:00 am, general supervisor #1 stated the following: (a) Blood bank antibody screens and blood typing were performed by the laboratory; (b) The specimens were processed in the Ortho MTS 5150-60 centrifuge at a speed of 895 rpm (revolutions per minute) +/- 25 RPM for 5 minutes. (2) A review of the procedure titled, "MTS Centrifuge Users Guide" stated, "The MTS 5150-60 will reach a speed of 895+/-25 RPM and has a time of ten minutes"; (3) A review of centrifuge function check records from December 2024 through the current date identified the speed check was not within the acceptable limits as follows: (a) On 05/31/2025 the centrifuge speed check was documented at 827 (RPM); (b) On 08/08/2025 the centrifuge speed check was documented at 860 (RPM); (4) The records were reviewed with general supervisor #1, who stated on 04 /01/2026 at 11:00 am, the laboratory had not followed their policy for function checks.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) (d)(3)(ii) Each qualitative procedure, include a negative and positive control material; This STANDARD is not met as evidenced by: Based on a review of records and interview with general supervisor #1, the laboratory failed to perform a negative and positive control material 18 of 18 days of patient urine drug screen testing. Findings include: (1) On 04/30/2026 at 01:35 pm, general supervisor #1 stated the McKesson Drugs of Abuse Test Cups 12-Drug Panel with Adulterants Test Device had been put into use for patient testing on or around 12/01 /2024 (refer to D5423 for specific information pertaining to the test kit not being FDA categorized and defaulting to a high complexity test system); (2) A review of QC (Quality Control) and patient testing records from December 2024 through the current

	date, revealed negative and positive QC materials had not been performed each day of patient testing for 18 of 18 days of patient testing and there was no evidence an IQCP (Individualized Quality Control Program) had been developed; (3) General supervisor #1 stated on 04/30/2026 at 01:35 pm negative and positive QC materials had not been performed each day of patient testing and an IQCP had not been developed because it was believed the test kit was categorized as waived; (4) The following were the days of patient testing reviewed when negative and positive QC materials had not been performed: (a) Patient #120624 - Testing performed on 12/06/2024 (b) Patient #120624 - Testing performed on 12/06/2024 (c) Patient #011925 - Testing performed on 01/20/2025 (d) Patient #031825 - Testing performed on 0318/2025 (e) Patient #032525 - Testing performed on 03/25/2025 (f) Patient #182761 - Testing performed on 04/03/2025 (g) Patient #042825 - Testing performed on 04/28/2025 (h) Patient #052825 - Testing performed on 05/28/2025 (i) Patient #061025 - Testing performed on 06/10/2025 (j) Patient #070125 - Testing performed on 07/01/2025 (k) Patient #120375 - Testing performed on 07/10/2025 (l) Patient #082025 - Testing performed on 08/20/2025 (m) Patient #082125 - Testing performed on 08/21/2025 (n) Patient #091925 - Testing performed on 09/19/2025 (o) Patient #102025 - Testing performed on 10/20/2025 (p) Patient #110425 - Testing performed on 11/04/2025 (q) Patient #123025 - Testing performed on 01/02/2026 (r) Patient #011926 - Testing performed on 01/19/2026 (s) Patient #022526 - Testing performed on 02/25/2026