

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0404531	(X3) Date Survey Completed 06/14/2023
Name of Provider or Supplier Gundersen La Crescent Clinic	Street Address, City, State 226 N Second St, La Crescent, 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	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>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.</p> <p>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 08:05 a.m. on June 14, 2023. 2. The empty manual differential stain jars and Zeiss AX10 microscope used to perform manual blood smears were observed as present and available for use during the tour of the laboratory. 3. In an interview at 8:09 a.m. on June 14, 2023, TP1 confirmed the lot number and expiration date of the staining material were not getting documented in a way that clearly defined what lot was used for each day of patient testing. TP1 further confirmed that she performed approximately 10-15 manual blood smears per month. 4. A patient who had a manual blood smear performed on January 4, 2022 (MRN XXX249) was reviewed on the day of survey. Records of the lot numbers and expiration of the staining material used could not be found. The laboratory was unable to provide the records at request. 5. In an interview at 10:17 a.m. on June 14, 2023, the TC confirmed the above findings. .</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p>

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.

This STANDARD is not met as evidenced by:

. Based on observation and interview with laboratory personnel, the laboratory failed to ensure three of five available blood collection vacutainers used for collection of blood for coagulation testing was not used after the expiration date had been exceeded. Findings are as follows: 1. Three of the five Becton Dickinson Vacutainer Buffered Sodium Citrate, 0.109 M, 3.2% trisodium citrate blood collection tubes with lot number 2228631 and expiration date 05/31/2023 were observed as present and available for use in the patient draw area #1 during the tour. 2. In an interview at 8:05 a.m. on June 14, 2023, the Technical Consultant confirmed the above finding. .

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 one of eight 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 one of eight 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, and urine sediment as confirmed the Technical Consultant

(TC) and Testing Personnel 1 (TP1) during a tour of the laboratory at 8:05 a.m. on June 14, 2023. The laboratory performed approximately 7,895 moderate complexity tests annually. 2. Documentation of a high school education was not found for Testing Personnel 7 (TP7) during review of laboratory documents. An Associate degree in Radiography for TP7 was provided. 3. Survey document Form CMS-209, signed by the Laboratory Director (LD) on June 14, 2023, listed TP7 as qualified to perform moderate complexity testing. 4. In an interview at 11:45 a.m. on June 14, 2023, the TC and LD confirmed documentation of a high school education was not present for TP7. The laboratory was given an opportunity to provide the credentials within 2 days of the survey. 5. In an email dated June 15, 2023, received at 3:49 p.m., the LD indicated the diploma or official documentation of high school education had not been received for TP7.