Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0404587	06/13/2023
Name of Provider or Supplier	**Street Address, City, State**	
Gundersen Spring Grove Clinic	123 5th Avenue Southeast, Spring Grove, 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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: . Based on document review, observation, and an interview with laboratory personnel, the laboratory failed to retain all analytic records of activities as specified in 493.1256 (e)(2), specifically records of lot numbers and expiration dates of the stains used by the laboratory each day of use in 2022 and 2023. Findings are as follows: 1. The laboratory performed manual differential blood smear testing under the specialty of Hematology as confirmed the Technical Consultant (TC) and Testing Personnel 1 (TP1) during a tour of the laboratory at 10:55 a.m. on June 13, 2023. 2. The Camco Quick Stains and Olympus BH-2 microscope to perform manual blood smears were observed as present and available for use during the tour of the laboratory. 3. In an interview at 11:04 a.m. on June 13, 2023, TP1 confirmed that the lot number and expiration date of the staining material was not getting documented in a way that clearly defined what lot was used for each day of patient testing. 4. A patient who had a manual blood smear performed on December 20, 2022 (MRN XXX084) was reviewed on the day of survey. Records of the lot numbers and expiration dates of the staining material used on December 20, 2022, could not be found. The laboratory was unable to provide the records at request. 5. In an interview at 1:45 p.m. on June 13, 2023, TP1 confirmed the above findings and stated he performed approximately 1 manual blood smear per month. .
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a)

	A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: . Based on document review, observation, and interview with laboratory personnel, the laboratory failed to follow written Chemistry quality control (QC) procedures for four of seven months in 2022 and 2023. Findings are as follows: 1. The laboratory performed Chemistry testing on the i-STAT point of care instrument, including the EG6+ cartridge as confirmed by the Technical Consultant (TC) and Testing Personnel 1 (TP1) during a tour of the laboratory at 10:55 a.m. on June 13, 2023. 2. An i-STAT point of care instrument was observed as present and available for use during a tour the tour of the laboratory. 3. Liquid QC performance frequency was established by the laboratory in the Chemistry Testing Using i-STAT EC8+, EG6+, Crea, Chem8+ Cartridge Types, Lab-0911 procedure found in PolicyStat as follows: The staff verifies each new lot number and new shipment of cartridges using Level 1 and Level 3 QC samples, prior to use for patient testing. The lab staff is responsible for completing the liquid quality control testing samples during the lab's designated monthly scheduled date range pre-programmed into RALS middleware. 4. The laboratories designated monthly schedule for liquid QC performance on the i-STAT was found in the Gundersen Spring Grove Clinic Quality Control Plan Test: i-STAT EG6+ as follows: Perform two levels of external quality control the 1st working clinic day of the month. 5. Liquid QC Level 1 and Level 3 performed by the laboratory were reviewed for the period of December 2022 through June 2023. Four of the seven months reviewed the laboratory failed to perform the QC on the 1st working clinic day of the month. Dates performed are as follows: December 9, 12, 28, 29, 2022 January 4, 12, 31, 2023 February 1, 14, 2023 March 13, 2023 April 7, 2023 May 12, 2023 June 12, 2023 6. In an interview at 3:30 p.m. on June 13, 2023, TC1 and the Laboratory Director confirmed the above findings. .
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (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 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 observation, document review, and interview with laboratory personnel, the laboratory failed to perform and document Chemistry analyzer calibration verification at least once every 6 months from August 2022 through June 2023. Findings are as follows: 1. The laboratory performed Chemistry testing on the i-STAT point of care instrument, including the EG6+ cartridge as confirmed by the Technical Consultant (TC) and Testing Personnel 1 (TP1) during a tour of the laboratory at 10: 55 a.m. on June 13, 2023. 2. An i-STAT point of care instrument was observed as present and available for use during a tour the tour of the laboratory. 3. In an interview at 11:06 a.m. on June 13, 2023, the Laboratory Director (LD) and the TC confirmed the current i-STAT was newly implemented in the fall of 2022. Review of performance verification records showed the new i-STAT was signed off on August 31, 2022, for patient testing. 4. i-STAT analyzer calibration verification was required at six months intervals as established in the Chemistry Testing Using i-STAT EC8+, EG6+, Crea, Chem8+ Cartridge Types, Lab-0911 procedure found in PolicyStat. 5. Calibration verification was performed as part of the performance verification done in August 2022, and was not performed again until June 8, 2023, as indicated in laboratory records. Nine months elapsed between the calibration verification dates. The laboratory was unable to provide documents confirming calibration verification performance every 6 months upon request. 6. In an interview at 3:20 p.m. on June 13, 2023, the LD confirmed the above finding stating the laboratory probably got off schedule with the implementation of the new analyzer in August 2022. .
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to document Hematology quality control (QC) procedures performed to test Camco Quick stain for intended reactivity each day of use from July 2021 through June 2023. Findings are as follows: 1. The laboratory performed manual differential blood smear testing under the specialty of Hematology as confirmed the Technical Consultant (TC) and Testing Personnel 1 (TP1) during a tour of the laboratory at 10:55 a.m. on June 13, 2023. 2. The Camco Quick Stains and Olympus BH-2 microscope used to perform manual blood smears were observed as present and available for use during the tour of the laboratory. 3. The Differential: Counting and Morphology, Lab-5074 found in PolicyStat, established QC requirement for the stain as follows: Quality Control. The quality of each slide is assessed for correct color of the inner structure. Slide Quality Control should be documented daily. 4. The hematology printout for patient MRN: XXX084 who had a blood smear performed on December 20, 2022, was reviewed on the day of survey June 13, 2023. Documentation of the stain QC check could not be found as indicated it should by procedure. 5. QC documentation for each day of patient testing was requested and

