Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	99D1066287	04/03/2018
Name of Provider or Supplier	**Street Address, City, State**	
Centro De Genetica Clinica/Cgc Genetics	Rua Manuel Pinto De Azevedo Numero 173, Not Available, FN	

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	Based on review of the Standard Operative Procedure SOP.804- Next Generation Sequencing and email correspondence with laboratory staff, the laboratory failed to include two quality control materials at least once each day patient samples were assayed. Findings: 1. Review of SOP.804 - Next Generation Sequencing revealed the procedure included criteria for Quality Control. This criteria did not include the testing of two control materials each day patient samples are tested. 2. Email correspondence with the laboratory's quality manager dated July 3, 2018 stated " ...the NGS quality control procedure: every three months we test a male DNA (Human Male Genomic DNA , Promega) as a quality control material in order to evaluate the robustness and reproducibility of our assays." 3. Email correspondence with the laboratory's quality manager dated June 23, 2018 stated " ...the policy of our lab is as follows: In our assays we do not include a positive control. Following the international recommendations (ACMG Practice guidelines, PMID: 23887774), and "similar to Sanger-based sequencing, positive controls do not need to be tested concurrent with routine clinical tests". We have though, strategies to evaluate and control for eventual contaminations. We perform in average three assays per week and samples are tested for different panels, a second technician performs visual double verification of sample ID, and since we perform Sanger sequencing for confirmation of variants reported in result it is common that in each assay at least one sample will be further confirmed independently by a different method (Sanger sequencing)."