Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0917945	03/09/2023
Name of Provider or Supplier	**Street Address, City, State**	
Reproductive Solutions	435 N Mulford Rd, Ste 9, Rockford, IL	

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
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 direct observation, review of laboratory records, lack of documentation, and interview with Testing Personnel (TP1); the laboratory failed to meet the requirements for the specialty of hematology. Findings Include: 1. The laboratory failed to assess the competency of the technical supervisor. See D5209. 2. The laboratory failed to follow all aspects of the facility's testing procedure for Semen Analysis. See D5401. 3. The laboratory failed to perform two control materials of different concentrations at least once a day that Semen Analysis was performed from April 2022 through March 1, 2023, before reporting patient test results for 19 out of 33 days and affecting 25 patients test results. See D5447. 4. The laboratory failed to follow the manufacturer's test system criteria for control materials acceptability before reporting patient test results for 14 out of 14 days that Semen Analysis performed since April 2022, affecting 23 patients test results. See D5481. 5. The laboratory failed to establish, identify, and correct problems with analytical performance for Semen Analysis testing performed April 2022 through March 1, 2023. See D5791. 6. The laboratory failed to ensure two out of four patient test reports for Semen Analysis testing was accurately transcribed into the electronic medical record. See D5801. 7. The laboratory failed to follow written policies and procedures to monitor, assess, and when indicated correct problems identified in the post-analytic systems. See D5891.
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 the laboratory records, lack of documentation, and interview with Testing Personnel (TP1); the laboratory failed to assess the competency of the technical supervisor. Findings Include: 1. Review of competency records found no competency assessments for the individual listed as the technical supervisor on the CMS-209 (Laboratory Personnel Report). 2. Review of the laboratory records found no procedure for competency assessments. 3. On survey date 03-09-2023, at 11:40 am, TP1 confirmed the laboratory failed to assess the competency for the technical supervisor.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory records and interview with Testing Personnel (TP1); the laboratory failed to follow all aspects of the facility's testing procedure for Semen Analysis. Findings Include: 1. Direct observation on 03-09-2023, at 8:14 am, TP1 was observed demonstrating the testing process for Semen Analysis. TP1 used a pipette dropper to place a sample of semen on a Makler counting chamber to count sperm under a microscope. TP1 was also observed using QC-Beads for the high- and low-Quality Control. 2. Review of the testing policy and procedure manual for Semen Analysis stated: a. "Place approximately 5uL of sample onto a Microcell counting chamber." b. "Quality Control (QC): Obtain two concentrations of the current lot number of Accu-beads. (High- and Low-level control.)" 3. During survey date 03-09-2023, at 10:18 am, TP1 confirmed the laboratory is not following the procedure for Semen Analysis that was provided.
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 record review and lack of documentation, the laboratory failed to perform two control materials of different concentrations at least once a day that Semen Analysis was performed from April 2022 through March 1, 2023 before reporting patient test results for 19 out of 33 days and affecting 25 patients test results.

	Findings: 1. The facility's Semen Analysis Policy and Procedure stated, "Record on the Daily Control Count worksheet the concentration for the high- and low-level controls. Indicate if the counts fall within the acceptable range and are within 10% of each other. If counts do not meet the required limits, repeat and document corrective action on the worksheet. Quality controls should be reviewed and acceptable prior to reporting patient results. Frequency: This process should be performed at the beginning of each shift when sperm concentrations are determined." 2. Review of the laboratory's Semen Analysis Specimen Processing Log and the Accubead Quality Control (QC) Log found the laboratory failed to perform QC for both the Hi and Low QC-Bead controls for 19 of 33 days reviewed from April 2022 through March 1, 2023 before reporting patient test results. Date Low QC Hi QC 05-11-22 No QC recorded 05-17-22 No QC recorded 06-24-22 No QC recorded 07-19-22 No QC recorded 08-16-22 No QC recorded 08-24-22 No QC recorded 09-07-22 No QC recorded 09-13-22 No QC recorded 10-11-22 No QC recorded 10-13-22 No QC recorded 11-16-22 No QC recorded 11-18-22 No QC recorded 11-29-22 No QC recorded 12-27-22 No QC recorded 01-31-23 No QC recorded 02-04-23 No QC recorded 02-07-23 No QC recorded 02-21-23 No QC recorded 03-01-23 No QC recorded 3. 25 patients were tested for Semen Analysis when the laboratory failed to perform QC from April 2022 to March 1, 2023.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview with Testing Personnel (TP1), the laboratory failed to follow the manufacturer's test system criteria for control materials acceptability before reporting patient test results for 14 out of 14 days that Semen Analysis performed since April 2022, affecting 23 patients test results. Findings: 1. The laboratory's policy and procedure manual for Semin Analysis stated that the "Quality Control obtain two concentrations of the current lot number of Accu-beads. (High- and Low- level controls.)" 2. The facility's Patient Test Management and Record Keeping states that, "Verification Qualified Testing Personnel shall verify all results released for reporting. The following criteria shall be used in verifying patient results: QC criteria of the laboratory are met. Patient test results are not reported when QC values are outside the established acceptable range." 3. Review of laboratory documents found the laboratory failed to use the correct ranges for the facility's Quality Control (QC) product QC-Beads for Semin Analysis. a. The QC-Beads product insert stated, "The expected values for the Makler Chamber Hi QC-Beads is between 53-67 million beads/ml and between 25-34 million beads/ml for the Lo QC-Beads." b. The facility was using 30-40 million beads/ml for the Hi and between 15.5-20.5 million beads/ml for the Lo and these ranges were located on the Accu-beads product insert and QC Worksheet that were in use at the time of survey. 4. Review of QC records found the facility switched from Accu-beads to QC-Beads in April of 2022 but failed to update the acceptable QC ranges based on the manufacturer's insert for the QC-Beads. 5. Review of the laboratory's QC records found QC values failed to meet the manufacturer's acceptability criteria for both the Hi and Low QC-Bead controls for 14 of 14 days reviewed from April 2022 through January 24, 2023. Date Low QC Hi QC 04-08-22 17.0 32.3 04-18-22 20.0 37.3 04-22-

