

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2066797	(X3) Date Survey Completed 06/03/2019
Name of Provider or Supplier Igenomix Usa Inc	Street Address, City, State 5201 Waterford District Drive Suite 100, Miami, FL	
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
D0000	An announced CLIA initial certification survey was conducted at Igenomix USA LLC on 6/3/2019. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D5431	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: Based on maintenance records and interview with laboratory director (LD), the laboratory failed to have documentation of the daily and weekly maintenance for 3 out of 3 months (2019) reviewed. Findings include: Review of the user manual for 3100 Genetic Analyzer maintenance task list, revealed the list of tasks required: Before each run: ensure the reservoir septa are firmly seated and flat, ensure the plate assemblies were put together properly, ensure the plate assemblies are positioned on the plate deck properly. Daily Maintenance: replenish water, check for bubbles, check the loading-end header to ensure capillary tips are not crushed or damaged, check polymer level to ensure at least is 1 ml, check for dried polymer around the polymer block, check leaks, check database space. Weekly Maintenance: Clean syringes, clean water and buffer reservoirs, clean polymer blocks, replace polymer syringes, check storage conditions of used arrays. Review of the maintenance record from March to June 2019 revealed that the laboratory kept record of the monthly maintenance but there was no documentation of the daily and weekly maintenance. During an Interview on 6/3/2019 at 11:30 am, the LD confirmed that the laboratory failed to have documentation of the daily and weekly maintenance for the period of reference</p>