Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0873828	10/12/2021
Name of Provider or Supplier	**Street Address, City, State**	
Mid Iowa Fertility, Pc	1371 Nw 121st Street, Clive, IA	

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
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 10: 30 am on 10/12/21, the laboratory failed to retain the proficiency testing attestation statements for five out of five proficiency testing events from 1/1/2020 - 10/12/2021. The findings include: 1. For 2020 PT event 1, the laboratory did not have attestation statements for antimullerian hormone and thyroid microsomal antibody testing. 2. For 2020 PT event 2, the laboratory did not have the attestation statement for thyroid microsomal antibody testing. 3. For 2020 PT event 3, the laboratory did not have the attestation statement for thyroid microsomal antibody testing. 4. For 2021 PT event 1, the laboratory did not have attestation statements for antimullerian hormone and thyroid microsomal antibody testing. 5. For 2021 PT event 2, the laboratory did not have the attestation statement for thyroid microsomal antibody testing. 6. At the time of the survey, the laboratory did not have attestation statements for the above PT events.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

	This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and confirmed by laboratory personnel identifier #1 (refer to Laboratory Personnel Report) at approximately 10:30 am on 10/12/21, the laboratory failed to perform a self evaluation of ungraded PT scores for two out of four testing events from 1/1/2020 - 10/12/2021. The findings include: 1. The laboratory enrolled in sperm count PT testing through the American Association of Bioanalysts, and received two events per calendar year. 2. For 2020 PT event 1, the laboratory received an ungraded PT score for the analyte, sperm count - sample 2. 3. For 2021 PT event 1, the laboratory received an ungraded PT score for the analyte, sperm count - sample 2. 4. At the time of the survey, the laboratory did not perform a self evaluation for the ungraded PT scores.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on review of patient test reports and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 11:15 am on 10/12/21, the laboratory failed to have a record system in place to confirm the identity of the personnel performing testing on two of out four patient test reports from June 2021. The findings include: 1. On 6/3/2021, patient identifier A had thyroid stimulating hormone, testosterone, thyroid peroxidase antibody, prolactin, estradiol, anti-mullerian hormone, rubella IgG, follicle stimulating hormone, luteinizing hormone, thyroxine, progesterone, and human chorionic gonadotropin testing performed. 2. On 6/11/2021, patient identifier B had thyroid stimulating hormone, testosterone, thyroid peroxidase antibody, prolactin, estradiol, anti-mullerian hormone, rubella IgG, follicle stimulating hormone, luteinizing hormone, thyroxine, progesterone, and human chorionic gonadotropin testing performed. 3. At the time of the survey, the laboratory did not have a record system in place to confirm the identity of the personnel performing the testing on the above patients.
D5805	TEST REPORT CFR(s): 493.1291(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 review of patient test reports and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 11:15 am on 10/12/21, the laboratory test report failed to have the correct name for estradiol on two out of two patient test reports from June 2021. The findings include: 1. On 6/4/2021, patient identifier A had estradiol testing performed. 2. On 6/11/2021, patient identifier B had estradiol testing performed. 3. The test reports for patient identifiers A & B listed estradiol testing as [SNSE2].