Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D1003005	04/21/2023
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
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: . Based on record review and interview with laboratory personnel, the laboratory failed to report SARS-CoV-2 positive test results for 16 of 16 days of testing in January 2023 through April 2023. Findings are as follows: 1. The laboratory performed SARS-CoV-2 testing using the BinaxNOW COVID-19 Antigen Card as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory at 10:20 a.m. on 04/21/23. 2. During the tour, TP1 indicated positive SARS-CoV-2 results had not been reported to the appropriate health authorities since test implementation. At 10:35 a.m. on 04/21/23, the Laboratory Director (LD) confirmed positive SARS-CoV-2 test results had not been reported since BinaxNOW COVID-19 Antigen Card test implementation in January 2023. 3. Manual patient testing logs were not completed for the testing. Results were available in the laboratory's electronic medical records (EMR) system. A BinaxNOW COVID-19 Antigen Card positive result report from the EMR was provided by the LD on date of survey. 4. The laboratory performed 19 positive SARS-CoV-2 tests between 01/18/23 through 04/05/23 as indicated on the EMR report. 19 of 19 SARS-CoV-2 positive test results were not reported as required. Number of days of non-reporting are indicated below. 2023 Days not reported January

	2 February 7 March 6 April 1 5. In an interview at 12:30 p.m. on 04/21/23, the LD confirmed the above findings.
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 observation, document review, and interview with laboratory personnel, the laboratory failed to retain Hematology calibration verification records for at least 2 years. 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 04/21/23. 2. A Horiba ABX Micros 60 hematology analyzer was observed as present and available for use during the tour of the laboratory. 3. Hematology analyzer calibration verification was required every six months as established in the Laboratory Calendar found in the Laboratory Policies and Procedures Manual. 4. Calibration verification was performed by the Horiba service technician in August 2022 as indicated in the service report. Calibration verification documentation from August 2022 was not found in laboratory records. 5. Laboratory record retention was required for two years as established in the Quality Assurance section of the Laboratory Policies and Procedures Manual. 6. In an interview at 2:00 p.m. on 04/21/23, TP1 confirmed the above finding. .
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: . Based on proficiency testing, procedure, test report, calibration verification, and quality assurance record review and interview with laboratory personnel, the laboratory failed to meet requirements for the specialty of Hematology as specified in 493.1236, 493.1251, 493.1255, and 493.1289. Findings are as follows: 1. The laboratory failed to investigate one unacceptable Hematology proficiency testing (PT) result out of fifteen challenges completed in 2022. See D5211 2. The laboratory failed to include accurate Hematology reference ranges in the procedure manual for five of five analytes reviewed for Complete Blood Count testing since April 2021. See D5403 3. The laboratory failed to perform and document calibration verification on a Hematology analyzer at least once every 6 months in 2021. See D5439 4. The laboratory failed to follow established quality assurance procedures in 2021 and 2022. See D5791 .
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing

	performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to investigate one unacceptable Hematology proficiency testing (PT) result out of fifteen challenges completed in 2022. 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 04/21/23. 2. The laboratory performed PT using the American Academy of Family Physicians (AAFP) provider. 3. The laboratory received one unacceptable PT result of fifteen Granulocyte testing challenges completed in 2022 as indicated in AAFP reports. See below. 2022 - C event Test: Granulocytes Sample: HD-15 Laboratory Result: 24.7 AAFP expected range: 89.2-93.4 4. Investigation of unacceptable PT results was required as established in the laboratory's Proficiency Testing Policy located in the Laboratory Policies and Procedures Manual. 5. Investigation documentation for the unsuccessful score was not found in laboratory records. The laboratory was unable to provide evidence of PT result investigation and corrective action records for this event upon request. 6. In an interview at 1:50 p.m. on 04/21/23, TP1 confirmed the above finding. .
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 and interview with laboratory personnel, the laboratory failed to establish a written procedure for reporting SARS-CoV-2 results to the required health authorities. Findings are as follows: 1. The laboratory performed SARS-CoV-2 testing using the BinaxNOW COVID-19 Antigen Card as confirmed by Testing Personnel 1 during a tour of the laboratory at 10:20 a.m. on 04/21/23. 2. The Laboratory Director (LD) indicated the BinaxNOW COVID-19 Antigen Card testing was implemented in January 2023. 3. A procedure for reporting SARS-CoV-2 test results to the required authorities was not found during review of the Laboratory Policies and Procedures Manual. 4. The laboratory was unable to provide a reporting procedure upon request. 5. The laboratory failed to report 19 of 19 positive SARS-CoV-2 results to the appropriate health authorities between 01/18/23 through 04/21 /23. See D3000. 6. In an interview at 1:55 p.m. on 04/21/23, the LD confirmed the above findings.
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 five of five analytes reviewed for Complete Blood Count (CBC) testing since April 2021. 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 04/21/23. 2. A Horiba ABX Micros 60 hematology analyzer was observed as present and available for use during the tour of the laboratory. The laboratory began using this analyzer in April 2021 as indicated by TP1. 3. Reference ranges for five of five reviewed CBC analytes were inaccurate in the ABX Micros 60 IM procedure, found in the Laboratory Policies and Procedures Manual, when compared to a patient CBC test report from 01/12/22. The inaccurate analytes were White Blood Cells (WBC), Red Blood Cells (RBC), Hemoglobin (HGB), Hematocrit (HCT), and Platelets (PLT). See below. Patient report from 01/12 /22 Analyte Procedure Report WBC 3.5-10.0 3.8-10.8 RBC 3.8-5.8 3.8-5.10 HGB 11.0-16.5 11.7-15.5 HCT 35-50 35-45 PLT 150-450 140-400 4. In an interview at 2: 00 p.m. on 04/21/23, the Laboratory Director confirmed the above finding. .
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 Hematology analyzer calibration verification at least once every 6 months in 2021. 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 04/21/23. 2. A Horiba ABX Micros 60 hematology analyzer was observed as present and available for use during the tour of the laboratory. 3. Hematology analyzer calibration verification was required every six months as established in the Laboratory Calendar found in the Laboratory Policies and Procedures Manual. 4. Calibration verification was performed on 03/09/21 and 02/22/22 as indicated in laboratory records. Eleven months and three days elapsed between the calibration verification dates. Documentation for a calibration verification performed between 03/09/21 and 02/22/22 was not found. The laboratory was unable to provide the missing documentation upon request. 5. In an interview at 1:20 p.m. on 04/21/23, TP1 confirmed the above finding. .
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. (c) The laboratory must document all analytic systems assessment activities. 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 in 2021 and 2022. 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 04/21/23. 2. A Horiba ABX Micros 60 hematology analyzer was observed as present and available for use during the tour of the laboratory. 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 Quarterly - perform laboratory QA audit 4. The laboratory failed to complete monthly actives in the established timeframe in 2021 and 2022 as indicated on hematology monthly reports reviewed on date of survey. See below Month of report Date printed April - December 2021 04/20/23 January - September 2022 04/21/23 October - December 2022 04/20/23 5. Quarterly audit documentation from 2021 and 2022 was not found during review of QA records. The laboratory was unable to provide the missing documentation upon request. 6. In an interview at 1:25 p.m., TP1 stated quarterly audits were not performed in 2021 and 2022. In an interview at 2:05 p.m. on 04/21/23, TP1 confirmed the 2021 and 2022 monthly reports were printed in April 2023. .