Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2094825	04/24/2024
Name of Provider or Supplier	**Street Address, City, State**	
Raintree Fertility Laboratory, Llc	980 Raintree Circle Suite 200, Allen, 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	The laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions for use, laboratory procedures, andrology logs, patient reports, and confirmed in interview, the laboratory failed to define and document the intended reactivity for staining material each day of use to ensure predictable staining characteristics for the Quick III stain QC (quality control) for 25 of 25 days in 2022 (11/2022 through 12/2022) and 58 of 58 days in 2023 and 2024 (10/2023 through 01/2024). Findings included: 1. Review of the Quick III package insert revealed: "Stained Specimen Results ... Specimen Spermatozoa Nuclues dark blue" 2. Review of the laboratory's procedure "MORPHOLOGY EVALUATION" stated: "IV. PROCEDURE ... C. STAINING SLIDES 1. Stain slides according to the Quick III method. 2. Slides are reviewed under oil immersion. 3. Slides are stored in the slide file for at least 30 days. D. QUALITY CONTROL 1. Staining a) Stain slide according to Quick III procedure. b) Compare the stained slide with pictures of normally stained blood cells to verify the staining solution is working properly. c) Record all data on the Morphology QC Data Sheet. d) If the blood cells did not stain properly, change the staining solutions and repeat the procedure." The policy did not define intended reactivity of the Quick III stain to ensure predictable characteristics. 3. Review of the "Andrology Startup and Shutdown" logs revealed the

	following: The log had column for "date" and rows for "Morphology Done" and "Check Morph Stains". Each day QC was documented under the "Check Morph Stain" column with a "Y". The log failed to specify what the "Y" meant. The following dates in 2022, 2023 and 2024 were observed to be documented with a "Y": 2022 November: 1, 8, 9, 10, 11, 12, 15, 16, 17, 21, 22, 23, 28, 30 December: 1, 6, 7, 12, 15, 17, 19, 21, 22, 23, 29 2023 October: 3, 4, 6, 7, 8, 9, 16, 17, 18, 19, 20, 23, 24, 25, 26, 27, 31 November: 3, 4, 6, 7, 9, 10, 15, 16, 17, 20, 22, 27, 30 December: 4, 5, 6, 7, 8, 11, 12, 13, 15, 18, 19, 20, 22 2024 January: 8, 9, 10, 11, 15, 16, 17, 18, 19, 22, 24, 25, 26, 29, 30 The laboratory failed to document the staining characteristics for the Quick III stain. 4. The following random sampling of patients were tested and reported when the laboratory failed to document the intended reactivity to ensure predictable characteristics of the Quick III stain: 07/15/2022 Patient Accession #: 229 /22 07/18/2022 Patient Accession #: 233/22 07/22/2022 Patient Accession #s: 241/22, 239/22, 240/22 10/04/2023 Patient Accession #: 352/23 10/16/2023 Patient Accession #s: 363/23, 360/23 10/20/2023 Patient Accession #: 368/23 10/25/2023 Patient Accession #: 376/23 01/22/2024 Patient Accession #s: 21/24, 19/24 01/25/24 Patient Accession #: 23/24 01/26/2024 Patient Accession #: 24/24 01/29/2024 Patient Accession #: 26/24 5. During an interview on 04/24/2024 at 1:559 pm, the Laboratory Director confirmed the laboratory failed to define and document the intended reactivity for staining material each day of use to ensure predictable staining characteristics for the Quick III stain.
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 package inserts, laboratory policy, quality control (QC) records, patient records, and staff interview, the laboratory failed to follow the manufacturer's instructions for performing quality control procedures using the accu-beads (used as quality control material for sperm counts) in duplicate for two of two months reviewed from November 2022 through December 2022 and four of four months reviewed from October 2023 through January 20204. Findings included: 1.Review of the package insert for the accu-beads (used as quality control material for sperm counts) revealed: "Manual Counting Procedures 1. Count the beads according to a standard counting procedure. 2. When using an eyepiece reticle, at least 10 squares in 5 different fields should be counted. The number of beads counted should be at least a minimum 200. For a higher degree of accuracy, count more fields. 3. When using a fixed chamber with a gridded coverslip or a gridded slide, follow the chamber manufacturer's counting instructions. 4. Calculate the bead concentration according to the chamber manufacturer's instructions. 5. Count another aliquot of the same sample. The results should be within 10% of each other to be considered valid. 6. If the results are valid, average the two counts and compare to the accu-beads acceptable ranges listed above. 7. The counting procedure above should be performed with all accu-beads concentrations. 8. Record all results along with pertinent information such as the chamber used and the name of the person performing the QC procedure. 2. Review of the laboratory's policy "SEMEM ANALYSIS" revealed no procedures for performing quality control using the accu-beads. 3. A random review of quality

