

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2068321	(X3) Date Survey Completed 09/28/2021
Name of Provider or Supplier Aspire Fertility Institute	Street Address, City, State 911 W 38th St Ste 402, Austin, TX	
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
D0000	The laboratory was found out of compliance with the CLIA regulations. The conditions not met were: D6168 - 42 C.F.R. 493.1487 Condition: Laboratories performing high complexity testing; testing personnel.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of competency evaluations and interview, the laboratory failed to assess competency for one of one clinical consultant, one of one technical supervisor, and one of one technical consultant. Findings follow. A. Review of competency evaluations showed none for the positions of clinical consultant, technical supervisor and technical consultant. B. Interview with the Laboratory Director on September 28, 2021 at 1000 hours in the break room confirmed they had not been performed.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p>

This STANDARD is not met as evidenced by:
 Based on review of manufacturer's instructions, laboratory temperature records, and interview, the laboratory failed to define and monitor the room temperature required for test system performance using the Roche Hitachi Cobas e 411 Endocrinology analyzer used for three of three months reviewed. Findings follow. A. Review of the Cobas e 411 Analyzer Operator's Manual, version 3.2 2019, Chapter 3 Specifications under Environment for temperature stated, "Operation: 18 to 32 degrees Celsius". B. Review of the Reflexions computer application (app) from May - July 2021 used to document tasks performed in the laboratory, showed no criteria in place to monitor the laboratory's room temperature. C. Interview with the Laboratory Director on September 28, 2021 at 1530 hours in the break room confirmed after investigation, that the room temperature acceptable range had not been set in the Reflexions app. The Laboratory Director entered the range during the survey, and showed some daily temperatures now appeared to be out of range, and explained the app would have notified testing personnel real time if the temperature was out of range, requiring documentation of corrective action, had the acceptable range been set up.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
 CFR(s): 493.1253(b)(1)

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.

This STANDARD is not met as evidenced by:
 Based on review of the validation studies and interview, the laboratory failed to verify the normal patient reference ranges for the Roche Hitachi Cobas e 411 Endocrinology analyzer for five of five analytes. Findings follow. A. Review of the verification of performance specifications for the Cobas e 411, validated on April 29, 2020, did not include the verification of normal patient reference range for the following analytes: Luteinizing Hormone (LH), Estradiol (E2), Beta Human Chorionic Gonadotropin (B HCG), Thyroid Stimulating Hormone (TSH), and Progesterone. B. Interview with the Laboratory Director on September 28, 2021 at 1320 hours in the break room maintained they do not have reference ranges for the hormones. Follow up interview at 1710 hours in the break room confirmed reference ranges were printed on the patient test reports for the hormones, and confirmed a verification of the reference ranges was not performed with the validation of the instrument.

D5429

MAINTENANCE AND FUNCTION CHECKS
 CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on review of manufacturer's instructions, maintenance records, and interview, the laboratory failed to have a mechanism in place to show when monthly and every 2-week maintenance was performed on the Roche Hitachi Cobas e 411 Endocrinology analyzer for two of two months reviewed. Findings follow. A. Review of the Cobas e 411 Analyzer Operator's Manual, version 3.2 2019, under chapter 11 described every 2 week and monthly maintenance required. Review of the Cobas e 411 Analyzer Maintenance Log defined it as follows: Every 2 weeks: Clean rinse stations Perform liquid flow cleaning Monthly: Replace pinch valve tubing B. Random review of the Reflexions computer application records used to document maintenance on the Cobas e 411 were reviewed from July 1, 2021 - August 31, 2021 and showed every 2 week and monthly maintenance were marked as performed every week. C. Interview with the Laboratory Director on September 28, 2021 at 1355 hours in the break room acknowledged the documentation of every 2 week and monthly maintenance every week indicated the maintenance had been performed for that time period. Interview with testing personnel #6 on the CMS form 209, on September 28, 2021 at 1400 hours in the laboratory confirmed she checks the box weekly that every 2 week and monthly maintenance was performed, but did not perform it at the frequency as indicated in the documentation. She stated monthly maintenance is performed the first week of every month, and when asked how do you keep up with it and how do other techs know when it was actually performed, she presented a calendar with the schedule showing highlighted days. Interview with the Laboratory Director on September 28, 2021 at 1410 hours in the break room confirmed the documentation of every 2 week and monthly maintenance was not accurately documented showing the actual date of performance.

