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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 34D2120437 | (X3) Date Survey Completed 09/28/2021 |
| Name of Provider or Supplier Care Fertility, Pllc DbA Reproductive | Street Address, City, State 105 Landings Drive, Suite 202, Mooresville, NC | |
| 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 |
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| D3037 | <p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records, the absence of PT(proficiency testing) records, and interview with the LD(laboratory director) 9/28/21, the laboratory failed to retain PT records for semen analysis for at least 2 years. Findings: Review of laboratory records on 9/28/21 revealed the 2019 AAB(American Association of Bioanalysts) PT records for semen analysis were unavailable. At approximately 9:45 a.m., the LD stated she could not locate the 2019 AAB PT records for semen analysis. She was able to obtain screen shots from AAB showing the laboratory participated in April 2019 and November 2019, but the PT testing records, signed attestation statements, PT results and scores, documentation of review and record of any corrective action were not available for review.</p> |
| D5805 | <p>TEST REPORT CFR(s): 493.1291(c)</p> <p>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.</p> |

This STANDARD is not met as evidenced by:

Based on review of random patient test reports and interview with the LD(laboratory director) on 9/28/21, the laboratory failed to ensure the test reports included all required information. Findings: Review of random patient semen analysis test reports (#5930963, #649352, #6461204) in the Artworks EMR(electronic medical record) revealed the analyzing location where the tests were performed was listed as the location of the laboratory's sister clinic. At approximately 12:50 p.m, the LD confirmed the analyzing location on the test reports were incorrect.