	could not be provided by the laboratory for the previous 2 years. 6. In an interview at 1:45 p.m. on June 13, 2023, TP1 confirmed the above findings and stated he performed approximately 1 manual blood smear per month. .
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the Technical Consultant failed to assess competency at least annually for one of seven testing personnel in 2022. Findings are as follows: 1. The laboratory performed mom-waived Chemistry, Hematology, and Microscopic Examinations for bacteria, parasites, fungus, sperm, and urine sediment testing as confirmed the Technical Consultant (TC) and Testing Personnel 1 (TP1) during a tour of the laboratory at 10: 55 a.m. on June 13, 2023. 2. The Abbott i-STAT chemistry, Sysmex KX-21N hematology analyzers, as well as the Olympus BH-2 microscope on which Microscopic Examinations procedures were performed were present and available for use during the tour. 3. Annual competency assessments were required as established in the Competency Assessment policy found within the Quality Assurance for Laboratory Testing, Lab-0135 policy found in PolicyStat. 4. 2022 annual competency assessment records for the Testing Personnel 6 were not found for the following non-waived tests: KX-21 I STAT Post Vas Manual Differential Wet Prep Urine Microscopic 5. The laboratory was unable to provide the missing records upon request. 6. In an interview at 1:30 p.m. on June 13, 2023, the TC confirmed the above findings. .
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: . Based on review of personnel records and interview with laboratory personnel, the laboratory failed to ensure staff performing moderately complex testing meet the qualification requirements of 493.1423 to perform the functions specified in 493.1425 for the complexity of testing performed. Findings are as follows: Documentation was not provided for two of seven testing personnel showing educational requirements under 493.1423 were met. See D6065. .
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a

	chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to ensure two of seven testing personnel had the required educational credentials to perform moderate complexity testing. Findings are as follows: 1. The laboratory performed Chemistry and Hematology testing and Microscopic Examinations for bacteria, parasites, fungus, sperm, and urine sediment as confirmed the Technical Consultant (TC) and Testing Personnel 1 (TP1) during a tour of the laboratory at 10:55 a.m. on June 13, 2023. The laboratory performed approximately 4,847 moderate complexity tests annually. 2. Documentation of a high school education was not found for Testing Personnel 2 (TP2), or Testing Personnel 6 (TP6), during review of laboratory documents. Associate degrees in Radiography for TP2 and TP6 were provided. 3. Survey document Form CMS-209, signed by the Laboratory Director (LD) on June 13, 2023, listed TP2 and TP6 as qualified to perform moderate complexity testing. 4. In an interview at 12:15 a.m. on June 13, 2023, the TC and LD confirmed documentation of a high school education was not present for TP2 or TP6. The laboratory was given an opportunity to provide the credentials within 3 days of the survey. 5. In an email dated June 15, 2023, received at 3:49 p.m., the LD indicated the diplomas or official documentation of high school education had not been received for TP2 and TP6. .