

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  21D2161577	<b>(X3) Date Survey Completed</b>  10/30/2024
<b>Name of Provider or Supplier</b>  Cosmosid Ngs Laboratory Services, Llc	<b>Street Address, City, State</b>  20030 Century Blvd, Suite 300, Germantown, MD	
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>D5781</b>	<p><b>CORRECTIVE ACTIONS</b> CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on procedure manual and temperature log record review and interview with the quality assurance (QA) Senior Manager, the laboratory failed to document corrective action when room temperatures were out of range. Findings: 1. The laboratory performs WGS (whole genome sequencing) microbiome analysis on stool and vaginal swab specimens. Patient specimens are stored at ambient (room) temperature. 2. The procedure, "EQ SOP 3344 Eupry Temperature Monitoring System Use and Maintenance," section "12.3. Temperature Excursion Setup" states that the "Ambient Laboratory Temperature" range "as defined by CosmosID" is "+10C [Celsius] to +30C." 3. A review of room temperature logs from June 2024 showed that room temperature was out of the acceptable range from 06/19/2024 at 3:00 PM through 06/20/2024 at 2:00 AM in "Lab112" where patient specimens are stored. The maximum temperature recorded during that time period was "33.86 C." 4. A review of "Eupry Monitoring" records showed that on 06/20/2024 at 10:36 AM, the laboratory noted in the "Logbook" the comment, "Elevated room temperature due to A/C issues." Record review showed that there was no documentation of what corrective actions were taken to ensure that patient specimens were not affected by the out of range temperatures. 5.</p>

During an interview on 10/30/2024 at 4:45 PM, the QA Senior Manager confirmed that there were no corrective actions documented for the days that the room temperatures were out of range.