Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1021548	05/21/2024
Name of Provider or Supplier	**Street Address, City, State**	
Fpg Labs Of Austin, Llc Dba Ovation Fertility	6500 North Mopac, Bldg 3, Suite 3102, Austin, TX	

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	Based on an unannounced validation revisit, the laboratory was found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780. A standard level deficiency remains uncorrected. _____ Based on an announced validation inspection, the laboratory was found NOT to be in compliance with the CLIA regulations found at 42 CFR 493 CLIA requirements. The conditions not met were: D5024 - 42 C.F.R. 493.1215 Condition: Hematology; D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director; D6033 - 42 C.F.R. 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on observation, review of manufacturer's instructions, and interview, the laboratory failed to record the open date on a vial of QwikCheck Reagent Strips for Semen Analysis used for Leukocytes and pH testing on one (1) of one (1) open vial reviewed. Findings follow. A. During a tour of the laboratory on May 21, 2024 at 1550 hours surveyor observed an open vial of QwikCheck Reagent Strips for Semen Analysis, Lot 23B10_080323, showed on the label "open vial expiration = 90 days" and had a space to record the open date. No open date was recorded on the vial. B. Interview with testing personnel #5 on May 21, 2024 at 1550 hours in the laboratory acknowledged the date should have been documented on the vial and confirmed they only used one or two strips per day.

D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review competency evaluations, proficiency testing, accuracy assessments, validation records, manufacturer's instructions, calibration verifications, quality control (QC) records, test reports, comparison of test results, corrective actions, patient logs, pre-survey paperwork, and interview found the laboratory failed to meet the requirements for the specialty of Hematology. Findings Included: 1. The laboratory failed to assess competency for two of two technical supervisors and one of one general supervisors (see D5209). 2. The laboratory failed to perform twice a year accuracy assessments for their automated sperm motility and morphology reported on semen analysis performed by their primary method of reporting using the Medical Electronic Systems (MES) SQA-Vision analyzer in 2022 and 2023 for four (4) of four (4) events reviewed (see D5217). 3. The laboratory failed to perform calibration verifications at least every six (6) months for the sperm count reported in the semen analysis performed on the automated Medical Electronic Systems (MES) SQA-Vision analyzer in 2022 and 2023 for three (3) of four (4) events reviewed (see D5439). 4. The laboratory failed to have an alternate mechanism to detect immediate errors and monitor test system performance over time for automated motility and morphology performed on the Medical Electronic Systems (MES) SQA-Vision analyzer for 21 of 21 months reviewed (see D5485). 5. The laboratory failed to compare test results for sperm motility and morphology reported in a semen analysis performed on the automated Medical Electronic Systems (MES) SQA-Vision analyzer and by manual method twice a year to evaluate the correlation of test results in 2022 and 2023 for three (3) of four (4) events reviewed (see D5775). 6. The laboratory failed to evaluate patient testing back to the last successful quality control (QC) run after the laboratory performed maintenance as corrective action for failed QC on the Medical Electronic Systems (MES) SQA-Vision analyzer for automated semen counts and negative motility for four (4) or four (4) events reviewed (see D5783).
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 competency evaluations and interview, the laboratory failed to assess competency for two of two technical supervisors and one of one general supervisors. Findings follow. A. Review of competency evaluations showed none for the positions of technical supervisor and general supervisor. B. Interview with Technical Supervisor #1 (as listed on the CMS Form 209) on May 21, 2024 at 1700 hours in the office confirmed they only performed testing personnel competency evaluations.

