Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D2022613	03/22/2021
Name of Provider or Supplier	**Street Address, City, State**	
Center For American Indian Resources	221 W 4th Street, Duluth, 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 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 as confirmed by the Laboratory Director (LD) during a tour of the laboratory at 9:05 a.m. on 03/22/21. Laboratory records indicated the first patient result was completed on 06/30/20. 2. The procedures provided by the laboratory did

	not include criteria for reporting SARS-CoV-2 test results to the required authorities. 3. The laboratory was unable to provide this reporting procedure upon request. 4. In an interview at 11:45 a.m., on 03/22/21, the LD confirmed the above findings.