

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2081782	(X3) Date Survey Completed 08/02/2018
Name of Provider or Supplier Gago Center For Fertility (Lansing)	Street Address, City, State 1515 Lake Lansing Road Suite F, Lansing, 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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: . Based on record review and interview, the laboratory failed to enroll in a proficiency testing program for four (events 1st-3rd 2017 and 1st event 2018) of four events for the speciality of chemistry endocrinology beta human chorionic gonadotropin (BHcg) testing. Findings include: 1. On August 1, 2018 at 10:35 AM, record review revealed there was no documentation of proficiency testing for four (events 1st-3rd 2017 and 1st event 2018) of four events for the regulated analyte BHcg. 2. During the interview on August 1, 2018 at 10:35 AM, the general supervisor as listed on the CMS-209 confirmed the laboratory was not enrolled in a proficiency testing program for the BHcg testing.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p>

This STANDARD is not met as evidenced by:

. Based on record review and interview, the laboratory failed to verify the accuracy of testing for 1) the hematology sperm count and motility and 2) the endocrinology estradiol, progesterone, follicle stimulating hormone (FSH), and the lutenizing hormone (LH) for one (2017) of two years of testing. Findings include: 1. On August 2, 2018 at 11:18 AM, record review revealed for one (2017) of two years of testing the laboratory did not have documentation to show the verification of accuracy was completed as least twice annually in 2017 for the hematology and endocrinology testing. 2. On August 2, 2018 at 11:18 AM when queried, the general supervisor as listed on the CMS-209 was not able to provide documentation to show the verification of accuracy was completed at least twice annually in 2017. 3. During the interview on August 2, 2018 at 11:18 AM, the general supervisor confirmed the verification of accuracy for the hematology and endocrinology testing was not performed and documented in 2017.