

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  19D0705675	<b>(X3) Date Survey Completed</b>  10/14/2025
<b>Name of Provider or Supplier</b>  Reproductive Resources Inc	<b>Street Address, City, State</b>  3941 Houma Boulevard, Suite 2 C, Metairie, LA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An Initial survey was performed at Reproductive Resources, INC, CLIA ID 19D0705675, on October 14, 2025. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
<b>D5481</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(f)(g)</p> <p>(f) Results of control materials must meet the laboratorys and, as applicable, the manufacturers test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: I. Based on review of the laboratory's policies, quality control records, test menu, and interview with personnel, the laboratory failed to document values of the semen analysis cell count quality controls (QC) that were performed in duplicate. Findings: 1. Review of the laboratory's "Quality Control and Quality Assurance" policies under the " Andrology Laboratory: Quality Control Procedures for Techniques Performed in Andrology Lab" section revealed "Control specimens are tested in the same manner and by the same personnel as patient specimens. Each workday that a semen analysis is performed one high-count and one low-count aliquot is analyzed by each technician who is performing semen analysis that day." 2. Review of the laboratory's "QC Beads" logs for August 19, 2024 through September 17, 2025 revealed "Sperm Count Controls each taken as average of 2 counts." The laboratory documented the average value of each control level, not each individual value, as well as, the average. 3. In interview on October 14, 2025 at 11:28 am, the Laboratory Director stated she tested each level of control in duplicate like the patients. The Laboratory Director further stated she did not document the individual values for each control that is tested in duplicate. The Laboratory Director stated she documented the average value of each control only. 4. Review of the laboratory's test menu revealed the laboratory performs</p>

forty eight (48) semen analysis samples annually. II. Based on review of the laboratory's policies, quality control records, patient test records, and interview with personnel, the laboratory failed to document two (2) levels of pH quality controls (QC) each day of patient testing for semen analysis testing for three (3) of twenty one (21) days reviewed. Findings: 1. Review of the laboratory's "Quality Control and Quality Assurance" policies under the " Andrology Laboratory: Quality Control Procedures for Techniques Performed in Andrology Lab" section revealed "Control specimens are tested in the same manner and by the same personnel as patient specimens. Each work day that a semen analysis is done, a pH strip (7-8) is tested against 7.0 and 8.0 control solutions. Results are recorded on the pH Strip QC Log in the General Lab and Andrology QC Log book. The results are reviewed during the quarterly QC/QA review." 2. Review of the January 2025 through September 2025 "pH Strip QC Log" and patient test records revealed the laboratory did not perform the pH QC for the following three (3) days and patients: January 13, 2025: Patient Met27956 February 14, 2025: Patient Met27964 August 8, 2025: Patient BR3542 3. In interview on October 14, 2025 at 11:20 am, the Laboratory Director confirmed the pH QC was not performed for the identified three (3) dates and patients.

**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.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory policies, quality control records, patient test reports, test menu, and interview with personnel, the laboratory failed to perform quality control (QC) every eight (8) hours of patient testing for manual sperm counts for two (2) of twenty six (26) patients reviewed. Findings: 1. Review of the laboratory's "Quality Control and Quality Assurance Manual" under the "Andrology Laboratory" section revealed "Control specimens are tested in the same manner and by the same personnel as patient specimens. Techniques requiring QC include semen analysis and insemination preparation. Each workday that a semen analysis is performed one high-count and one low-count aliquot is analyzed by each technician who is performing semen analysis that day. The laboratory director monitors this data during her routine quarterly QC review and makes recommendations as appropriate." 2. Review of the laboratory's test menu revealed the laboratory utilizes Accubeads as their quality control for semen analysis testing. 3. Review of the laboratory's January 2025 through September 2025 quality control (QC) and patient test records revealed the laboratory did not perform at least one level of QC every eight (8) hours for the following two (2) of twenty six (26) patients: January 13, 2025: Patient Met27956 August 8, 2025: Patient BR3542 4. In interview on October 14, 2025 at 11:20 am, the Laboratory Director confirmed the sperm count QC was not performed for the identified two (2) dates and patients.

**D5893**

**POSTANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1299(b)(c)

(b) The postanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of

postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policies, patient final test reports, and interview with personnel, the laboratory failed to ensure established quality assurance monitors were able to identify issues within the postanalytic system for two (2) of twenty six (26) patient reports reviewed. Findings: 1. Review of the laboratory's "Quality Control and Quality Assurance Manual" under the "Quality Assurance/Quality Improvement" section revealed "Our quality assurance program provides a mechanism for the review and analysis of data to identify problems and avoid clerical and decanting errors." Prior to sending results to the referring physician, the Laboratory Director or her designees reviews all results from semen analyses, client semen cryopreservation and semen preparation to detect transcriptional and analytical errors and, if appropriate, to assure controls have been run. The Laboratory or her designee reviews each completed lab form daily or on her next workday, checking that all spaces are filled in and calculations are correct." 2. Review of patient final test reports revealed the laboratory's quality assessment monitors did not identify the following issues: February 10, 2025: Patient M27962: the time the results were reported was not documented February 14, 2025: Patient Met27964: the room temperature acceptability was not documented 3. In interview on October 14, 2025 at 11:31 am, the Laboratory Director confirmed the laboratory's quality assessment monitors did not identify two (2) incomplete patient final reports.

**D6093**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(5)

(e)(5) Ensure that the quality control and 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 record review and interview with personnel, the Laboratory Director failed to ensure the quality control and assessment programs were maintained to assure the quality of laboratory testing. Findings: 1. The laboratory failed to document values of the semen analysis cell count quality controls (QC) that were performed in duplicate. Refer to D5481 I. 2. The laboratory failed to document two (2) levels of pH quality controls (QC) each day of patient testing for semen analysis testing for three (3) of twenty one (21) days reviewed. Refer to D5481 II. 3. The laboratory failed to perform quality control (QC) every eight (8) hours of patient testing for manual sperm counts for two (2) of twenty six (26) patients reviewed. Refer to D5543.

**D6107**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(15)

(e)(15) Specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Laboratory Director failed to provide written job descriptions for all laboratory personnel. Findings: 1. Review of the laboratory's personnel records and laboratory policies revealed the laboratory did not have written job descriptions for Technical Supervisor, General Supervisor, and Testing Personnel duties. 2. In interview on October 14, 2025 at 10:47 am, the Laboratory Director confirmed the laboratory did not have job descriptions for the identified personnel roles.