Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	35D0691722	02/27/2019
Name of Provider or Supplier	**Street Address, City, State**	
Nd Department Of Health & Human Services	2635 East Main Avenue, Bismarck, ND	

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
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 review of IQCP documentation and staff interview, two of three IQCPs reviewed did not have risk assessments that supported quality control frequency established by the IQCP. Findings include: 1. Review of the Verigene and Solana platforms IQCP plans revealed each had quality control data collected from a 10 day and three day period respectively, to establish quality control frequency. 2. The quality control frequency stated for both instrument platforms in the IQCP and method procedure stated quality control was to be performed every 30 days or with each new lot and shipment of assays. 3. In an interview conducted on 02/26/2019 at approximately 12:00 PM, the Quality Assurance Manager and Laboratory Manager confirmed quality control data from the Verigene was only collected for a 10 day period, and for the Solana instrument over a three day timeframe and that additional quality control data collection would provide better validity to the respective IQCPs mentioned above.
D5805	TEST REPORT CFR(s): 493.1291(c)

	The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of test reports and interview with staff, the laboratory failed to have the name and address of the laboratory performing the test for one of one test report reviewed. Findings include: 1. Review of a test report received from the Centers for Disease Control and Prevention (CDC) that was sent from the North Dakota Public Health Laboratory revealed the address for the CDC location was not on the report sent to the provider for specimen ID A18017503. 2. In an interview conducted on 02 /26/2019 at approximately 1:00 PM, the Quality Assurance Manager confirmed the address for the CDC location was not on the test report sent to providers for specimens sent to and received from CDC.