Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2213338	08/12/2025
Name of Provider or Supplier	**Street Address, City, State**	
Gago Center For Fertility	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
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: . Based on observation and interview with the general supervisor, the laboratory failed to ensure blood specimen collection tubes had not exceeded expiration dates for 90 of 106 total tubes in the phlebotomy room. Findings include: 1. The surveyor observed the following blood specimen collection tubes that had exceeded manufacturer expiration dates in the phlebotomy room on 8/12/25 at 12:58 pm: a. Nine green-top sodium heparin tubes with the expiration date of 3/31/22. b. Two serum red-top tubes with the expiration date of 3/31/25. c. 72 sodium citrate blue-top tubes with the expiration date of 9/30/24. d. Seven sodium citrate blue-top tubes with the expiration date of 12/31/24. 2. An interview on 8/12/25 at 12:58 pm with the general supervisor confirmed the tubes above had exceeded expiration dates.
D5805	TEST REPORT CFR(s): 493.1291(c) (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.

	This STANDARD is not met as evidenced by: . Based on record review and interview with the general supervisor, the laboratory failed to include the name and address of the laboratory performing sperm morphology testing for seven (Patients 1-7) of seven patient test reports reviewed. Findings include: 1. A review of the laboratory's test menu revealed the laboratory performs only sperm count and motility testing. 2. A review of patient test reports revealed all patients included results for "SPERM MORPHOLOGY KRUGER": a. Patient #1 had semen analysis performed on 07/31/25. b. Patient #2 had semen analysis performed on 04/17/25. c. Patient #3 had semen analysis performed on 11/21 /24. d. Patient #4 had semen analysis performed on 09/05/24. e. Patient #5 had semen analysis performed on 04/11/24. f. Patient #6 had semen analysis performed on 02/15 /24. g. Patient #7 had semen analysis performed on 10/05/23. 3. An interview on 8/12 /25 at 1:52 pm with the general supervisor revealed the laboratory sends its semen specimens to another laboratory for the morphology testing and confirmed it had not included the name and address of the laboratory reporting those results on the test reports.