

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D2272329	<b>(X3) Date Survey Completed</b>  07/26/2023
<b>Name of Provider or Supplier</b>  Opus Genomics, Llc	<b>Street Address, City, State</b>  5110 Campus Drive, Suite 130, Plymouth Meeting, PA	
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>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the temperature records, and an interview with the Technical Supervisor (TS) #3 (CMS 209) and Laboratory Director (LD), the laboratory failed to define criteria for the Room and Heat Block Temperature for the Chemistry department from 06/15/2023 to the day of survey. Findings include: 1. On the day of the survey, 07/26/2023 at 11:12 AM, a review of the laboratory's temperature logs revealed that the laboratory could not provide documentation of the defined criteria established by the laboratory for the room and heat block temperature range from 6/15/2023 to 7/26/2023. 2. Laboratory Failed to document RT for 28 of 28 days of patient testing. 3. The following reagents were found to be stored at RT. Buffer AE Elution Buffer-15 ml Buffer AL Lysis Buffer-12 ml Buffer AW1 Wash Buffer 1 Buffer AW2 Wash Buffer 2 4. Interview with TS #3 and LD confirmed the findings above on 07/26/2023 at 12:31 PM.</p>