Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D1003005	07/25/2025
Name of Provider or Supplier	**Street Address, City, State**	
Native American Community Clinic	1213 E Franklin Ave, Minneapolis, 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
D0000	. The Native American Community Clinic laboratory was found to be out of compliance with the regulations of the Clinical Laboratory Improvement Amendments of 1988 (42 C.F.R. part 493) upon completion of the recertification survey performed on July 25, 2025. The following standard-level deficiencies were cited: 493.1251 Procedure manual 493.1253 Establishment and verification of performance specifications 493.1254 Maintenance and function checks 493.1289 Analytic Systems Quality Assessment 493.1407 Laboratory director responsibilities .
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(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 the reference interval and the reportable range in the procedure manual for one of one new chemistry analyzers implemented in 2023. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory at 10:20 a.m. on 07/25 /2025. 2. An Abbott Afinion 2 analyzer was observed as present and available for use during the tour. The laboratory performed moderate complexity Hemoglobin A1c (HbA1c) testing on this analyzer from 09/18/23 through 06/21/24. 3. The HbA1c reference interval and reportable range were not found in the Hemoglobin A1C on Alere Afinion HA1cDx procedure found in the Lab Policies and Procedures Manual. 4. In an interview at 2:58 p.m. on 7/25/25, the TP1 confirmed the above findings. 5. The laboratory performed 945 HbA1c tests in 2023 and 2024 as indicated by TP1 in an email received at 3:56 p.m. on 07/29/25. .
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i) (A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to complete one of four required performance (PV) activities for one of one new analyzers implemented by the laboratory in 2023. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory at 10:20 a.m. on 07/25/2025. 2. An Abbott Afinion 2 analyzer was observed as present and available for use during the tour. The laboratory performed moderate complexity Hemoglobin A1c (HbA1c) testing on this analyzer from 09/18/23 through 06/21/24. 3. HbA1c reportable range verification documents were not found with PV documents located in the Lab Policies and Procedures Manual. The laboratory was unable to provide the missing documentation upon request. The laboratory director approved the PV activities on 07 /27/23. 4. In an interview at 2:55 a.m. on 07/25/25, the Technical Consultant confirmed the above findings. 5. The laboratory performed 945 HbA1c tests in 2023 and 2024 as indicated by TP1 in an email received at 3:56 p.m. on 07/29/25. .
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) (a)(2) Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturers established limits before patient testing is conducted. (b) Equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer. The laboratory must do the following:

	This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to ensure monthly maintenance for one of one Chemistry analyzers was performed and documented as required by the manufacturer in 2023 and 2024. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory at 10:20 a.m. on 07/25/2025. 2. An Abbott Afinion 2 analyzer was observed as present and available for use during the tour. The laboratory performed moderate complexity Hemoglobin A1c (HbA1c) testing on this analyzer from 09/18/23 through 06/21/24. 3. The manufacturer required monthly cartridge chamber cleaning as indicated in the Hemoglobin A1C on Alere Afinion HA1cDx procedure found in the Lab Policies and Procedures Manual. 4. Abbott Afinion 2 maintenance records were not found during review of laboratory records. The laboratory was unable to provide this documentation upon request. 5. In an interview at 2:50 p.m. on 07/25/25, TP1 confirmed the above finding. 6. The laboratory performed 945 HbA1c tests in 2023 and 2024 as indicated by TP1 in an email received at 3:56 p.m. on 07/29/25. .
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to follow established quality assurance (QA) procedures for one of one hematology analyzers in 2023, 2024, and 2025. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the Testing Personnel 1 (TP1) during a tour of the laboratory at 10:20 a.m. on 07/25/25. 2. A Horiba ABX Micros 60 hematology analyzer was observed as present and available for use during the tour of the laboratory. The laboratory performed Complete Blood Count testing on this analyzer. 3. The following QA activities were required as established in the Laboratory Responsibilities procedure found in the Laboratory Policies and Procedures Manual: Monthly - print all hematology analyzer logs for quality control, Levi-Jennings, service, reagents, problems, patients, and background checks 4. The laboratory failed to complete monthly actives in the established timeframe in 17 of 26 months from May 2023 through June 2025 as indicated on hematology monthly logs reviewed on date of survey. See below Month of report Date printed December 2023 Not found January-February 2024 03/03/25 March-June 2024 07/24/25 July-October 2024 Not found November-December 2024 07/24/25 January 2025 07/24/25 February-March 2025 07/14/25 April 2025 06/09/25 5. In an interview at 3:55 p.m. on 07/25 /25, TP1 confirmed the above finding. *This deficiency was cited during the 04/21/23 survey* .
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

	This STANDARD is not met as evidenced by: . Based on review of laboratory policies and procedures, laboratory records, and interview with laboratory personnel, the Laboratory Director failed to ensure quality assessment (QA) activities were completed in 2023, 2024, and 2025. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the Testing Personnel 1 (TP1) during a tour of the laboratory at 10:20 a.m. on 07/25/25. 2. A Horiba ABX Micros 60 hematology analyzer was observed as present and available for use during the tour of the laboratory. The laboratory performed Complete Blood Count testing on this analyzer. 3. Required QA activities for the Horiba Micros 60 hematology analyzer were not performed as required in 17 of 26 months in the time period of May 2023 through June 2025. See D5791. 4. This deficiency was previously cited during the 04/21/23 survey. 5. In an interview at 3:55 p.m. on 07/25/25, Testing Personnel 1 confirmed the above finding. .