

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2062280	(X3) Date Survey Completed 07/28/2025
Name of Provider or Supplier Conceptions Fertility Laboratories Llc	Street Address, City, State 4425 Ponce De Leon Blvd Suite 110, Miami, 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 CONCEPTIONS FERTILITY LABORATORIES LLC on July 17, 2025 to July 28, 2025. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
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 review of Patient Reports and staff interview, the laboratory failed to include the name of the laboratory that performed the Hematology and Endocrinology testing on 5 out of 5 (Patients #1, #2, #3, #4 and #5) reports reviewed. Findings included: 1- Review of random patient final reports pulled 03/12/2024 (#1- Hematology), 05/16/2024 (#2- Endocrinology), 05/14/2025 (#3-Hematology), 05/20/2025 (#4-Endocrinology), and 07/14/2025 (#5-Endocrinology) revealed that all five reports failed to include the name of the laboratory that performed the testing. 2- During a phone interview on 07/25/2025 at approximately 10:00 AM, the Technical Consultant confirmed that the Laboratory name was not on the final reports</p>