D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: Based on review of proficiency testing, accuracy assessments, validation records, and interview, the laboratory failed to perform twice a year accuracy assessments for their automated sperm motility and morphology reported on semen analysis performed by their primary method of reporting using the Medical Electronic Systems (MES) SQA-Vision analyzer in 2022 and 2023 for four (4) of four (4) events reviewed. Findings follow. A. Review of the College of American Proficiency Testing from 2022 and 2023 showed proficiency testing on the automated MES SQA-Vision analyzer for semen counts only. B. Review of accuracy assessments for 2022 and 2023 for automated sperm motility and morphology performed on the MES SQA-Vision analyzer showed none available for review. C. Review of the verification of performance specifications showed the analyzer was installed on 05/16/2022. D. Interview with Technical Supervisor #1 on May 21, 2024 at 1310 hours confirmed the semen analysis comprised of sperm count, motility, and morphology reported on the MES SQA-Vision was the primary method of reporting with manual semen analysis as their secondary method. They participated in proficiency testing for automated sperm count and manual motility and morphology, but there was none available for the automated motility and morphology. No other accuracy assessments were performed.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of validation, manufacturer's instructions, calibration verifications,

	pre-survey paperwork, and interview, the laboratory failed to perform calibration verifications at least every six (6) months for the sperm count reported in the semen analysis performed on the automated Medical Electronic Systems (MES) SQA-Vision analyzer in 2022 and 2023 for three (3) of four (4) events reviewed. Findings follow. A. Review of the verification of performance specifications showed the analyzer was installed on 05/16/2022. B. Review of the calibration verification report titled Medical Electronic Systems SQA-Vision Manufacturer's Validation Kit stated, "The Medical Electronic System's Manufacturer's Validation Kit was designed as a proficiency, training, and validation tool for the SQA-Vision sperm analyzer. It can be used to validate most aspects of Accuracy, Precision, and Reportable Range per the new CLIA Method Validation Regulations... The approach in method validation is to perform a series of experiments designed to estimate certain types of analytical errors, e.g., a linearity experiment to determine reportable range, a replication experiment to estimate imprecision or random error, a comparison of methods experiment to estimate inaccuracy or systematic error, and a detection limit experiment to characterize analytical sensitivity. Due to the fragile biological nature of sperm, parameters influenced by motion have been omitted from this Validation kit... The SQA-Vision Validation Kit is also highly recommended as a training tool and for running periodic proficiency challenges for all personnel that operate the SQA-Vision instrument. After successfully completing the Validation Kit's Accuracy, Precision and Reportable Range testing, users will have extensive knowledge of the SQA-Vision's operation, capillary loading, results reporting, and more. In addition, annual or semi-annual personnel re-testing using the Validation Kit will demonstrate ongoing operator proficiency and the laboratory's commitment to accuracy, precision, and quality of care." Review of the document showed results for Linearity and Reportable Range. Review of calibration verifications from 05/16/2022 - 03/04/2024 for sperm counts performed on the automated MES SQA-Vision analyzer revealed one calibration verification performed on 08/02/2022 (elapsed time from 08/02/2022 - 03 /04/2024 was 19 months, equivalent to 3 additional calibration verifications). Additional calibration verifications were requested on May 21, 2004 at 1320 and 1400 hours in the office but not provided. C. Review of the presurvey paperwork titled CMS-116 showed the annual test volume for sperm count was 685. D. Interview with the Laboratory Director on May 21, 2024 at 1720 hours in the office acknowledged the manufacturer came in and performed checks on the analyzer every six (6) months, but the laboratory failed to purchase and provide the validation kits required to perform the calibration verifications.
D5485	CONTROL PROCEDURES CFR(s): 493.1256(h) If control materials are not available, the laboratory must have an alternative mechanism to detect immediate errors and monitor test system performance over time. The performance of alternative control procedures must be documented. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, quality control (QC) records, test reports, validation records, pre-survey paperwork, and interview the laboratory failed to have an alternate mechanism to detect immediate errors and monitor test system performance over time for automated motility and morphology performed on the Medical Electronic Systems (MES) SQA-Vision analyzer for 21 of 21 months reviewed. Findings follow. A. Review of the MES SQA-Vision User Guide, Version 104.14.5 April 2021, Section 1: System Specifications and Requirements under

