

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2270100	(X3) Date Survey Completed 02/08/2024
Name of Provider or Supplier Osh Pathology Laboratory Associates, Inc	Street Address, City, State 2408 E 81st St, Ste 105, Tulsa, OK	
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
D0000	The initial survey was performed on 02/08/2024. The laboratory was found in compliance with a standard-level deficiency cited. The findings were reviewed with the executive director of PLA and laboratory support during an exit conference performed at the conclusion of the survey.
D5429	<p>MAINTENANCE AND FUNCTION CHECKS 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 a review of records and interview with the executive director of PLA (Pathology Laboratory Associates) and laboratory support, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures for one of one cryostat reviewed from October 2022 through December 2023. Findings include: (1) On 02/08/2024 at 10:30 am, the executive director of PLA stated frozen specimen preparations were performed using the Leica CM1850 UV cryostat; (2) A review of the manufacturer's maintenance log showed the following required weekly maintenance procedures: (a) "Apply drop of oil to coupling" (b) "Lubricate specimen cylinder" (3) A review of maintenance logs from October 2022 through December 2023 identified no documentation weekly maintenance had been performed between: (a) 11/17/2022 and 01/02/2023; (b) 03/01/2023 and 03/25/2023; (c) 03/25/2023 and 04/05/2023; (d) 05/30/2023 and 09/12/2023 - (June, July, and August had been documented as performed with initials only and no dates, therefore it could not be definitively concluded if maintenance had been performed weekly); (e) 09/12/2023 and 09/26/2023. (4) The records were reviewed with the executive director of PLA and laboratory support who stated on 02/08/2024 at 12:00 pm, the weekly maintenance had not been documented as performed as shown above.</p>