| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 52D0856468 | 04/19/2023 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Lancaster Family Medical Center Sc | 9177 Old Potosi Rd, Lancaster, WI | |

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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| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of two culture procedures and interview with laboratory personnel, one of the two procedures did not include step by step instructions for evaluation of growth on the culture plates or the length of time for incubation. Findings include: 1. Review of the "Throat Culture Setup" procedure showed no indication of the length of time for incubation of the culture plates after inoculation and did not provide step-by-step instructions for testing personnel to evaluate bacterial growth to determine what organisms were present or how personnel determine what they should report. 2. Interview with laboratory personnel (staff A) on April 19, 2023 |

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| | at 11:00 AM confirmed the throat culture procedure did not include instructions for incubation timing or the evaluation of growth. This is a repeat deficiency previously cited on April 26, 2017. |
| **D5417** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(d)<br><br>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 surveyor observation of blood collection supplies and interview with laboratory personnel, the laboratory had one of two expired sodium citrate tubes available for use in the specimen collection area. Finding include: 1. Observation of blood collection supplies available on April 19, 2023 at 10:45 AM revealed one (lot number 2160737) of two 3.2 % sodium citrate tubes in the supply drawer had expired on February 28, 2023. 2. Interview with laboratory personnel (staff A) on April 19, 2023 at 11:00 AM confirmed one of the two 3.2% sodium citrate tubes expired on February 28, 2023 and was available for use in the specimen collection area. This is a repeat deficiency previously cited on April 13, 2021. |
| **D5463** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(7)(g)<br><br>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Over time, rotate control material testing among all operators who perform the test. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of quality control (QC) records and interview with laboratory personnel, personnel did not rotate the QC testing of bacitracin discs between the two testing personnel who read throat cultures using the bacitracin discs. Laboratory personnel who do not interpret cultures with bacitracin discs evaluated the QC results for five of five weeks from March 20 to April 18, 2023. Findings include: 1. Review of the 'Bacitracin 0.04 Unit Disc QC Log' in use after March 20, 2023 showed QC testing was completed five times. The record showed staff A performed the QC testing for each of the five evaluations. 2. Interview with laboratory personnel (staff A) on April 19, 2023 at 11:00 AM confirmed the Bacitracin QC testing is performed by personnel who do not interpret cultures and confirmed the QC testing was not rotated over time among the two testing personnel who evaluate cultures with bacitracin discs. |
| **D6046** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(8)<br><br>(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. |

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| | This STANDARD is not met as evidenced by:<br>Based on surveyor review of the 'Laboratory Personnel Report' (CMS Form 209) and personnel records and interview with laboratory personnel, the technical consultant (who is the laboratory director) or another qualified individual did not document evaluation of the competence of two of two testing personnel that interpreted throat and urine cultures. Findings include: 1. Review of the CMS Form 209 provided for the survey showed two testing personnel (Staff C and D) performed non-waived testing. Further review showed staff A and B perform only waived testing. 2. Review of the 2021 and 2022 'Competency Assessment Event Log' forms for staff C and D showed staff B completed the forms. The forms showed no indication of review or evaluation by the technical consultant or another qualified individual. 3. Interview with laboratory personnel (staff A) on April 19, 2023 at 11:00 AM confirmed staff B did not perform non-waived testing and confirmed the technical consultant or another qualified individual did not document competence evaluation of the two staff members performing culture interpretations. This is a repeat deficiency previously cited on April 13, 2021. |