D5439

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:
Based on review of verification of performance specifications, calibration verification and interview, the laboratory failed to perform calibration verifications on the Roche Hitachi Cobas e 411 Endocrinology analyzer for six of six analytes every six months

for one of two events reviewed. Findings follow. A. Review of the verification of performance specifications showed the Cobas e 411 was validated on 4/29/2020. B. Review of calibration verifications performed on the Cobas e 411 showed calibration verifications for Luteinizing Hormone (LH), Estradiol (E2), Beta Human Chorionic Gonadotropin (B HCG), Thyroid Stimulating Hormone (TSH), and Progesterone were performed on 3/11/2021. Additional six-month calibration verifications were requested but not provided. Performance specifications were performed on 4/29/2020 and calibration verification was performed on 3/11/2021, elapsed time was 10 months, 11 days. C. Interview with the Technical Consultant on September 28, 2021 at 1455 hours via phone call from the break room, confirmed no calibration verifications were performed in 2020 after start-up.

D5469

CONTROL PROCEDURES
CFR(s): 493.1256(d)(10)(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-- 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 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.

This STANDARD is not met as evidenced by:
Based on review of the manufacturer's instructions for use and assay sheet, quality control (QC) records, and interview, the laboratory failed to define the acceptable limits of QC as required by the manufacturer, on the Roche Hitachi Cobas e 411 Endocrinology analyzer for five out of five analytes reviewed. Findings follow. A. Review of the Bio Rad Liquid Assayed Multiqual control package insert for Lot 40370 (rev 2019 10) under Assignment of Values stated, "The mean values and corresponding +/- 3SD ranges in the Assignment of Values Data Charts (available separately) were derived from replicate analysis and are specific for this lot or product...It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides." The following analytes for Cobas e Systems were listed for Lot 40370 for Levels 1, 2 and 3 on the Bio Rad Liquid Assayed Multiqual (rev 2019 10), respectively, with the following ranges: 1. Luteinizing Hormone (LH): Level 1 mean 1.89, range 1.58 -2.19 (1SD 0.1); Level 2 mean 20.2, range 17.5 - 23.0 (1SD 0.93); Level 3 mean 72.9, range 64.0 - 81.8 (1SD 2.97) 2. Estradiol (E2): Level 1 mean 79.1, range 56.8 - 101 (1SD 7.3); Level 2 mean 232, range 189 - 275 (1SD 14.3); Level 3 mean 397, range 332 - 462 (1SD 22) 3. Beta Human Chorionic Gonadotropin (B HCG): Level 1 mean 3.01, range 2.09 - 3.94 (1SD 0.31); Level 2 mean 19.3, range 15.7 - 22.8 (1SD 1.2); Level 3 mean 139, range 115 - 164 (1SD 8) 4. Thyroid Stimulating Hormone (TSH): Level 1 mean 0.463, range 0.409 - 0.517 (1SD 0.018); Level 2 mean 5.41, range 4.75 - 6.08 (1SD 0.22); Level 3 mean 36.7, range 32.0 - 41.3 (1SD 1.5) 5. Progesterone: Level 1 mean 0.801, range 0.608 - 0.993 (1SD 0.064); Level 2 mean 11.6, range 9.30 - 13.8 (1SD 0.73); Level 3 mean 29.1, range 23.4 - 34.7 (1SD 1.9) B. Random review of the daily instrument QC

