

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2226270	(X3) Date Survey Completed 05/31/2024
Name of Provider or Supplier Kindbody Of Florida Medical Practice Pa	Street Address, City, State 1530 Celebration Blvd Suite 200, Celebration, 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	Validation survey was conducted from 5/02/2024 to 5/31/2024. Kindbody clinical laboratory was not in compliance with 42 CFR Part 493, requirements for clinical laboratories.
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>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 record review, and interview with testing staff A, the laboratory failed to have written results for aggregation in semen analysis for 1 out of 5 patients reviewed, (#5). Findings included: Review of Semen analysis final reports revealed the following patient #5's final semen analysis report was missing an aggregation result for 3/22/2022. Review of Semen Analysis- Manual Preparation effective date 1/3 /2024 read, "Raw data on the semen analysis worksheet is transcribed into EMR (electronic medical record). Print and save. The final report is scanned and stored electronically in patient's EMR record." On 5/21/2024 at 5:44 PM, testing personnel A confirmed aggregation result was missing in patient #5's semen analysis final report for 3/22/22.</p>