Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0405317	(X3) Date Survey Completed 03/29/2024
Name of Provider or Supplier Sanford Tracy Medical Center	**Street Address, City, State** 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: . Based on a review of proficiency testing (PT) documents and an interview with laboratory personnel, the laboratory failed to ensure the individual(s) testing the proficiency samples attested to the routine integration of the PT samples into the laboratory's routine workload and methods. This was found for two of 13 events reviewed in 2022. Findings are as follows: 1. The laboratory participated in the American Proficiency Institute PT program for all PT performed by the laboratory. 2. Signing the attestation statements was required by all testing personnel as established in the Proficiency Testing - Enterprise procedure, Item 6 Reporting of Results, of the Procedure section of the established procedure. 3. The attestation statements for 13 PT events in 2022 were reviewed. Laboratory testing personnel failed to sign the following two attestation statements for 2022: -2022 Chemistry - Core 3rd Event (specifically the Blood Gas testing personnel did not sign). -2022 Immunology /Immunohematology - 3rd Event 4. During an interview at 2:40 p.m. on March 28, 2024, the General Supervisor confirmed the above findings. .
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.

	This STANDARD is not met as evidenced by: . Based on document review, and interview with laboratory personnel, the laboratory failed to ensure function checks for one of one blood gas Chemistry analyzer was performed and documented as required in 2023. Findings are as follows: 1. The laboratory performed blood gas analysis which falls under the specialty of Chemistry as confirmed by the General Supervisor (GS) during a tour of the laboratory at 1:50 p. m. on March 28, 2024. 2. An OPTI CCA blood gas analyzer was present and available for use by the Respiratory Therapy (RT) department on the day of survey as confirmed by the GS during the tour of the laboratory. 3. Calibration of the tHb channel was required every 3 months by the laboratory if reporting tHb and/or SO2 as established in the OPTI CCA TS2 Calibration, Quality Control, Maintenance and PI - Tracy procedure found in the OPTI binder kept by PT. The GS confirmed the laboratory performs and results oxygen saturation (S02) values for patients using the OPTI blood gas analyzer during an interview at 10:47 a.m. on March 29, 2024. 4. Calibration of the tHb channel was performed on 01/19/2023, 06/04/2023, 09/06 /2023, and 12/22/2023 as indicated in laboratory records. 5. Documented performance of the tHb channel calibration between 1/19/2023 to 6/4/2023 (5+ months) was not found in laboratory records. The laboratory was unable to provide this documentation upon request. 6. During an interview at 10:50 a.m. on March 29, 2024, the GS confirmed the above finding. .
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) 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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on document review, and interview with laboratory personnel, the laboratory failed to perform quality control (QC) activities as the laboratory established in their Individualized Quality Control Plan (IQCP) in 3 of 7 months reviewed in 2023. Findings are as follows: 1. The laboratory performed blood gas analysis which falls under the specialty of Chemistry as confirmed by the General Supervisor (GS) during a tour of the laboratory at 1:50 p.m. on March 28, 2024. 2. An OPTI CCA blood gas analyzer was present and available for use by the Respiratory Therapy (RT) department on the day of survey as confirmed by the GS during the tour of the laboratory. 3. Blood gas QC performance on the OPTI CCA was required prior to initial use and with each shipment of cassettes and at one month intervals thereafter as established in the OPTI CCA TS2 Calibration, Quality control, Maintenance and PI - Tracy procedure found in the OPTI binder kept by RT. 4. The laboratory exceeded the one month time interval for QC performance in 3 of 7 months reviewed, having the potential to affect patient results. See below: QC date Days lapse # days overdue/ patients affected 01/19/2023 01/27/2023, 8 DAYS N/A 02/24/2023, 28 Days N/A 03 /30/2023, 34 Days 4 days/Confirmed no patients tested 04/03/2023, 04 Days N/A 05

	/13/2023, 40 Days 10 Days/Unsure if patients were tested 06/02/2023, 20 Days N/A 07 /06/2023, 34 Days 4 days/Unsure if patients were tested 5. In an interview at 10:50 a. m. on March 29, 2024, the GS confirmed the above findings. .
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: . Based observation, document review, and interview with laboratory personnel, the Technical Supervisor failed to assess the competency at least semi-annually during the first year of patient specimen testing for two of two testing personnel hired in 2022. Findings are as follows: 1. The laboratory performed Microbiology, Diagnostic Immunology, Chemistry, Hematology, and Immunohematology testing as confirmed by General Supervisor (GS) during a tour of the laboratory at 1:50 p.m. on March 28, 2024. 2. The following non-waived test systems, analyzers, devices, and test kits were observed as present and available for use during the tour: Abbott Architect Plus chemistry analyzer Ortho Gel and Tube Immunohematology test system OPTI CCA blood gas test analyzer Sysmex XN-450 hematology analyzer Stago STA Satellite coagulation analyzer ALCOR MiniiSED device Cepheid GeneExpert PCR system BioRad Tox/See test system Cardinal Health Serum hCG BioFire Film Array Blood Culture ID system BactT Alert Blood Culture system Microscopes and stains for microscopic examinations Fungal exam Vaginal preparation Gram Stain Manual differential 3. Personnel competency assessment was required at six months, one year, and annually thereafter for lab personnel as established in the Competency Assessment - South Region procedure found in the laboratory procedure manual. The procedure goes on to establish that all six elements required by CLIA must be included in a competency assessment. 4. Initial training was performed and documented for testing personnel #2 (TP2) in September 2022, and for testing personnel #3 (TP3) in October 2022, as indicated on the Competency Review Checklists. 5. A six month competency, including all six element required by laboratory procedure and CLIA was not found in laboratory records for TP2 or TP3. 6. The laboratory was unable to provide the missing documents upon request. 7. During an interview at 4:00 p.m. on March 28, 2024, the GS confirmed the above findings. .
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the Technical Supervisor failed to assess the competency at least annually for one of

	one tenured testing personnel in 2022. Findings are as follows: 1. The laboratory performed Microbiology, Diagnostic Immunology, Chemistry, Hematology, and Immunohematology testing as confirmed by General Supervisor (GS) during a tour of the laboratory at 1:50 p.m. on March 28, 2024. 2. The following non-waived test systems, analyzers, devices, and test kits were observed as present and available for use during the tour: Abbott Architect Plus chemistry analyzer Ortho Gel and Tube Immunohematology test system OPTI CCA blood gas test analyzer Sysmex XN-450 hematology analyzer Stago STA Satellite coagulation analyzer ALCOR MiniiSED device Cepheid GeneExpert PCR system BioRad Tox/See test system Cardinal Health Serum hCG BioFire Film Array Blood Culture ID system BactT Alert Blood Culture system Microscopes and stains for microscopic examinations Fungal exam Vaginal preparation Gram Stain Manual differential 3. Personnel competency assessment was required at six months, one year, and annually thereafter for lab personnel as established in the Competency Assessment - South Region procedure found in the laboratory procedure manual. 4. Annual competency assessment documentation for the above tests was not found during review of 2022 laboratory records for Testing Personnel #1 (TP1). 5. The laboratory was unable to provide the missing competency records for TP1 upon request. 6. During an interview at 4:00 p.m. on March 28, 2024, the GS confirmed that competency assessments for TP1 for the year 2022 could not be located. .