Requirements stated, "Quality Control Internal: Electronic Self-Test and Auto-Calibration. Runs automatically upon start-up. Besides that, reference values are verified prior to each test. External: Runs QC samples per laboratory protocol. Runs assayed latex bead control: QwikCheck Beads (supplied by Medical Electronic Systems) for concentration and negative control for motility/concentration OR non-assayed: Latex beads or stabilized sperm CAP or NEQAS for concentration." Appendix 13: Product Performance Data under Precision and Accuracy Established Against a Known Target (Latex beads) stated, "background: The precision and accuracy of the SQA-V was compared to a known target value using latex beads (Accu-beads). Latex beads are used as a quality control product to validate the accuracy of sperm counting methods for two known levels of concentration. In accordance with CLIA regulations such a control is used to demonstrate operator proficiency using the microscope and for validation of automated sperm counting methods... Limitations of method: Latex beads cannot: Measure sperm motility or morphology Correct for incorrect chamber depths or technician errors." The User Guide stated the Latex Bead controls were for sperm count and negative motility, and did not measure sperm [positive] motility or morphology. B. Review of the MES QwikCheck Beads, Rev 01 July 2020, under Introduction and Intended Use stated, "QwikCheck beads is an in-vitro use only external quality control material for automated and manual sperm counting systems. It has been developed as a tool to assess the accuracy and precision of the laboratory's sperm counting methods by providing a known target value and +/- range... QwikCheck beads is supplied in a kit containing known concentrations of 4-micron latex beads suspended in an aqueous solvent and negative concentration/motility control. The beads should be run according to the directions below for the type of system used in the lab. According to the CLIA '88 regulations, 'for most moderately complex tests, the general requirement is to analyze two levels of QC materials on each day of testing. It is recommended that QuikCheck beads are run on both the SQA automated and visualization systems prior to each day of semen analysis testing.'" Under Instructions for "running QwikCheck beads QC material on automated and manual sperm counting systems: SQA Automated System: 1. Refer to the SQA user Guide 'Controls' section for an explanation of how to set-up the SQA to test automated Level 1/Level 2 and Negative Control QwikCheck beads." And under Limitations stated, "QwikCheck beads cannot be used to perform quality control for motility or correct for technician errors or faulty equipment." The QC package insert described the Latex Bead controls as two (2) levels for sperm count and a negative sperm count and motility. Positive motility and morphology were not mentioned. C. Review of the manufacturer's Technical Release Bulletin, May 2022, under External Quality Control stated, "QwikCheck Beads are an assayed external quality control for testing Concentration and Zero Level Motility (manufactured by Medical Electronic Systems): Two positive concentration levels are provided in the kit. One Negative Control level of the QwikCheck beads kit verifies that the SQA is not reporting false positive readings for both Concentration and Motile Sperm Concentration (MSC)...." The Technical Bulletin described the Latex Bead controls as two (2) levels for sperm count and a negative sperm count and motility. Positive motility and morphology were not mentioned. D. Random review of QC from 06/01/2023 - 07/28/2023 and 01/02/2024 - 02/29/2024 showed QC results for the Negative Control and Levels 1& 2 Latex Beads each day of patient testing. There was no documentation of QC for positive motility or morphology. E. Random review of the SQA-Vision test reports for semen analysis showed the automated motility and morphology as listed by Date of Collection, Patient CLN, Motility and Morphology: 1. 05/03/2023 CL-261DM-1822632 % Motility: 77 % Rapidly Progressive: 56 % Slowly Progressive: 14 % Non-Progressive: 7 % Immotile: 23 % Normal Forms: 15 2. 05/04/2023 403072F83 % Motility: 41 % Rapidly Progressive: 4

