

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2146458	(X3) Date Survey Completed 02/03/2022
Name of Provider or Supplier Women's Center Of Fort Lauderdale, Llc	Street Address, City, State 2161 E Commercial Blvd Ste 400, Fort Lauderdale, 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 unannounced complaint survey, #2022001460, was conducted on February 3, 2022. Women's Center of Fort Lauderdale clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D3009	<p>FACILITIES CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to follow federal regulations requiring the laboratory notify HHS (Department of Health and Human Services) or its designee (Agency for Health Care Administration), within 30 days of changing Laboratory Director on 02/18/2020 and address on 11/18/2020. Findings: Review of the "State Operations Manual Appendix C - Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services," in Regulation 493.51 Notification requirements for laboratories issued a certificate of compliance noted "Laboratories issued a certificate of compliance must meet the following conditions: (a) Notify HHS or its designee within 30 days of any change in-- (1) Ownership; (2) Name; (3) Location; (4) Director . . .)" Review of an application to change Laboratory Directors, signed on 02/18/2020 by the new Laboratory Director, showed the application was incomplete. Laboratories are notified if their application is incomplete. Any application deemed incomplete and not corrected within 30 days is withdrawn. The following information was not filled in on the application: where to send the fee coupon and certificate, name of the new Laboratory Director and his credentials, type of certificate, list of non-waived tests performed, type of control, and list of laboratories the Laboratory Director is affiliated with. Review of the procedure manual showed the new Laboratory Director approved the procedures on 02/18/20.</p>

No documentation of the change of address was available for review. On 02/03/2022 at 11:02 AM, the Administrator stated they moved the laboratory on 11/18/2020. On 02/03/2022 at 11:31 AM, the Administrator stated the laboratory filled out an application to change Laboratory Director 02/18/2020, but was not aware the application was incomplete or if the laboratory received email notification of the corrections needed to be made on the application