

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2282939	(X3) Date Survey Completed 06/26/2025
Name of Provider or Supplier Wfmh Ii Llc	Street Address, City, State 12250 Tamiami Trail E Suite #201, Naples, 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 announced CLIA recertification survey was conducted at WFMH II LLC on June 26, 2025. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiency:
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p> <p>This STANDARD is not met as evidenced by: Based on Total Testosterone (Testo) and Prostate Specific Antigen (PSA) patient reports review and staff interview, the laboratory failed to ensure that the patient reports had the name of the Laboratory for 9 out of 9 reports from November 2023 to June 2025. Findings included: 1-Review of 9 final patient reports: P#1(date 11/28 /2023), P#2 (date 01/02/2024), P#3 (date 03/19/2024), P#4 (date 06/11/2024), P#5 (date 09/03/2024), P#6 (date 11/05/2024) P#7 (date 02/04/2025), P#8 (04/08/2025) and P#9 (06/10/2025) revealed that the reports failed to list the name of the laboratory that did Testo and PSA testing. 2-During an interview on 06/26/2025 at 02:45 PM, with the Lead Technician, he confirmed that the final reports reviewed failed to show the name of the laboratory that performed the testing instead they showed the name of the group.</p>