reports from July 01, 2021 - August 31, 2021 showed the mean and range for each analyte. The following represented the laboratory's established ranges (2SD), all greater than the manufacturer's 3SD published ranges: 1. Luteinizing Hormone (LH): Level 1 range 1.44 - 2.34 (1SD 0.945); Level 2 range 16.0 - 24.40 (1SD 2); Level 3 range 59.55 - 86.25 (1SD 6.68) 2. Estradiol (E2): Level 1 range 46.25 - 112.0 (1SD 16.44); Level 2 range 103.0 - 361.0 (1SD 64.5); Level 3 range 299.5 - 494.5 (1SD 48.75) 3. Beta Human Chorionic Gonadotropin (B HCG): Level 1 range 1.61 - 4.41 (1SD 0.7); Level 2 range 14.05 - 24.55 (1SD 2.63); Level 3 range 101.5 - 176.5 (1SD 18.8) 4. Thyroid Stimulating Hormone (TSH): Level 1 range 0.382 - 0.544 (1SD 0.041); Level 2 range 4.40 - 6.42 (1SD 0.51); Level 3 range 29.80 - 43.60 (1SD 3.45) 5. Progesterone: Level 1 range 0.462 - 1.03 (1SD 0.14); Level 2 range 7.65 - 14.55 (1SD 1.73); Level 3 range 19.60 - 36.40 (1SD 4.2) C. Interview with the Technical Consultant on September 28, 2021 at 1325 hours in the breakroom acknowledged she used the ranges from the Bio Rad package insert. Interview with the Laboratory director on September 28, 2021 at 1530 hours in the break room confirmed the findings after a review of the findings.

D6013

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(3)(ii)

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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

This STANDARD is not met as evidenced by:
Based on review of the validation studies and interview, the laboratory director failed to verify the normal patient reference ranges for the Roche Hitachi Cobas e 411 Endocrinology analyzer for five of five analytes. See D5421.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Based on review of competency evaluations and interview, the technical consultant failed to evaluate and document the performance of individuals at least semi-annually during the first year after validation of the Roche Hitachi Cobas e 411 (April 29, 2020) Endocrinology analyzer for two of three testing personnel reviewed. Findings follow. A. Review of competency evaluations showed testing personnel #3 and #4, on the CMS form 209, did not have the first semi-annual competency evaluations performed after the installation of the Cobas e 411: Testing personnel #3 had competency evaluations for hormone testing performed on 12/07/2020 (2nd six months) and 08/12/2021 (annual). Testing personnel #4 had competency evaluations for hormone testing performed on 12/07/2020 (2nd six months) and 08/12/2021

(annual). B. Interview with the Laboratory Director on September 28, 2021 at 1000 hours in the break room confirmed the findings.

D6128

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:

Based on review of competency evaluations and interview, the technical supervisor failed to evaluate and document the performance of individuals annually for Andrology testing for one of two years for two of two testing personnel reviewed. Findings follow. A. Review of competency evaluations showed testing personnel # 3 and #4, on the CMS form 209, did not have an annual competency evaluation performed for sperm count, morphology, and motility: Testing personnel #3 was hired 12/05/2017 and had competency evaluations for semen analysis performed on 08/12 /2021. Testing personnel #4 was hired on 08/07/2019 and had competency evaluations for semen analysis performed on 08/12/2021. Competency evaluations for 2020 were requested but not provided. B. Interview with the Laboratory Director on September 28, 2021 at 1000 hours in the break room confirmed the findings.

D6168

TESTING PERSONNEL

CFR(s): 493.1487

The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed.

This CONDITION is not met as evidenced by:

Based on review of educational credentials and interview, the laboratory failed to employ testing personnel that meet the educational requirements for two of five testing personnel in high complexity testing in Andrology (Hematology). See D6171.

D6171

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1489(b)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)

(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:

Based on review of educational credentials and interview, the laboratory failed to employ testing personnel that meet the educational requirements for two of five testing personnel in high complexity testing in Andrology (Hematology). Findings follow. A. Review of education credentials for testing personnel # four and five, on the CMS form 209, showed the following: 1. Testing personnel #4 had a Master and Bachelor of Science in Animal Science with 12 hours in Chemistry and six hours in Biology, lacking six hours in a combination of Chemistry/ Biology. 2. Testing personnel #5 had a Bachelor of Science in Geology with 16 hours in Chemistry, lacking six hours in Biology, and an additional two hours in Chemistry/ Biology. B. Interview with the Laboratory Director on September 28, 2021 at 1115 hours and

1225 hours in the break room confirmed the findings for both testing personnel after a review of the findings and acknowledged the previous Laboratory Director had hired the testing personnel.