

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0972650	(X3) Date Survey Completed 09/10/2025
Name of Provider or Supplier Ohh Op Cath Lab-Mwc	Street Address, City, State 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 recertification survey was performed on 09/10/2025. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with quality laboratory manager, point-of-care lead technologist, laboratory system director, and director of MWC/OPH/OHH at the conclusion of the survey.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of policies and procedures and interviews with the quality laboratory manager, and point-of-care lead technologist, the written competency assessment policy did not define the frequency of the assessments for the technical consultant based on the position responsibilities for two of two technical consultants. Findings include: (1) A review of the competency assessment policy titled, "Poin-Of-Care Annual Competency Assessment - Technical Consultant - MWC Cath Lab" identified it did not define the frequency of the assessments; (2) Interview with the quality laboratory manager and point-of-care lead technologist on 09/10/2025 at 10:39 am confirmed that although the competencies based on the position responsibilities of the technical consultant had been performed annually, the policy did not define the frequency of assessments.</p>
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>(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)</p>

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 quality laboratory manager and point-of-care lead technologist, the laboratory failed to perform calibration verification procedures at least once every six months for one of two AVOXimeter 1000E test systems during the review period of January 2024 through the current date. Findings include: (1) On 09/10/2025 at 10:00 am, the quality laboratory manager and point-of-care lead technologist stated the laboratory performed Oxyhemoglobin testing on two AVOXimeter 1000E analyzers (SN #3825 and SN #3826); (2) A review of records from January 2024 through the current date identified no evidence the calibration verification procedures had been performed for the AVOXimeter 1000E SN #3825 as follows; (a) Prior to 09/16/2024 (b) Between 09/16/2024 and 09/05/2025 (3) The findings were reviewed with the quality laboratory manager and point-of-care lead technologist, who stated on 09/10/2025 at 01:35 pm, the calibration verification procedures had not been performed every six months as stated above.

D5805

TEST REPORT
CFR(s): 493.1291(c)

(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the quality laboratory manager and point-of-care lead technologist, the laboratory failed to ensure test reports reflected the address of the laboratory location where the testing was performed for two of two reports reviewed. Findings include: (1) On 09/10/2025 at 10:00 am, the quality laboratory manager and point-of-care lead technologist stated the laboratory performed ACT (Activated Clotting Factor) testing using two i-STAT analyzers (SN #312507 and SN #330652) and Kaolin ACT cartridge; (2) A review of patient reports identified the address of the laboratory on the reports (4050 W. Memorial Rd.

Oklahoma City, OK 73120) did not match the address on the CLIA certificate (8121 National Ave., Ste.104, Midwest City, OK 73110) for the following: (a) Patient Medical Record #1346677 reported on 08/19/2025 (b) Patient Medical Record #1476213 reported on 08/27/2025 (3) The findings were reviewed with the quality laboratory manager and point-of-care lead technologist, who stated on 09/10/2025 02:00 pm, the address on the patient reports did not match the CLIA certificate.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(i)

(e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the quality laboratory manager and point-of-care lead technologist, the laboratory director failed to attest that, at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H for one of five proficiency testing events reviewed in 2024 and 2025. Findings include: (1) On 09/10/2025 at 11:05 am, a review of 2024 and 2025 proficiency testing events identified attestation statements had been signed after the graded evaluations were completed by the proficiency testing program for one of five events reviewed: (a) Second event 2024 Chemistry-Core - The graded evaluation was completed on 06/21/2024 and the attestation statement had not been signed by the laboratory director until 06/21/2024; (2) The records were reviewed with the quality laboratory manager and point-of-care lead technologist who stated on 09/10/2025 at 11:07 am, the attestation statements had not been signed timely as stated above.

D6018

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(iii)

(e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; and

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the quality laboratory manager and point-of-care lead technologist, the laboratory director failed to ensure proficiency testing reports were reviewed for one of five Chemistry - Core events reviewed in 2024 and 2025. Findings include: (1) A review of 2024 and 2025 Chemistry - Core proficiency testing events identified the "Performance Evaluations" included a space for the laboratory director or designee's signature and date (indicating review of the graded evaluation). The following was identified for one of five events: (a) API Second event of 2024 - There was no evidence the Performance Evaluation had been signed and dated as reviewed by the laboratory director or designee; (2) The records were reviewed with the quality laboratory manager and point-of-care lead technologist on 09/10/2025 at 11:07 am, the graded evaluation, as indicated above, had not been signed and dated as reviewed by the laboratory director or designee.