

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 38D2059408	(X3) Date Survey Completed 04/18/2023
Name of Provider or Supplier Oregon Urology Institute	Street Address, City, State 2550 Nw Edenbower Boulevard, Suite 102, Roseburg, OR	
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
D5413	<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 review of daily temperature records and interview with the Office Manager, the laboratory failed to respond to temperature outliers for the microbiology incubator. Findings include: 1. Upon request for written documentatin of the refrigerator and incubator temperature logs, it was revealed that the incubator used to keep microbiology cultures at 36 degrees Celcius (body temperature) waiting to be transported to the main lab for this facility, had been out of range for 189 days. 2. The laboratory's established temperature range for the incubator is 34 degrees - 37 degrees Celcius. 3. The written recorded temperature for the incubator from 08/24/2021 thru 04/18/2023 (189 days) was in the range of 23 degrees to 27 degrees Celcius. 4. Interview with the Compliance Manager and Medical Assistant 1 (MA1) during survey 04/18/2023 at approximately 12:00 pm confirmed that instrument had been out of temperature range since 08/24/2021 (189 days).</p>
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken</p>

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.

This STANDARD is not met as evidenced by:

Based on review of temperature records for the incubator used to incubate microbiological cultures waiting to be transferred to the main lab, the laboratory failed to address and initiate corrective action for temperature outliers. Findings include: 1. The microbiology incubator in use failed to meet the laboratory's established temperature range of 34 - 37 degrees Celcius beginning 08/24/2021 and continued to remain out of range up until this survey 04/18/2023 or 189 days. 2. No procedure for addressing temperature outliers and corrective action for this instrument could be produced during survey. 3. Upon request for written documentation of corrective action performed for temperature outliers for this instrument, none could be produced. 4. Interview with the Office Manager at approximately 12:00 pm during survey 04/18/2023 confirmed that there was no Standard Operating Procedure (SOP) or corrective action regarding temperature outliers for this laboratory.