Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D1002863	10/15/2024
Name of Provider or Supplier	**Street Address, City, State**	
Fertility Answers Lafayette	206 East Farrel Road, Lafayette, LA	

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
D0000	A Recertification survey was performed at Fertility Answers - CLIA ID 19D1002863 on October 15, 2024. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of laboratory policy and personnel records as well as interview with personnel, the laboratory failed to assess complete competency for all tests performed by three (3) of four (4) testing personnel in 2024. Findings: 1. Review of the laboratory's policy "Lab Director Delegation of Responsibilities" section "Competency Assessment Requirements" revealed "If they perform testing on patient specimens, they are required to have the six required procedures in their competency assessment ..." 2. Review of the laboratory's competency assessment form revealed the following procedures to be assessed: a) Direct observation of routine patient test performance b) Monitoring/reporting of test results c) Direct observation of routine patient tasks d) Review of work - Intermediate test results/worksheets/QC/PT and preventive maintenance e) Direct observation of instrument maintenance/function checks f) Assessment of test performance: Internal or external PT g) Problem solving skills 3. Review of personnel competency assessment records revealed the following personnel did not have the required six (6) parts of competency assessed as follows: a) Testing Personnel 1 * Semen Analysis Automated - Direct observation of patient testing - Monitoring the recording and reporting of test results - Performance of quality control - Direct observation of maintenance - Problem solving * Endocrinology - Direct observation of patient testing - Monitoring the recording and

	reporting of test results - Performance of quality control - Direct observation of maintenance - Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples b) Testing Personnel 3 * Endocrinology - Performance of quality control c) Testing Personnel 5 - Performance of quality control 4. In interview on October 15, 2024 at 11: 09, the General Supervisor confirmed competency was not assessed as identified above.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation, review of manufacturer's requirements, and interview with personnel, the laboratory failed to document the open expiration date for laboratory quality control and reagents as required. Findings: 1. Observation by surveyor during the laboratory tour on October 15, 2024 at 9:15 a.m. revealed the laboratory had the following open items but did not document the open expiration date: a) QwikCheck Beads: Level 1 Lot 110724001, Level 2 Lot 110724002, Level 3 Lot 110724003: Manufacturer's closed vial expiration date: July 2025; Documented open date: October 10, 2024 b) QwikCheck Test Strips: Lot 23F15_110124, Manufacturer's closed vial expiration date: July 11, 2025, Documented open date: October 1, 2024 2. Review of the QwikCheck Beads and Test Strips manufacturer instructions revealed stability upon opening of ninety (90) days. 3. In interview on October 15, 2024 at 9:30 a.m., the General Supervisor confirmed the open expiration date was not documented on the items identified above.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on observation, review of the laboratory's performance specification studies, and interview with personnel, the laboratory failed to verify complete performance specifications to include precision and reference range studies for endocrinology testing. Findings: 1. Observation by surveyor during the lab tour on October 15, 2024 at 9:15 a.m. revealed the laboratory utilized the Beckman Coulter Access to perform the following tests: Luteinizing Hormone, Human Chorionic Gonadotropin (hCG), and Progesterone. 2. Review of performance specification studies for the Beckman

