

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2213338	(X3) Date Survey Completed 01/18/2022
Name of Provider or Supplier Gago Center For Fertility	Street Address, City, State 2550 Dexter Ave, Ann Arbor, MI	
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
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: . Based on procedure manual review and interview with the General Supervisor (GS), the Laboratory Director (LD) failed to approve, sign, and date 4 of 4 revised procedures in the "OSHA Manual." Findings include: 1. Review of the "OSHA Manual" revealed for 4 of 4 revised procedures, the LD did not approve, sign, and date the revisions for the following: a. Hazard Communication Program b. Exposure Control Plan c. Fire Prevention d. Emergency Action Plan 2. During the interview on 01/18/2022 at 10:02 am, the GS confirmed the LD did not approve, sign, and date the revised procedures from 7/27/2021.</p>
D5431	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: . Based on lack of documentation and interview with the General Supervisor (GS), the laboratory failed to perform and document the function checks as required for the refrigerator and incubator for 2 months (February and June 2020) of 24 months reviewed. Findings include: 1. A record review revealed lack of documentation of the</p>

refrigerator and incubator temperatures as follows: a. February 2020 - lack of documentation for the month i. Patient testing on 2/06/20, 2/13/20, and 2/27/2020 b. June - lack of documentation for the month i. Patient testing on 6/11/2020 2. An interview on 1/18/2022 at 11:07 am, the GS confirmed there was no documentation for the 2 months listed above.