	control records from November 2022 through December 2022 and October 2023 through January 20204 found no documentation of duplicate counts for each level of quality control material tested. The following random patients were tested and reported when QC was not performed in duplicate on the following dates: 07/15/2022 Patient Accession #: 229/22 07/18/2022 Patient Accession #: 233/22 07/22/2022 Patient Accession #s: 241/22, 239/22, 240/22 10/04/2023 Patient Accession #: 352/23 10/16/2023 Patient Accession #s: 363/23, 360/23 10/20/2023 Patient Accession #: 368 /23 10/25/2023 Patient Accession #: 376/23 01/22/2024 Patient Accession #s: 21/24, 19/24 01/25/24 Patient Accession #: 23/24 01/26/2024 Patient Accession #: 24/24 01 /29/2024 Patient Accession #: 26/24 5. During an interview on 04/24/2024 at 12:41 pm, the Technical Supervisor confirmed the laboratory failed to document the testing of quality control in duplicate.
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 laboratory procedures, quality control (QC) records, corrective action logs, patient reports, and confirmed in interview, the laboratory failed to evaluate all patient test results after performing test system adjustments for QC failures and since the last acceptable test run to ensure accurate and reliable test results for two of two patients in 2024 (random review 01/2024-02/2024) the Access 2 endocrinology analyzer. Findings included: 1. Review of the laboratory's procedures "RUNNING CALIBRATORS, CONTROLS AND REAGENTS ON THE HORMONE ANALYZER" revealed: "I. Principle ... B. Controls ... All control results need to be checked prior to the running/reporting of patient results. No patient results should be reported without verifying the controls. The controls are expected to fall with a set range. This range should be less than standard deviations (3 S.D.). Should a control fall out of range for a given test on the same day: 1. Verify the proper working of the Beckman Coulter instrument. Inspect the lines for air bubbles and test the substrate flow. If the machine appears to be functioning improperly, The [sic] lab will repeat QC once. If it fails again, the lab will re-calibrate the test and re-run. 2. Repeat QC testing. 3. Re-calibrate and re-run QC testing. 4. For any out-of-range QC, the lab staff notates out-of-range QC in the QC Logs that are in the QC Binder in the lab, [sic] and input appropriate corrective action comments. a. lf one control for an assay is out of range, then QC is acceptable and patient results may be reported. b. If 2 control levels are out of range, then the out-of-range controls must be rerun with freshly aliquoted controls. Alternatively, the lab can send out patient specimens to outside referral labs for that day. c. All controls must be tested in the same manner as patient specimens. d. The laboratory must document and maintain records of all quality control activities for at least two years. e. QC charts will be reviewed by the technician on a weekly basis, and monthly by the lab director or delegated supervisor. 5. If the controls are still out of range with significant issues, call Beckman Coulter for Technical Service and additional testing procedures. 6. After QC is acceptable, re-

	run all patient samples for the test that is out of range. Physicians are notified if results expected to be reported later than posted turnaround time." The policy failed to state to evaluate all patient test results after performing test system adjustments for QC failures and since the last acceptable test run. 2. Random review of Access 2 QC analyzer data and corrective action documentation revealed the troubleshooting the laboratory performed for the following sampling of QC test events in 2024: TSH QC level 1 lot #27031A, expiration date: 03/31/2027 acceptable range: 0.1138 - 0.1326 QC level 2 lot #27032A, expiration date: 03/31/2027 acceptable range: 10.9925 - 12.6321 QC level 3 lot #27033A expiration date: 03/31/2027 acceptable range: 21.7792 - 25.5284 01/29/2024 Level 2 9:06 am QC failed; result: 12.797 9:40 am QC repeated and failed; result: 13.506 11:49 am QC repeated and failed; result: 12.938 Level 3 9:10 am QC failed; result: 25.531 9:41 am QC repeated and failed; result: 27.009 10:49 am QC repeated and passed Corrective action was documented as: "OOR on 2 levels, repeat QC" and "still OOR recalibrate" The following patients were not evaluated to ensure accurate and reliable test results since the last acceptable QC run with test system adjustments performed (01/26/2024) Patient ID: 10351 02/26 /2024 Level 1 8:58 am QC failed; result: 0.140 9:33 am QC repeated and failed; result: 0.136 10:49 am QC repeated and passed Level 2 8:59 am QC failed; result: 12.727 9:34 am QC repeated and failed; result: 12.916 10:49 am QC repeated and passed Corrective action was documented as: "TSH out on 2 levels twice, To be recalibrated & reran" The following patients were not evaluated to ensure accurate and reliable test results since the last acceptable QC run with test system adjustments performed (02/23/2024) Patient ID: 10750 3. During an interview on 04/24/2024 at 12: 20 pm, the Technical Consultant confirmed the above findings. Word Key: TSH- thyroid stimulating hormone OOR- out of range