	Coulter Access revealed the laboratory did not include the following: a) Precision to include day-to-day, run-to-run, and operator variance b) Raw data to support within run precision c) Reference range studies 3. In interview on October 15, 2024 at 5:30 p. m., the General Supervisor stated Beckman Coulter performed the verification studies for the analyzer along with one of the laboratory's testing personnel.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation, review of laboratory policy, manufacturer's instructions, and quality control records, as well as interview with personnel, the laboratory failed to establish their own mean and ranges for quality control (QC) material utilized for endocrinology testing as required by the laboratory. Findings: 1. Observation by surveyor during the lab tour on October 15, 2024 at 9:15 a.m. revealed the laboratory utilized the Beckman Coulter Access to perform the following tests: Luteinizing Hormone (LH), Human Chorionic Gonadotropin (hCG), Estradiol, and Progesterone. 2. Review of the laboratory's policy "V2 Hormone Assay Protocol" section "Quality Control" revealed the following: - "Quality control for the Beckman Coulter Access 2 is performed using Bio Rad Liquicheck Immunoassay Plus control materials." - "Acceptability ranges for all controls are provided per lot by the manufacturer. These values serve as the acceptable reference range for each assay until enough measurements are collected to calculate the control limits that apply specifically to this laboratory. A minimum of 20 measurements are used to calculate the mean and standard deviation for each assay at the three Levels of control material using the mean and SD calculated by the Access 2. It is preferable to use more than 20 measurements collected over a longer period to observe the variation expected within this laboratory." - "In practice, calculations of the mean and standard deviation are made using monthly data. This data may be added to previously collected data to calculate the cumulative mean and standard deviation which can be used to reestablish control limits to better represent precision of tests." - "New acceptability reference ranges must be established for each new lot of control material." 3. Review of the "Bio-Rad Liquichek Immunoassay Plus Control Levels 1, 2, and 3" package insert section "Assignment of Values" revealed "The mean values and corresponding +/- 3SD ranges in the Assignment of Values Data Charts (available separately) were derived from replicate analyses and are specific for this lot of product" and that each laboratory "establish its own acceptable ranges and use those provided only as a guide." 4. Review of current quality control ranges in the analyzer revealed means and standard deviations (SD) to include, but not limited to, the following: a) BioRad Level

	1, Lot 85351, hCG: - Mean 8.0845, SD 1.0000 b) BioRad Level 1, Lot 85351, LH: - Mean 4.4221, SD 1.5000 c) BioRad Level 3, Lot 85353, Progesterone: - Mean 21.8424, SD 3.0000 5. Review of quality control records revealed the laboratory did not have the raw data to support the means and standard deviations from the analyzer, as well as, documentation when the current lot of QC was put into use. 6. In interview on October 15, 2024 at 5:05 p.m., Testing Personnel 2 confirmed the laboratory did not have the raw data to support the establishment of quality control ranges as identified above.
D5543	HEMATOLOGY CFR(s): 493.1269(a)(d) (a) For manual cell counts performed using a hemocytometer-- (a)(1) One control material must be tested each 8 hours of operation; and (a)(2) Patient specimens and control materials must be tested in duplicate. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of manufacturer's requirements and quality control records as well as interview with personnel, the laboratory failed to ensure control material was tested in duplicate for manual semen analysis testing. Findings: 1. Review of the manufacturer's package insert for "QwikCheck Beads Quality Control Beads for Automated and Manual Sperm Counting Devices" revealed instructions to perform duplicate counts and calculate the "sum and difference" of the two (2) counts. It further instructed to then "Refer to table 2.4 of the WHO manual, 5th edition to determine if the sum and difference of the two counts are acceptable" and if counts were acceptable, calculate an average. 2. Review of quality control records for semen analysis manual method revealed one count documented by testing personnel. 3. In interview on October 15, 2024 at 5:58 p.m., the General Supervisor stated for manual semen analysis quality control testing personnel perform two (2) counts and check the difference between the counts for acceptability. She further stated if the counts are acceptable, they calculate and document the average. She confirmed testing personnel did not document both original counts.
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 records and interview with personnel, the laboratory failed to ensure the patient final test report included the name and/or address of the laboratory where testing was performed for four (4) of four (4) patients reviewed. Findings: 1. Review of a random selection of final patient test reports revealed the

	laboratory did not include the name and address where testing was performed for the following patient: Patient 108642 2. Further review of final patient test reports revealed two laboratory names and addresses, but did not indicate which facility and location testing was performed for the following patients: Patient 109940 Patient 99271 Patient 100832 3. In interview on October 15, 2024 at 6:30 p.m., the Laboratory Director confirmed the final patient reports did not include the laboratory name and address as identified above.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of patient test records and laboratory policies as well as interview with laboratory personnel, the laboratory failed to have Quality Assurance (QA) monitors in place to identify and correct problems identified with the postanalytic system. Findings: 1. Review of a random selection of patient test records revealed the following three (3) of ten (10) final patient test reports had specimen collection, receipt, and/or analyzed times that did not match the laboratory's semen analysis forms with manual documentation of time collected, received, and analyzed: a) Patient 100832 September 25, 2024 - Final report documented specimen received time: 8:58 p.m. - Semen analysis form documented received time: 2:58 p.m. b) Patient 99271 September 17, 20224 - Final report documented specimen collected time: 10:31 a.m. - Semen analysis form documented collected time: Not specified c) Patient 109939 September 23, 2024 - Final report documented specimen received time: 12:20 p.m. - Semen analysis form documented received time: 1:20 p.m. - Final report documented time analyzed: 3:22 p.m. - Semen analysis form documented analysis time: 1:22 p.m. 2. In interview on October 15, 2024 at 4:09 p.m., the General Supervisor stated the errors identified above were clerical errors.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on observation, review of the laboratory's performance specification studies, and interview with personnel, the Laboratory Director failed to establish complete performance specifications for testing. Refer to D5421.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii)

