

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D2077738	<b>(X3) Date Survey Completed</b>  10/28/2021
<b>Name of Provider or Supplier</b>  Juno Genetics Us Inc	<b>Street Address, City, State</b>  140 Allen Road, Suite 300, Basking Ridge, NJ	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5775</b>	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p> <p>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Laboratory Records and interview with the General Supervisor (GS), the laboratory failed to perform comparison studies for the Illumina NextSeq 550 instruments in use from October 2019 to the date of the survey. The finding includes: 1. There was no documented evidence the laboratory performed comparison studies between the two Illumina NextSeq 550 instruments twice a year. 2. The GS confirmed on 10/28/21 at 3:00 pm that the laboratory failed to perform comparison studies.</p>