	% Slowly Progressive: 22 % Non-Progressive: 15 % Immotile: 59 % Normal Forms: 4 3. 05/05/2023 436099F86 % Motility: 56 % Rapidly Progressive: 27 % Slowly Progressive: 24 % Non-Progressive: 5 % Immotile: 44 % Normal Forms: 10 4. 05/08 /2023 436300F86 % Motility: 48 % Rapidly Progressive: 20 % Slowly Progressive: 18 % Non-Progressive: 10 % Immotile: 52 % Normal Forms: 7 5. 05/09/2023 435724F82 % Motility: 52 % Rapidly Progressive: 25 % Slowly Progressive: 18 % Non-Progressive: 9 % Immotile: 48 % Normal Forms: 8 6. 02/07/2024 448784F97 % Motility: 61 % Rapidly Progressive: 10 % Slowly Progressive: 41 % Non-Progressive: 10 % Immotile: 39 % Normal Forms: 8 7. 02/14/2024 489932F90 % Motility: 77 % Rapidly Progressive: 45 % Slowly Progressive: 25 % Non-Progressive: 7 % Immotile: 23 % Normal Forms: 15 8. 02/16/2024 273350F76 % Motility: 67 % Rapidly Progressive: 35 % Slowly Progressive: 25 % Non-Progressive: 7 % Immotile: 33 % Normal Forms: 13 9. 02/26/2024 CL-263MS-1907291 % Motility: 56 % Rapidly Progressive: 34 % Slowly Progressive: 15 % Non-Progressive: 7 % Immotile: 44 % Normal Forms: 10 F. Review of the verification of performance specifications showed the analyzer was installed on 05/16/2022 (elapsed time to 03/04/2022 was 21 months). G. Review of the pre-survey paperwork titled CMS-116 showed an annual test volume for sperm motility and morphology to be 685 each, respectively. H. Interview with testing personnel #5 on May 21, 2024 at 1515 hours in the laboratory confirmed they used the SQA Testing Capillaries for patient samples, the analyzer reported sperm count, motility, and morphology, and confirmed the QC beads only checked for the sperm count [and negative motility]. Interview with the Laboratory Director on May 21, 2024 at 1635 hours in the office confirmed they were not performing any other method of quality control [for the automated] motility and morphology.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, comparison of test results, pre-survey paperwork, and interview, the laboratory failed to compare test results for sperm motility and morphology reported in a semen analysis performed on the automated Medical Electronic Systems (MES) SQA-Vision analyzer and by manual method twice a year to evaluate the correlation of test results in 2022 and 2023 for three (3) of four (4) events reviewed. Findings follow. A. Review of the manufacturer's Technical Release Bulletin, May 2022, under Optional/Additional stated, "In coordination with the QwikCheck Beads Precision and Linearity kit, MES recommends comparing several fresh semen samples against an alternate (backup) method twice per year. Concentration, Motility, and Morphology should be compared to confirm the automated sperm analyzer's accuracy and the user proficiency. The following is a protocol for running the automated analyzer and comparing the results to the back-up method: Run 5 to 10 fresh semen samples on the SQA. In parallel assess Concentration, Motility and Morphology of the same samples under the microscope per WHO 5th or 6th Edition Manual guidelines. Run samples at room temperature within a 2 minute timeframe between the two methods (manual Morphology can be

	assessed > 2 minutes following the laboratory protocol for manual morphology assessment). Compare the automated and manual results (all data can be sent to MES for statistical evaluation). In conjunction with the Auto-Calibration, Self-Test, External Daily QC, Calibration Parameter Confirmation and running Validation kits, this routine mini-validation proves system function, accuracy and user proficiency for Concentration, Motility and Morphology." B. Review of the comparison of test results for 2022 and 2023 for sperm motility and morphology performed on the automated MES SQA-Vision analyzer against the manual method showed one comparison performed at installation on 05/16/2022 (elapsed time to 03/04/2024 was 21 months). C. Review of the presurvey paperwork titled CMS-116 showed the annual test volume for sperm motility and morphology to be 685 each, respectively. D. Interview with the Laboratory Director on May 21, 2024 at 1400 hours verified he checked with the manufacturer that they should be performing a motility and morphology comparison on fresh samples every six (6) months and confirmed they had not been doing that.
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 an unannounced validation revisit, review of manufacturer's instructions, quality control (QC) records, corrective actions, patient logs, and interview, the laboratory failed to evaluate patient testing back to the last successful quality control (QC) run after the laboratory performed maintenance as corrective action for failed QC on the Medical Electronic Systems (MES) SQA-Vision analyzer for automated semen counts and negative motility for six of six events reviewed from 05/21/2024 - 06/28/2024. Findings follow. A. Review of the MES SQA-Vision User Guide, Version 104.14.5 April 2021, Section 1: System Specifications and Requirements under Maintenance Schedule stated, "Daily: Clean measurement compartment daily when running samples and after 10-15 tests and/or for ANY spillage. Follow manufacturer's cleaning instructions using manufacturer cleaning kit..." B. Review of the QC records from 05/21/2024 - 06/28/2024 showed documentation of corrective action for failed QC on six events was to clean system and re-test as listed by date performed with the number of patients reported and patient IDs: 1. 05/28/2024 Negative Control failed with 0.0/1.6 "Clean system re-test" Negative Control passed with 0.0/0.0 last successful run was 05/24/2024 Five patients were reported since last successful QC IDs: 1744143, 1948273, 1947018, 1835507, 1947145 2. 