	The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5415.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure the quality control program was maintained to assure the quality of laboratory testing. Refer to D5469.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided. Refer to D5891.
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory

	director must-- (e)(8) Ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure final reports for hematology and endocrinology testing included pertinent information. Refer to D5805.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, CMS 209 form (Laboratory Personnel Report), and personnel records; as well as interview with personnel, the technical consultant failed to perform annual competencies in 2024 for four (4) of four (4) testing personnel reviewed. Findings: 1. Review of the laboratory's policy "Lab Director Delegation of Responsibilities" section "Competency Assessment Requirements" revealed "If they perform testing on patient specimens, they are required to have the six required procedures in their competency assessment ..." 2. Further review of the laboratory's policy "Lab Director Delegation of Responsibilities" section "Qualifications of Individuals Assessing Competency" revealed "Individuals responsible for competency assessments have the education and experience to evaluate the complexity of the testing being assessed. NOTE: The laboratory director must delegate, in writing, the performance of competency assessment to qualified personnel. The required qualifications for the assessor vary by the complexity of the testing." 3. Review of the laboratory's CMS 209 form revealed the Laboratory Director served as Technical Consultant. 4. Review of personnel records revealed the following personnel had competency assessments performed by personnel not designated as Technical Consultant: a) Testing Personnel 1 - Competency performed by Testing Personnel 3 b) Testing Personnel 2 - Competency performed by Testing Personnel 3 c) Testing Personnel 3 - Competency performed by Testing Personnel 2 d) Testing Personnel 5 - Competency performed by Testing Personnel 1 and Testing Personnel 3 5. In interview on October 15, 2024 at 11:09, the General Supervisor confirmed the Technical Consultant did not perform competency assessments as identified above.
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 record review and interview with personnel, the Laboratory Director failed to ensure that a quality control program was maintained to assure the quality of laboratory testing. Refer to D5543.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on review of policies, personnel records, and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Refer to D5209.
D6112	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451 The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Supervisor failed to provide technical and scientific oversight for the laboratory. Refer to D5543.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS-209 form (Laboratory Personnel Record) and personnel records as well as interview with personnel, the Technical Supervisor failed to perform annual competencies for two (2) of two (2) testing personnel reviewed for manual semen analysis testing. Findings: 1. Review of the CMS 209 form revealed Testing Personnel 1 served as the Technical Supervisor. 2. Review of the personnel records from 2023 and 2024 revealed the laboratory did not have documentation of competency assessment for manual semen analysis for the following personnel: a) Testing Personnel 2 b) Testing Personnel 5 3. In interview on

	October 15, 20224 at 6:31 p.m., the General Supervisor confirmed the competency assessments for the personnel identified above did not include manual semen analysis.
D6170	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(a) Each individual performing high complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required. This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS-209 form (Laboratory Personnel Record) and personnel records as well as interview with personnel, the laboratory failed to ensure two (2) of five (5) Testing Personnel met the state of Louisiana licensure requirement to perform high complexity testing in Hematology. Findings: 1. Review of the laboratory's CMS-209 form and personnel records revealed the following personnel did not have a state of Louisiana license for high complexity testing: a) Testing Personnel 3: Clinical Laboratory Scientist - Laboratory Assistant b) Testing Personnel 4: Clinical Laboratory Scientist - Laboratory Assistant 2. In interview on October 15, 2024 at 11:09 a.m., the General Supervisor confirmed the testing personnel identified above held licenses for Laboratory Assistant.