

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2176775	(X3) Date Survey Completed 03/13/2024
Name of Provider or Supplier Conceptions Fertility Laboratories Llc	Street Address, City, State 2750 Sw 145th Ave Suite 103, Miramar, 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 March 12-13, 2024. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory supervisor failed to monitor monthly quality control (QC) logs for Daily Temperature log and Liquid Nitrogen QC log for 10 out of 12 months in 2023. Findings included: 1- Review of the Daily Temperature logs and Liquid Nitrogen QC logs revealed that 10 (January, February, March, April, May, June, July, August, September, and November) out of 12 months reviewed in year 2023 were not signed by laboratory supervisor. 2 - Based on interview 3/12/2024 at 3:54 PM the Laboratory Supervisor admitted to have missed the review of the QC logs and signature of the QC logs was not done. 3- The laboratory supervisor signed all Daily Temperature and Liquid Nitrogen QC logs for each month before survey exit.</p>