Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0402688	(X3) Date Survey Completed 12/09/2021
Name of Provider or Supplier Northwest Family Clinics	**Street Address, City, State** 5700 Bottineau Blvd Ste 100, Crystal, 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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) 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 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. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to include accurate Hematology reference ranges in the procedure manual for four of nine reported parameters. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by Testing Personnel 1 during a tour of the laboratory at 1:10 p.m. on 12/09/21. 2. A Sysmex XP-300 hematology analyzer was observed as present and available for use during the tour of the laboratory. 3. Reference ranges for four of nine reported parameters were inaccurate in the Complete Blood Count of Whole Blood on the Sysmex XP300

	procedure, found in the Crystal Lab Manual, when compared to an adult female patient test report from 11/20/19 and an adult male test report from 12/18/21. The inaccurate parameters were Red Blood Cells (RBC), Hemoglobin (HGB), Hematocrit (HCT), Mean Corpuscular Volume (MCV). See below. Adult Female report from 11 /20/19 Parameter Procedure Report RBC 3.8-5.2 4.2-5.4 HCT 35-47 36-48 MCV 80-98 80-100 Adult Male report from 12/18/20 Parameter Procedure Report RBC 4.4-6.0 4.6-6.2 HGB 13-18 14-18 HCT 40-52 40-54 MCV 80-96 80-100 4. In an interview at 3:30 p.m. on 12/09/21, Technical Consultant 1 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 moderate complexity 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 eleven 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 eleven testing personnel had the required educational credentials to perform moderate complexity testing. Findings are as follows: 1. The laboratory performed Hematology testing and Microscopic Examinations for bacteria, parasites, fungus, and urine sediment as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory at 1:10 p.m. on 12/09/21. The laboratory performed approximately 7,833 moderate complexity tests annually. 2. High School diplomas were not found for Testing Personnel 6 (TP6) and Testing Personnel 9 (TP9) during review of laboratory documents. Medical Assisting diplomas for TP6 and TP9 were provided. 3. Survey document Form CMS-209 listed TP6 and TP9 as qualified to perform moderate complexity testing. 4. In an interview on 12/09/21 at 1:45 p.m.,

	Testing Personnel 1 (TP1) confirmed High School diplomas were not present for TP6 and TP9. The laboratory was given an opportunity to provide the credentials within 5 days of the survey. 5. In an email dated 12/14/21 at 11:17 a.m., TP1 indicated the diplomas or official documentation of high school education had not been received for TP6 nor TP9.