| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 46D2156484 | 07/10/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Conceptions Fertility Center | 1900 North State Street, #105, Provo, UT | |

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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| **D5421** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(1)<br><br>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.<br><br>This STANDARD is not met as evidenced by:<br>Based on laboratory test record review, lack of documentation, and interview with staff, the laboratory failed to verify test accuracy and precision for 1 of 1 tests performed (semen analysis). The laboratory began semen analysis testing in 01/2019 and performs approximately 300 tests annually. Findings include: 1. Laboratory tests records failed to include documentation semen analysis testing had been evaluated for accuracy and precision prior to reporting patient test results. 2. The technical supervisor stated during the survey on 07/10/2019 during a telephone interview they were unable to locate test method verification studies for semen analysis testing. |
| **D5447** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(3)(i)(g)<br><br>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. |

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| | This STANDARD is not met as evidenced by:<br>Based on patient semen analysis test record review, quality control (QC) record review, and interview with staff, the laboratory failed to document 2 levels of QC each day of semen analysis testing for 2 of 4 days of testing reviewed. Findings include: 1. Patient test records document semen analysis testing on 02/25/2019 and 03/21/2019. 2. QC records failed to include documentation of semen QC performance on 02/25/2019 and 03/21/2019. 3. The director confirmed on 07/10/2019 during survey the laboratory did not have documentation of 2 levels of QC on 02/25/19 and 03/21/2019. |
| **D5805** | TEST REPORT<br>CFR(s): 493.1291(c)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on test report review and interview with staff, the test report failed to include the name and address of the laboratory location where testing was performed for the morphology portion of semen analysis testing for 4 of 4 patient report reviewed. Findings include: 1. The surveyor reviewed 4 patient test reports from 02/25/2019, 03/21/2019, 05/03/2019, and 06/28/2019. 2. The test reports failed to include the location where sperm morphology testing was performed. 3. During an interview with the director on 07/10/2019 at approximately 2:00 pm, the director stated the technical supervisor (TS) also worked at a CLIA certified laboratory in Kentucky, and the sperm morphology portion of semen analysis testing was performed by the TS in Kentucky. 4. In a telephone interview with the TS on 07/10/2019 at approximately 2:00 pm, the TS confirmed he had performed the sperm morphology portion of the analysis from Kentucky. |
| **D6102** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(12)<br><br>The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.<br><br>This STANDARD is not met as evidenced by:<br>Based on patient test record review, lack of documentation, and interview with the director, the laboratory director failed to ensure 1 of 3 testing personnel reporting semen analysis testing had received training and had demonstrated they could perform testing accurately for 1 of 1 tests performed (semen analysis). Findings include: 1. |

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| | Four patient test records reviewed from 02/25/2019, 03/21/2019, 05/03/2019, and 06 /28/2019 document testing performed by 3 different testing personnel (the director, employee A, and employee B). 1. Semen analysis test records reviewed for one patient on 05/03/2019 include documentation testing was performed by employee B. 3. The laboratory lacked documentation that employee B had been trained and had demonstrated they could perform semen analysis testing accurately before reporting results on 05/03/2019. 4. In an interview on 07/10/2019 at approximately 2:00 pm, the director confirmed they failed to document employee B could perform semen testing accurately before reporting patient samples. |