05/30/2024 Negative Control failed with 0.0/1.6 "Clean system re-test" Negative Control passed with 0.0/0.0 last successful run was 05/29/2024 Two patients were reported since last successful QC IDs: 1938562, 1948344 3. 06/05/2024 Negative Control failed with 1.5 /1.6 "Clean system re-test" Negative Control passed with 0.0/0.0 last successful run was 06/03/2024 Four patients were reported since last successful QC IDs: 1949513, 1577841, 1947913, 1946211 4. 06/11/2024 Negative Control failed with 3.5/1.6 "Clean system re-test" Negative Control passed with 0.0/0.0 last successful run was 06 /10/2024 Four patients were reported since last successful QC IDs: 1950521,

	1950990, 1950072, 1950834 5. 06/12/2024 Negative Control failed with 0.0/1.6 "Clean system re-test" Negative Control passed with 0.0/0.0 last successful run was 06 /11/2024 One patient was reported since last successful QC IDs: 1950531 6. 06/24 /2024 Negative Control failed with 0.0/1.6 and 2.1/0.0 "Clean system re-test" Negative Control passed with 0.0/0.0 last successful run was 06/21/2024 Three patients were reported since last successful QC IDs: 1952775, 1952082, 1952694 Units were in Conc/MSC C. Interview with the Laboratory Director on August 7, 2024 at 1230 confirmed they did not evaluate patient testing back to the last successful QC run when maintenance was required to remediate QC since the last survey. _____ Based on review of manufacturer's instructions, quality control (QC) records, corrective actions, patient logs, and interview, the laboratory failed to evaluate patient testing back to the last successful quality control (QC) run after the laboratory performed maintenance as corrective action for failed QC on the Medical Electronic Systems (MES) SQA-Vision analyzer for automated semen counts and negative motility for four (4) or four (4) events reviewed. Findings follow. A. Review of the MES SQA-Vision User Guide, Version 104.14.5 April 2021, Section 1: System Specifications and Requirements under Maintenance Schedule stated, "Daily: Clean measurement compartment daily when running samples and after 10-15 tests and/or for ANY spillage. Follow manufacturer's cleaning instructions using manufacturer cleaning kit..." B. Random review of the QC records from 02/07/2024 -02/19/2024 showed documentation of corrective action for failed QC on four (4) events was to clean system and re-test as listed by date performed with the number of patients reported and a representative ID: 1. 02/07/2024 Level 2 failed with 19.2 (target 20.0 - 30.0) "Clean system and re-test" Level 2 passed with 23.5 last successful run was 02/06 /2024 Four (4) patients were reported since last successful QC One patient reported was ID 1903313 2. 02/08/2024 Level 1 failed with 38.5 (target 40.4 - 53.6) "Clean system and re-test" Level 1 passed with 48.1 last successful run was 02/07/2024 One (1) patient was reported since last successful QC One patient reported was ID 448784 3. 02/15/2024 Negative Control failed with 4.8/0.0 "Clean system re-test" Negative Control passed with 0.0/0.0 last successful run was 02/14/2024 Three (3) patients were reported since last successful QC One patient reported was ID 489932 4. 02/19 /2024 Level 1 failed with 35.7 (target 40.4 - 53.6) "Clean system and re-test" Level 1 passed with 47.4 last successful run was 02/16/2024 Two (2) patients were reported since last successful QC One patient reported was ID 1577791 Units were in Conc /MSC C. Interview with the Laboratory Director on May 21, 2024 at 1650 confirmed they do not evaluate patient testing back to the last successful QC run when maintenance was required to remediate QC.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of validation records, manufacturer's instructions, calibration verifications, quality control (QC) records, test reports, comparison of test results, corrective actions, patient logs, pre-survey paperwork, and interview, the Laboratory Director failed to provide technical and scientific oversight of the laboratory for 21 of 21 months reviewed. Findings follow. 1. Based on review of validation records,

	manufacturer's instructions, calibration verifications, quality control (QC) records, test reports, comparison of test results, corrective actions, patient logs, pre-survey paperwork, and interview, the laboratory director failed to monitor and evaluate the overall quality of the analytic and post analytic systems; and correct problems in testing performed in Hematology for semen analysis for 21 of 21 months reviewed (refer to D6007). 2. Based on review of manufacturer's instructions, quality control (QC) records, test reports, validation records, pre-survey paperwork, and interview the laboratory director failed to ensure a quality control program was established for its automated motility and morphology performed on the Medical Electronic Systems (MES) SQA-Vision analyzer for 21 of 21 months reviewed (refer to D6020).
