

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 38D2040640	<b>(X3) Date Survey Completed</b> 03/13/2024
<b>Name of Provider or Supplier</b> Zoomcare Laboratory	<b>Street Address, City, State</b> 11956 Sw Garden Pl, Tigard, OR	
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>D5429</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on review of preventive maintenance (PM) records and interview with the laboratory director (LD), the laboratory failed to perform PM of two instruments used in the laboratory. Findings include: 1. Review of PM records for the Select Medical Product PSS602 Serial Number (SN) 1202161 centrifuge revealed no PM records for the year 2023 and 2024. 2. Review of PM records for the Lumeon microscope SN G3AL20120909 revealed that last PM was done 04/2022. No PM records for the year 2023 and 2024. 3. Interview with the LD on 03/13/2024 at 15:52 confirmed that PM for these two instruments were not perform. 4. The laboratory reports 218,000 chemistry assays and 108,000 hematology assays annually.</p>
<b>D5807</b>	<p><b>TEST REPORT</b> CFR(s): 493.1291(d)</p> <p>Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.</p> <p>This STANDARD is not met as evidenced by: Based on review of the approved normal values in the laboratory procedure manual, review of patient report, and interview with the laboratory director (LD), the laboratory failed to ensure the test report included pertinent normal ranges as</p>

determined by the laboratory. One (1) out of fourteen (14) chemistry normal values listed on the laboratory information system (LIS) report differed from those in the approved procedure manual. Findings include: 1. Review of patient report 21-027-00044 from the LIS system revealed the following. LIS Patient Report Procedure Manual Total 0.3 - 1.3 MG/DL 0.3 - 1.0 MG/DL Bilirubin 2.. Interview with the LD on 03/13/2024 at 15:30 confirmed the laboratory failed to ensure correct references ranges approved in the procedure manual were the same as in the LIS patient reports. 3. The laboratory reports 218,000 chemistry assays annually.