| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 23D2277972 | 08/11/2025 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Mclaren Macomb | 21510 Harrington, Clinton Township, MI | |

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 |
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| **D5417** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(d)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>. Based on observation and interview with the phlebotomy staff, the laboratory failed to ensure blood specimen tubes had not exceeded expiration dates for three pearl-white BD Vacutainer tubes out of 18 total tubes at the phlebotomy station. Findings include: 1. The surveyor observed three pearl-white BD Vacutainer tubes with the expiration date of 4/30/25 on the table in the phlebotomy station on 8/11/25 at 9:32 am. 2. An interview on 8/11/25 at 9:35 am with the phlebotomy staff confirmed the tubes had been expired and indicated they were used to collect specimens for Parathyroid Hormone (PTH) testing. |
| **D5439** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(b)<br><br>(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 |

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| | 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.<br><br>This STANDARD is not met as evidenced by:<br>. Based on record review and interview with the technical consultant, the laboratory failed to perform and document calibration verification for its Stat Sensor creatinine testing at least every six months for one (June 2025) of four calibration verification events reviewed. Findings include: 1. A review of the laboratory's Stat Sensor creatinine calibration verification documentation revealed the most recent event was dated 1/29/25. 2. The surveyor requested documentation of calibration performed from the 1/29/25 date on 8/11/25 at 12:27 pm and it was not made available. 3. An interview on 8/11/25 at 12:32 pm with the technical consultant confirmed the laboratory had not performed and documentation calibration verification at least every six months for its Stat Sensor creatinine testing. |
| **D6020** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5)<br><br>(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;<br><br>This STANDARD is not met as evidenced by:<br>. Based on record review and interview with the technical consultant, the laboratory director failed to ensure the quality assessment program established was maintained for two (August 2023 to August 2025) of two years reviewed. Findings include: 1. A review of the laboratory's "POC Policy" revealed a section titled "XXXII. Quality Management" stating, 1. "The Quality Management Program is designed to continuously evaluate and improve performance by: a. Promoting positive patient outcomes through the application of optimal service based on clinically sound principles and best practices. b. Focusing on pre-analytic, analytic, and/or post-analytic indicators related to improved service outcomes and the prevention and reduction of errors. c. Identifying and evaluating errors, incidents and other unusual occurrences that may interfere with patient care services. d. Identifying, on an ongoing basis and in a coordinated and collaborative manner, areas for improvement in the quality of care, safety and services provided. e. Offering continuing education opportunities for staff. f. The Quality Management Program and quality improvement presses are coordinated with, and supportive or, McLaren process improvement practices. g. Works with the laboratory Quality Best Practice committee to determine system key indicators, review issues, assist with corrective action and evaluate follow-up as needed. h. The QMS is implemented as designed and is assessed at least annually for effectiveness. 2. Quality Indicators: a. Point of Care will work with the Quality Best Practice Committee and the Laboratory Medical Director to establish department specific Quality Indicators. b. The MML laboratory medical director is a member of the Corporate Quality Management committee and assists with determining the monitors for the Patient Safety Dashboard. c. There must be documentation that the selected indicators are regularly compared against a |

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| | benchmark when available." 2. An interview on 8/11/25 at 11:23 am with the technical consultant revealed the laboratory had not established quality indictors and had not documented annual quality reviews in accordance with the policy above. |