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) 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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on review of validation records, manufacturer's instructions, calibration verifications, quality control (QC) records, test reports, comparison of test results, corrective actions, patient logs, pre-survey paperwork, and interview, the laboratory director failed to monitor and evaluate the overall quality of the analytic and post analytic systems; and correct problems in testing performed in Hematology for semen analysis for 21 of 21 months reviewed. Findings follow. 1. The laboratory failed to perform calibration verifications at least every six (6) months for the sperm count reported in the semen analysis performed on the automated Medical Electronic Systems (MES) SQA-Vision analyzer in 2022 and 2023 for three (3) of four (4) events reviewed (see D5439). 2. The laboratory failed to have an alternate mechanism to detect immediate errors and monitor test system performance over time for automated motility and morphology performed on the Medical Electronic Systems (MES) SQA-Vision analyzer for 21 of 21 months reviewed (see D5485). 3. The laboratory failed to compare test results for sperm motility and morphology reported in a semen analysis performed on the automated Medical Electronic Systems (MES) SQA-Vision analyzer and by manual method twice a year to evaluate the correlation of test results in 2022 and 2023 for three (3) of four (4) events reviewed (see D5775). 4. The laboratory failed to evaluate patient testing back to the last successful quality control (QC) run after the laboratory performed maintenance as corrective action for failed QC on the Medical Electronic Systems (MES) SQA-Vision analyzer for automated semen counts and negative motility for four (4) or four (4) events reviewed (see D5783).
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 review of manufacturer's instructions, quality control (QC) records, test reports, validation records, pre-survey paperwork, and interview the laboratory director failed to ensure a quality control program was established for its automated motility and morphology performed on the Medical Electronic Systems (MES) SQA-Vision analyzer for 21 of 21 months reviewed (see D5485).
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on review competency evaluations, proficiency testing, accuracy assessments, validation records, manufacturer's instructions, calibration verifications, quality control (QC) records, test reports, comparison of test results, corrective actions, patient logs, pre-survey paperwork, and interview the technical consultant failed to provide technical oversight of the laboratory for 21 of 21 months reviewed. Findings follow. 1. The technical consultant failed to provide technical and scientific oversight of the laboratory (refer to D6036). 2. The technical consultant failed to ensure a quality control program was established for its automated motility and morphology performed on the Medical Electronic Systems (MES) SQA-Vision analyzer for 21 of 21 months reviewed (refer to D6042).
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on review competency evaluations, proficiency testing, accuracy assessments, validation records, manufacturer's instructions, calibration verifications, quality control (QC) records, test reports, comparison of test results, corrective actions, patient logs, pre-survey paperwork, and interview the technical consultant failed to provide technical and scientific oversight of the laboratory. Findings follow. 1. The laboratory failed to perform twice a year accuracy assessments for their automated sperm motility and morphology reported on semen analysis performed by their primary method of reporting using the Medical Electronic Systems (MES) SQA-Vision analyzer in 2022 and 2023 for four (4) of four (4) events reviewed (see D5217). 2. The laboratory failed to perform calibration verifications at least every six (6) months for the sperm count reported in the semen analysis performed on the automated Medical Electronic Systems (MES) SQA-Vision analyzer in 2022 and

	2023 for three (3) of four (4) events reviewed (see D5439). 3. The laboratory failed to have an alternate mechanism to detect immediate errors and monitor test system performance over time for automated motility and morphology performed on the Medical Electronic Systems (MES) SQA-Vision analyzer for 21 of 21 months reviewed (see D5485). 4. The laboratory failed to compare test results for sperm motility and morphology reported in a semen analysis performed on the automated Medical Electronic Systems (MES) SQA-Vision analyzer and by manual method twice a year to evaluate the correlation of test results in 2022 and 2023 for three (3) of four (4) events reviewed (see D5775). 5. The laboratory failed to evaluate patient testing back to the last successful quality control (QC) run after the laboratory performed maintenance as corrective action for failed QC on the Medical Electronic Systems (MES) SQA-Vision analyzer for automated semen counts and negative motility for four (4) or four (4) events reviewed (see D5783).
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, quality control (QC) records, test reports, validation records, pre-survey paperwork, and interview the technical consultant failed to ensure a quality control program was established for its automated motility and morphology performed on the Medical Electronic Systems (MES) SQA-Vision analyzer for 21 of 21 months reviewed (see D5485).