Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0405851	(X3) Date Survey Completed 11/16/2023
Name of Provider or Supplier Alexandria Clinic	**Street Address, City, State** 610 30th Ave W, Alexandria, 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
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with laboratory personnel, the laboratory failed to follow the manufacturer's instructions to perform a study establishing the normal patient Prothrombin (PT) mean for each new lot ensuring the laboratory provided test results within stated performance specifications for Coagulation testing performed under the specialty of Hematology having the potential to affect 484 patient specimens in 2023.. Findings are as follows: 1. The laboratory performed Coagulation testing under the specialty of Hematology as confirmed by Technical Consultant 1 (TC1) during a tour of the laboratory at 10:45 a.m. on November 16, 2023. 2. The Instrumentation Laboratory ACL Top 350 Coagulation instrument was observed as present and available for use during the tour of the laboratory. 3. The package insert for the HemosIL RecombiPlasTin 2G (lot # N0138890) directed the laboratory to enter the International Sensitivity Index (ISI) value from the insert and establish the mean of the PT Normal Range with each new lot. 4. Documentation showing the new normal patient PT mean had been established with the most recent lot change was requested at 12:20 p.m. on November 16, 2023. The laboratory was unable to provide the documentation. 5. In an interview at 2:20 p. m. on November 16, 2023, TC1 confirmed the new lot had been put into use on July 26, 2023 and the laboratory had not performed a mean normal range study. TC1 further confirmed that the laboratory had performed 484 coagulation tests since switching to this new lot of RecombiPlasTin without establishing a new normal patient PT mean. .

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 observation, document review, and interview with laboratory personnel, the laboratory failed to perform minimum quality control activities required for a Toxicology test system for 2022 and 2023. Findings are as follows: 1. The laboratory performed Toxicology testing under the specialty of Chemistry as confirmed by Technical Consultant 1 (TC1) during a tour of the laboratory at 10:45 a.m. on November 16, 2023. 2. The Medtox Profile-V Scanner Toxicology instrument, used to perform urine drug screens, was observed as present and available for use during the tour of the laboratory. In an interview at 11:00 a.m., during the tour, TC1 confirmed the laboratory performs external quality control (QC) weekly on the instrument and that they had not performed and Individual Quality Control Plan (IQCP) to reduce the QC frequency from daily to weekly. 3. The Medtox Weekly QC logs provided evidence the laboratory had performed QC testing with positive and negative external control materials each week of use for the entire year of 2021 and 2023. 4. A Medtox Profile-V Individual Quality Control Plan to reduce the frequency of QC performance from 2 levels of control material each day of patient testing was not found in laboratory records. The laboratory was unable to provide an IQCP for the Medtox Profile-V upon request. 5. In an interview at 2:25 p.m. on November 16, 2023, TC1 confirmed the above finding. TC1 further confirmed the laboratory had performed 483 patient tests on the Medtox Profile-V in 2023. .
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 nine testing personnel in 2022. Findings are as follows: 1. The laboratory performed non-waived Chemistry, Hematology, and Microscopic Examinations for bacteria, parasites, fungus, sperm, and urine sediment testing as confirmed Technical Consultant (TC1) during a tour of the laboratory at 10:45 a.m. on November 16, 2023. 2. The Abbott Architect, Tosoh G8, MedTox Profile-V, ACL Top 350, Sysmex KN-1000, as well as the Olympus CX-43 and Nikon Eclipse E200 microscopes 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 laboratory General Policies and Procedures manual. 4. 2022 annual competency assessment records for the Testing Personnel 9 were not found for the following non-waived tests: Architect Tosoh G8 MedTox Profile ACL Top 350 Sysmex KN-1000 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 November 16, 2023, TC1 confirmed the above findings. .