Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2077172	03/14/2019
Name of Provider or Supplier	**Street Address, City, State**	
Nih Intramural Sequencing Center	5625 Fishers Lane, Rockville, MD	

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
D5455	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(v)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each molecular amplification procedure, include two control materials and, if reaction inhibition is a significant source of false negative results, a control material capable of detecting the inhibition. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of testing run worksheets, and interview, it was determined the laboratory failed to include positive and negative control materials with each run of patient specimens that are capable of detecting nucleic acid target amplification sequences by the testing method used in the facility. During the time period of April 7, 2017 through March 13, 2019 the facility tested approximately 400 patient samples for whole exome DNA sequencing analysis by a Next Generation Sequencing (NGS) in-house developed sequencing method for variants in 59 genes for breast cancer detection as recommended for reporting of secondary findings by the American College of Medical Genetics. Findings include: 1. The surveyor reviewed patient testing run number (C062) that included four (4) patient specimens (Sample numbers 400735, 400736, 400737 and 400738) for testing by NGS. 2. On testing run worksheets and the corresponding plate maps, the surveyor noted there was no identification/inclusion of known positive and negative control DNA sequences. 3. Interview with the laboratory director and technical supervisor on March 14, 2019 at approximately 11:00am confirmed the findings. The surveyor was told the laboratory believed the patient sample itself acted as the control due to the nature of the testing methology.