

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1079299	(X3) Date Survey Completed 11/30/2023
Name of Provider or Supplier J Morgan Odonoghue Pa	Street Address, City, State 1952 Field Rd, Sarasota, FL	
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	An on-site announced CLIA recertification survey was conducted at J Morgan O'Donoghue PA on 11/30/2023. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiency:
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview with the Practice Manager, the laboratory failed to ensure the histopathology reagents were not expired prior to performing 193 patient tests from 08/07/23- 11/27/23. Findings Included: A tour of the laboratory on 11/30/23 at 9:25 AM revealed the following histopathology reagents were expired: Eosin (lot number 131151, expiration 03/31/23), Scott's Tap Water (Lot number 2220817, expiration 08/09/2023), and Xylene Substitute (Lot number 1831109, expiration 11/12/23). Review of the Mohs Log dated 8/7/23 to 11/27/23 revealed 193 patient tests had been performed. On 11/30/23 at 10:00 AM, the Practice Manager confirmed the reagents were expired and had been used to test patients' specimens. Photographic evidence was obtained.</p>