Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0972650	02/15/2022
Name of Provider or Supplier	**Street Address, City, State**	
Ohh Op Cath Lab-Mwc	8121 National Ave, Suite 104, Midwest 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 initial survey was performed on 02/15/2022. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the technical consultant and laboratory manager at the conclusion of the survey.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a review of the procedure manual and interview with the technical consultant and laboratory manager, the laboratory failed to ensure the laboratory procedure manual had been approved, signed, and dated by the laboratory director. Findings include: (1) On 02/15/2022 at 10:00 am, the technical consultant stated to the surveyor the laboratory began performing the following testing on 02/11/2021: (a) BUN, CO2, Creatinine, Glucose, Hemoglobin, Hematocrit, Ionized Calcium, Potassium, and Sodium testing using the iSTAT 1 analyzer and the Chem 8 + cartridge; (b) ACT (Activated Clotting Time) testing using the iSTAT 1 analyzer and the ACT Celite cartridge; (c) PT/INR (Prothrombin Time/International Normalized Ratio) testing using the iSTAT 1 analyzer and the PT/INR cartridge; (d) % Oxyhemoglobin testing using the Avoximeter 1000e analyzer. (2) The surveyor reviewed the laboratory manual titled, "OHH OPC-MWC Procedure Manual". It had not been approved, signed, and dated by the laboratory director; (3) The surveyor showed the manual to the technical consultant and laboratory manager. Both stated on 02/15/2022 at 01:50 pm, the procedure manual had not been approved, signed, and dated by the laboratory director.
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, procedure manual, and interview with the technical consultant and laboratory manager, the laboratory failed to ensure the reportable ranges were utilized for one of four new test methods; and failed to ensure the reportable ranges had been demonstrated for two of four new test methods. Findings include: REPORTABLE RANGES UTILIZED (1) On 02/15/2021 at 10:00 am, the technical consultant stated to the surveyor the laboratory began performing BUN, CO2, Creatinine, Glucose, Hemoglobin, Hematocrit, Ionized Calcium, Potassium, and Sodium testing using the iSTAT 1 analyzer and the Chem 8 + cartridge on 02/11/2021; (2) The surveyor reviewed the performance specification records for the new test system and identified the laboratory had demonstrated the following reportable ranges: (a) BUN - 5-127 mg/dl (b) CO2 - 12-50 mmol/L (c) Creatinine - 0.2-16.7 mg/dl (d) Glucose - 27-582 mg/dl (e) Potassium - 2.3-7.9 mmol/L (3) The surveyor then reviewed the procedure manual to show the reportable ranges that were being utilized by the laboratory. The laboratory was using the following manufacturer's reportable ranges: (a) BUN - 3-140 mg/dl (b) CO2 - 5-50 mmol/L (c) Creatine - 0.2-20.0 mg/dl (d) Glucose - 20-700 mg/dl (e) Potassium - 2.0-9.0 mmol/L (4) The surveyor reviewed the findings with the technical consultant #1 and laboratory manager. Both stated on 02/15/2022 at 11:55 am, the laboratory was not using the reportable ranges that had been demonstrated by the laboratory as shown above. REPORTABLE RANGES DEMONSTRATED (1) On 02/15/2021 at 10:00 am, the technical consultant stated to the surveyor the laboratory began performing ACT (Activated Clotting Time) testing using the iSTAT 1 analyzer and the ACT Celite cartridge and PT/INR (Prothrombin Time/International Normalized Ratio) testing using the iSTAT 1 analyzer and the PT/INR cartridge on 02/11/2021; (2) The surveyor reviewed the performance specification records for the new test systems and could not locate documentation to proved the laboratory had demonstrated the reportable ranges; (3) The surveyor reviewed the findings with the technical consultant and laboratory manager. Both stated on 02/15/2022 at 11:45 am, the laboratory did not demonstrate the reportable ranges for ACT and PT/INR testing.