| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 24D0405317 | 05/24/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Sanford Tracy Medical Center | 251 5th St E, Tracy, MN | |

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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| **D5211** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(a)<br><br>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.<br><br>This STANDARD is not met as evidenced by:<br>. Based on document review and interview with laboratory personnel, the Laboratory Director or designee failed to review and evaluate proficiency testing (PT) results for 1 of 10 PT events in 2016. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 5/23/18 at 11:05 a.m. 2. The laboratory performed Proficiency Testing (PT) using American Proficiency Institute (API) as the provider. 3. Review of API PT documents revealed the following results were graded as unacceptable: Year: 2016 Survey: Chemistry / Group 2 Event: 3rd Sample: BG-11 Tests: pCO2* & pH 4. Documentation of review and corrective actions for the unacceptable results were not found. The laboratory was unable to provide the above records upon request. 5. In an interview at 1:15 p.m. on 5/23/18, the GS confirmed the above findings. * pCO2 = partial pressure of carbon dioxide . |
| **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 |

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| | 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 observation, document review and interview with laboratory personnel, the laboratory failed to include accurate reference ranges in the procedure manual. Findings are as follows: A. Chemistry 1. The laboratory performed Chemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 5/23 /18 at 11:05 a.m. 2. A Siemens Dimension Xpand and an Alere chemistry analyzer were observed as present and available for use during the tour of the laboratory. 3. Reference intervals for Troponin found in the Reference Range Procedure and the Triage Cardiac Panel procedure, both located in the Sanford Policy - Laboratory - Tracy Lab General on-line Manual., did not agree with that observed on a patient final test report (Date = 11/7/2017, Female - 69 yrs). See below. Test Report Table Procedure 0.00 - 0.05 0.0 - 0.1 0.0 - 0.4 4. In an interview at 10:15 a.m. on 5/24/18, the GS confirmed the above findings. A. Urine Microscopic 1. The laboratory performed Urinalysis testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 5/23/18 at 11:05 a.m. 2. A LaboMed microscope was observed as present and available for use during the tour of the laboratory. 3. Reference intervals for RBC's / Urine found in the Urine Microscopic procedure, located in the Sanford Policy - Laboratory - Tracy Lab General on-line Manual., did not agree with that observed on a patient final test report (Date = 2/27/2018, Female - 71 yrs). See below. Test Report Procedure Neg, 0-2 / hpf Neg, 0-3 / hpf 4. In an interview at 10:15 a.m. on 5/24/18, the GS confirmed the above findings. . |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.<br><br>This STANDARD is not met as evidenced by:<br>. Based on observation, document review and interview with laboratory personnel, the laboratory failed to identify criteria for and document proper storage conditions of reagents as specified by the manufacturer. 1. The laboratory performed Chemistry, Endocrinology, Hematology, Coagulation, Immunology, Immunohematology, and Microbiology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 05/23/18 at 11:05 a.m. 2. During the tour of the laboratory, test kits |

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| | for were observed as being stored in a Materials Management area separate from the laboratory. 3. In an interview at 11:15 a.m. on 05/023/2018, the GS confirmed that the test kits had indicated storage conditions of 15 - 30 C. but that the laboratory did not monitor or record the room temperature in the Materials Management storage area. . |
| **D5429** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(a)(1)<br><br>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.<br><br>This STANDARD is not met as evidenced by:<br>. Based on observation, document review and interview with laboratory personnel, the laboratory failed to document required maintenance on equipment used for Chemistry and Endocrinology testing. Findings are as follows: 1. The laboratory performed Chemistry and Endocrinology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 5/23/18 at 11:05 a.m. 2. A Siemens Dimension Xpand chemistry analyzer was observed as present and available for use during the tour of the laboratory. 3. Requirements for weekly maintenance of the Xpand were established in the Sanford Policy - Laboratory - Tracy Lab General on-line Manual. 4. Documentation of weekly maintenance for the Xpand was not found for 6 of 24 weekly periods from 1/2/18 through 5/18/18 during review of laboratory records. The laboratory was unable to provide this documentation upon request. 5. In an interview at 10:15 a.m. on 5/24/18, the GS confirmed the above findings. . |