Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0873828	09/21/2023
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
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on review of quality control records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report), the laboratory failed to retain quality control records for at least two years as specified in the standard D3031.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at 1:40 pm on 09/19 /2023, the laboratory failed to retain endocrinology and immunology QC records for

	at least two years from 01/01/2022 to 06/20/2023. At the time of the survey, the laboratory did not have endocrinology or immunology QC records prior to 06/21 /2023.
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: Based on review of patient test reports, test requests, and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at 1:40 pm on 09/19 /2023, the laboratory failed to have a written or electronic test request for five out of 12 tests performed on one out of two patients (patient identifier A) reviewed having testing performed in May and September 2023. The findings include: 1. Patient identifier A had the following testing performed on 05/05/2023: ABO, Rh (D typing), anti mullerian hormone (AMH), thyroid peroxidase antibody (TPOAB), thyroid stimulating hormone (TSH), testosterone, rubella IGG, prolactin, follicle stimulating hormone (FSH), luteinizing hormone (LH), estradiol, and free thyroxine (FT4). 2. Patient A's associated test request included the following tests to be performed: ABO, Rh (D typing), estradiol, FSH, LH, TPOAB, and TSH. 3. At the time of the survey, personnel identifier #1 confirmed that the laboratory did not have a written or electronic test request for the AMH, testosterone, rubella IGG, prolactin, or FT4 testing performed on 05/05/2023.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of quality control (QC) records, calibration records, and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report), the laboratory failed to meet the analytic systems requirements for: having control procedures that monitor the accuracy and precision of the complete analytic process as specified in the standard D5441; performing two control materials of different concentrations as specified in the standard D5447; and taking and documenting corrective action when the results of control materials failed to meet the laboratory's established criteria for acceptability as specified in the standard D5783.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The

	laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of calibration and quality control (QC) records, and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at 1:38 pm on 09/21/2023, the laboratory failed to monitor the accuracy and precision of the estradiol reagent calibration with QC for one out of one lot number of reagent (lot 2272206, expiration 11/09/2023). In addition, the laboratory did not have a policy for monitoring the accuracy and precision of calibrations by performing QC after performing a calibration. The findings include: 1. The laboratory performed a calibration for estradiol lot number 2272206 (expiration 11/09/2023) at 9:15 am on 07 /21/2023. 2. The laboratory performed estradiol testing on 22 patients after performing the calibration on reagent lot number 2272206 (expiration 11/09/2023). 3. At the time of the survey, personnel identifier #1 confirmed that the laboratory did not perform QC after the calibration of estradiol reagent lot number 2272206 (expiration 11/09/2023) and prior to performing patient testing.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of Access 2 quality control (QC) records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at 1:38 pm on 09/21/2023, the laboratory failed to perform two levels of QC each day of patient testing for five out of 90 days of patient testing reviewed from 06/21/2023- 09 /19/2023. The findings include: 1. Review of Access 2 QC records revealed that the laboratory performed only one level of QC and reported patient test results on the following dates for the specified analytes: *08/10/2023- thyroid peroxidase antibodies (level 1); 1 patient reported *08/17/2023- thyroid peroxidase antibodies (level 1); 4 patients reported 2. Review of Access 2 QC records revealed that the laboratory did not perform any QC and reported patient test results on the following dates for the specified analytes: *07/07/2023- estradiol- 6 patients reported *07/07/2023- progesterone- 5 patients reported *07/07/2023- luteinizing hormone- 7 patients reported *07/07/2023- follicle stimulating hormone- 1 patient reported *07/10/2023- human chorionic gonadotropin- 9 patients reported *07/31/2023- anti mullerian hormone- 1 patient reported *07/31/2023- follicle stimulating hormone- 1 patient reported 3. At the time of the survey, personnel identifier #1 confirmed that the laboratory did not have additional QC records for the dates and analytes listed above.

D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of Access 2 quality control (QC) records, the laboratory's quality assurance policy, and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at 1:38 pm on 09/21/2023, the laboratory failed to take and document corrective action when endocrinology QC fell outside the laboratory's established criteria for acceptability for six out of 90 days of patient testing reviewed from 06/21/2023- 09/19/2023. The findings include: 1. The laboratory performs endocrinology testing on the Access 2 instrument. 2. The laboratory's Quality Assurance policy stated, "Patient samples: 3.5.4.2 If control values from that day are outside of acceptable limits, results are not reported, and the assay is inspected." It also stated, "Out of Range Control Values: 3.5.6.2 Remedial Action: Immediately re-analyze the same control. If this result is within limits, patient testing may proceed. The old control material is unsatisfactory for analysis." 3. Review of Access 2 QC records revealed that the laboratory had unacceptable QC results for the following dates and analytes: * 07/11/2023- progesterone (level 1); 7 patients reported * 07/26 /2023- progesterone (level 2); 5 patients reported * 07/28/2023- free throxine (level 3); 4 patients reported * 08/10/2023- progesterone (level 3); 7 patients reported * 08 /17/2023- free throxine (level 3); 4 patients reported * 08/24/2023- progesterone (level 1); 8 patients reported 4. At the time of the survey, personnel identifier #1 confirmed that the laboratory did not have documented corrective action for the unacceptable QC listed above.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of quality control and calibration records, review of the laboratory's quality assurance policy, lack of quality assurance records, and interview with laboratory personnel identifier #1 (refer to the Laboratory Personnel Report), the laboratory director failed to meet responsibility requirements including: ensuring a quality control program is established and maintained as specified in the standard D6093; ensuring a quality assessment program is established and maintained as specified in the standard D6094; ensuring the laboratory has taken and documented corrective action for deviations from the laboratory's established performance

	characteristics as specified in the standard D6096; and ensuring patient test results are reported only when test systems are functioning properly as specified in the standard D6097.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of Access 2 quality control (QC) and calibration records, review of the laboratory's quality assurance policy, and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at 1:38 pm on 09/21/2023, the laboratory director failed to ensure that quality control programs were established and maintained to assure the quality of immunology and endocrinology testing and identify failures in quality as they occur for six out of 90 days of patient testing reviewed from 06/21/2023- 09/19/2023 and one out of one lot number of reagent (lot 2272206, expiration 11/09/2023). Refer to the standards D5441, D5447, and D5783.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of quality control records, review of the laboratory's quality assurance policy, lack of quality assurance records, and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at 1:38 pm on 09/21 /2023, the laboratory director failed to ensure that quality assessment programs were established and maintained to assure the quality of immunology and endocrinology testing and identify failures in quality as they occur for six out of 90 days of patient testing reviewed from 06/21/2023- 09/19/2023 and one out of one lot number of reagent (lot 2272206, expiration 11/09/2023). Refer to the standards D5441, D5447, and D5783.
D6096	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records, the laboratory's quality assurance policy, and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at 1:38 pm on 09/21/2023, the laboratory director failed to ensure

	that the laboratory has taken and documented corrective action when endocrinology QC fell outside the laboratory's established criteria for acceptability for six out of 90 days of patient testing reviewed from 06/21/2023- 09/19/2023. Refer to the standard D5783.
D6097	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that patient test results are reported only when the system is functioning properly. This STANDARD is not met as evidenced by: Based on review of Access 2 quality control (QC) and calibration records, review of the laboratory's quality assurance policy, and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at 1:38 pm on 09/21/2023, the laboratory director failed to ensure that patient test results were reported only when the Access 2 test system properly functioned for six out of 90 days of patient testing reviewed from 06/21/2023- 09/19/2023 and one out of one lot number of reagent (lot 2272206, expiration 11/09/2023). Refer to the standards D5441, D5447, and D5783.