	22 17.3 37.6 05-27-22 17.6 35.3 06-03-22 17.6 35.6 06-08-22 17.0 39.0 07-22-22 20.3 33.0 07-29-22 17.3 37.3 08-03-22 18.3 34.6 10-05-22 19.3 34.6 10-19-22 18.3 34.3 11-10-22 19.6 36.6 01-10-23 19.0 33.7 01-24-23 19.0 33.7 6. 23 patients were tested for Semen Analysis when QC failed to meet acceptability criteria from April 2022 to January 24, 2023. 7. On survey conducted on 03-09-2023, at 11:40 am, TP1 confirmed the incorrect ranges were used for the QC-Beads resulting in QC being out of range.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the Testing Personnel (TP1); the laboratory failed to establish, identify and correct problems with analytical performance for Semen Analysis testing performed April 2022 through March 1, 2023. Findings Include: 1. The facility's Patient Test Management and Record Keeping stated, "When properly followed, the patient test management system will assure optimum patient specimen integrity and positive identification throughout the pre-analytic (pre-testing), analytic (testing), and post-analytic (post testing) processes." "Verification Qualified Testing Personnel shall verify all results released for reporting. The following criteria shall be used in verifying patient results: QC criteria of the laboratory are met. Patient test results are not reported when QC values are outside the established acceptable range. Out of control results and corrective actions are documented." 2. The laboratory failed to perform two control materials of different concentrations at least once a day that Semen Analysis was performed from April 2022 through March 1, 2023 before reporting patient test results for 19 out of 33 days and affecting 25 patients test results. See D5447. 3. The laboratory failed to follow control procedures that monitor the accuracy and precision of the complete analytic process for 14 out of 14 days that Semen Analysis has been performed since April 2022, affecting 23 patients test results. See D5481. 4. Review of laboratory QA records found the laboratory failed to document any corrective actions as indicated in the QA policy. 5. On survey date 03-09-2023, at 11:40 am, TP1 confirmed the laboratory failed to perform corrected actions as outlined in the QA policy.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

	This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with Testing Personnel (TP1); the laboratory failed to ensure two out of four patient test reports for Semen Analysis testing was accurately transcribed into the electronic medical record (EMR). Findings Include: 1. Review of two out of four patient test reports for patient one (P1), Chart NO: 113147, and patient four (P4), Chart NO: 112357 for Semen Analysis testing found the laboratory failed to accurately transcribe the Semen Analysis results into the laboratory's EMR from the patient's paper test reports. a. P1 paper copy of patient test report has the value of 350.9 for Total Motility and the patient test report that was scanned into the EMR was 352.8. b. P4 paper copy of patient test report has the value of 161.3 for Total Motility and the patient test report that was scanned into the EMR was 160.1. 2. On survey date 03-09-2023, at 11:49 am, TP1 confirmed the doctor uses the patient 's test report that has been scanned into the facility's electronic medical record and not the paper test reports that had been corrected after being scanned in.
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 laboratory records and lack of laboratory documentation; the laboratory failed to follow written policies and procedures to monitor, assess, and when indicated correct problems identified in the post-analytic systems specified for hematology. Findings Include: 1. The facility's Patient Test Management and Record Keeping stated, "The purpose of the patient test management system is to ensure proper patient preparation, proper specimen collection, identification, preservation, transportation (if applicable), processing and test result reporting. When properly followed, the patient test management system will assure optimum patient specimen integrity and positive identification throughout the pre-analytic (pre-testing), analytic (testing), and post-analytic (post testing) processes." "Verification Qualified Testing Personnel shall verify all results released for reporting. The following criteria shall be used in verifying patient results: QC criteria of the laboratory are met. Patient test results are not reported when QC values are outside the established acceptable range. Out of control results and corrective actions are documented. The Supervisor or designee at the start of the next routine working day must review results of all tests performed whenever the Supervisor or designee is absent. A laboratory roster sheet correlating names with signatures and initial of technical staff can be found in the Policy/Procedure Manual and at the end of this section. Detecting Errors Testing personnel must carefully review raw data documents, worksheets, and computer entries to ensure prevention of transcription and/or keying errors in a timely manner. Documentation When a discrepancy is noted and a remedial action is necessary, a Quality Assurance Data Collection form is completed and turned in to laboratory Supervisor and/or Technical Consultants." 2. Review of laboratory records show that Quality Assurance (QA) monitoring for post-analytic systems for Semen Analysis had not been done for the past 2 years. 3. Review of laboratory documents and lack of laboratory documentation show the laboratory failed to follow written policies and procedures to monitor, assess, and when indicated correct problems identified in the post-analytic systems. 4. The laboratory failed to ensure two out of four patient test reports for Semen Analysis testing was accurately transcribed into the electronic

	medical record. See D5801. 5. On survey date 03-09-2023, at 11:40 am, TP1 confirmed the laboratory failed to perform corrected actions as outlined in the QA policy.