| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 05D1014810 | 09/12/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Huntington Reproductive Center | 1220 La Venta Dr Ste 103, Westlake Village, CA | |

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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| **D3031** | RETENTION REQUIREMENTS<br>CFR(s): 493.1105(a)(3)<br><br>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.<br><br>This STANDARD is not met as evidenced by:<br>Based on request and the lack of documentation and monitoring for the room temperatures, and interview with the technical consultant, (9/12/2018, 1630), it was determined that the laboratory failed to retain room temperature records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. See D 5413. |
| **D5215** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(b)(2)<br><br>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).<br><br>This STANDARD is not met as evidenced by:<br>Based on review of second quarter (Q2-2016) of the American Association of Bioanalysts (AAB) proficiency testing records, laboratory's proficiency testing evaluation report, and interview with the technical consultant (9/12/2018, 1630), it was determined that the laboratory failed to verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect |

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| | laboratory test performance. The findings included: Forward Progression: a. Q2-2016, AAB reported an artificial 100% for Makler Forward Progression. Value Grading Reported Range Spec 1? 85 36-60 Spec 2? 40 0-24 AAB's footnote? = This score may not truly evaluate performance for this specimen which was not graded because of a lack of participant consensus. b. The laboratory's true proficiency testing score for Forward Progression should have been 0%. The laboratory lacks the documentation of any corrective action. c. For twelve (12) out of twelve random patient sampling test results reviewed covering period from 1/28/2016 to 9/4/2018, the laboratory analyzed and reported twelve patient test results for Forward Progression which its accuracy and validity cannot be assured. Based on the laboratory's annual testing volume declaration submitted for 2017-2018, the laboratory analyzed and reported 324 Sperm analysis. d. The technical consultant affirmed (9/12/2018, 1630) that the laboratory should have reviewed and indicated corrective action for the failed proficiency testing score for the Forward Progression. |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.<br><br>This STANDARD is not met as evidenced by:<br>Based on request and the lack of documentation and monitoring for the room temperatures, and interview with the technical consultant, (9/12/2018, 1630), it was determined that the laboratory failed to follow manufacturer's instructions, monitor and document room temperature for years 2016, 2017, and 2018. The findings included. a. The laboratory uses Accu-Beads quality control (QC) materials and is stored at room temperature as what manufacturer instructions indicated on the QC box container. b. The laboratory has no documentation to show its room temperatures for the years 2016, 2017 and 2018. c. For twelve (12) out of twelve random patient sampling test results reviewed covering period from 1/28/2016 to 9/4/2018, the laboratory analyzed and reported twelve patient test results for Semen analysis which its accuracy and validity cannot be assured. Based on the laboratory's annual testing volume declaration submitted for 2017-2018, the laboratory analyzed and reported 324 Sperm analysis. d. The technical consultant affirmed (9/12/2018, 1630) that the laboratory failed to monitor and document room temperatures for the years: 2016, 2017 and 2018. |
| **D5469** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value |

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| | of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on request and the lack of documentation for the Accu-Beads quality control (QC) materials being performed by the laboratory, and interview with the technical consultant (9/12/2018, 1630) it was determined that the laboratory did not establish, verify and indicate lot number and expiration dates whenever QC materials are ran. The findings included: a. The laboratory uses Accu-Beads quality control (QC) materials. Each vial bears the lot number and expiration dates for the user to be aware as up to when it will be used. b. Based on review of QC results print out, there were no lot numbers and expiration dates indicated on the results, therefore, there was no way to determine if the QC materials are ran within its expiration dates. c. For twelve (12) out of twelve random patient sampling test results reviewed covering period from 1/28/2016 to 9/4/2018, the laboratory analyzed and reported twelve patient test results for Semen analysis which its accuracy and validity cannot be assured. Based on the laboratory's annual testing volume declaration submitted for 2017-2018, the laboratory analyzed and reported 324 Sperm analysis. d. The technical consultant affirmed (9/12/2018, 1630) that the laboratory failed to establish, verify and indicate lot numbers and expiration dates whenever QC materials are performed. |
| **D6021** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5)<br><br>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.<br><br>This STANDARD is not met as evidenced by:<br>Based on review and the lack of documentation: for room temperatures for 2016, 2016, 1nd 2017, review of the second quarter (Q2-2016) of the American Association of Bioanalysts (AAB) proficiency testing records, laboratory's proficiency testing evaluation report, Accu-Beads QC materials records, it was determined that the laboratory director failed to ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. See D 3031, D 5215, D 5413, and D5469. |