Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2115146	07/16/2024
Name of Provider or Supplier	**Street Address, City, State**	
Assisted Reproductive Labs	9817 N 95th St, Bldg I, Ste 107, Scottsdale, AZ	

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	A recertification survey was performed on July 16, 2024. The facility was found to be NOT in compliance with the following CLIA conditions for specialties/subspecialties surveyed for 42 CFR: 493.1487: Testing Personnel
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 lack of calibration verification documentation for the Tosoh AIA-360 analyzer and interview with the testing personnel (TP-1), the laboratory failed to

	perform and document calibration verification procedures for the analytes, LH (Luteinizing Hormone) and beta-hCG, at least once every 6 months during 2022 and 2023. Findings include: 1. No documentation was presented for review to indicate the laboratory performed calibration verification procedures for the analytes, LH and beta-hCG, at least once every six months during 2022 and 2023, 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. 2. TP-1 interviewed on July 16, 2024 at 12:15 PM confirmed the laboratory failed to perform calibration verification procedures for LH and beta-hCG on the Tosoh analyzer during 2022 and 2023 . 3. The laboratory's reported annual test volume in the subspecialty of Endocrinology is 4,000.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of Quality Control (QC) documentation for the Quick III stain and interview with the technical supervisor (TS-1), the laboratory failed to test staining materials on 158 days during 2023 and 2024, for intended reactivity to ensure predictable staining characteristics for andrology testing performed in the specialty of Hematology. Findings include: 1. The laboratory performs andrology testing in the specialty of Hematology, with an approximate annual test volume of 207. 2. The laboratory failed to document the acceptability of the Quick III stain on 158 out of 158 testing days from May 1, 2023 through June 26, 2024. 3. The TS-1 interviewed on July 16, 2024 at 12:20 PM confirmed the laboratory failed to document the acceptability of the Quick III stain for intended reactivity to ensure predictable staining characteristics during the timeframe indicated above. 4. The number of patients tested on each of the 158 testing days indicated above could not be determined at the time of the survey.
D5543	HEMATOLOGY CFR(s): 493.1269(a)(d) (a) For manual cell counts performed using a hemocytometer-- (a)(1) One control material must be tested each 8 hours of operation; and (a)(2) Patient specimens and control materials must be tested in duplicate. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of patient test records and interview with the Technical Supervisor (TS-1), the laboratory failed to perform duplicate cell counts on 1 out of 2 patient's specimens using a hemacytometer. Findings include: 1. The laboratory performs semen analysis testing using a hemacytometer, with an reported annual test volume of 207. It is the practice of the laboratory to perform each patient cell count and each control cell count in duplicate. 2. One out of two patient test records reviewed during

	the survey (# 010909) failed to include a duplicate cell count for semen analysis testing performed on 5/28/2024. 3. TS-1 interviewed on 7/16/24 at 11:40 AM confirmed the laboratory failed to perform a duplicate cell count on the specimen indicated above.
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 patient test reports and interview with the Technical Supervisor (TS-1), the laboratory failed to have a system in place to ensure the accuracy of test results that are manually entered into the patients' Electronic Medical Record (EMR). Findings include: 1. The laboratory performs semen analysis testing under the specialty of Hematology and performs testing for LH, FSH, Progesterone, Estradiol, and beta-hCG on the Tosoh AIA-360 analyzer under the subspecialty of Endocrinology, with a reported annual test volume of 4,207. 2. The test results generated from the analyzer and the test results obtained from the semen analysis are manually entered by testing personnel into the patients' EMR. 3. No documentation was presented for review to indicate the laboratory has a system in place to ensure the accuracy of patient test results that are manually entered into the patients' EMR. 4. TP-1 interviewed on July 16, 2024 at 12:40 PM confirmed the laboratory failed to have a system in place to verify the accuracy of patient test results that are manually entered into the EMR.
D6054	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 annually, after the first year. This STANDARD is not met as evidenced by: Based on lack of performance evaluation documentation from 2023 and interview with the technical supervisor (TS-1), the technical consultant failed to evaluate and document the performance of one out of one individuals responsible for moderate complexity testing at least annually. Findings include: 1. No documentation of annual competency evaluation from 2023 was presented for review for one out of one testing personnel (TP-1) who performs testing on the Tosoh analyzer in the subspecialty of Endocrinology. 2. The TS-1 interviewed on 7/16/24 at 10:12 AM confirmed the technical consultant failed to evaluate and document the performance of TP-1 at least annually during 2023.

D6127	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 semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on lack of documentation of a semiannual competency evaluation for 3 of 3 testing personnel and interview with technical supervisor (TS-1), the technical supervisor failed to evaluate and document the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. Findings include: 1. No evidence of a semiannual competency evaluation was presented for review for three out of three testing personnel (TP-1, TP-2, TP-3) who perform andrology testing on patient specimens. 2. TS-1 interviewed on 7/16/24 at 10:10 AM confirmed the technical supervisor failed to document a semiannual competency evaluation for the testing personnel indicated above.
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 lack of documentation of an annual competency evaluation from 2023 and interview with the Technical Supervisor (TS-1), the technical supervisor failed to evaluate and document the performance for 1 of 1 individuals responsible for high complexity testing at least annually after the first year the individual tested patient specimens. Findings include: 1. No evidence of an annual competency evaluation was presented for review from 2023 for one out of one testing personnel (TP-1) who performs andrology testing on patient specimens. 2. TS-1 interviewed on 7/16/24 at 10:12 AM confirmed the technical supervisor failed to document an annual competency evaluation for the testing personnel indicated above.
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 personnel records and interview with the laboratory director, the laboratory failed to provide evidence of academic credentials required to qualify one out of one testing personnel who performs high complexity testing under the specialty of Hematology. See D6171 for findings.

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 personnel records and interview with Laboratory Director, the laboratory failed to provide documentation of academic credentials to qualify one out of three testing personnel (TP-2) for high complexity testing. Findings include: 1. The laboratory performs 207 tests annually under the specialty of Hematology. 2. Review of the personnel records for 1 of 3 testing personnel revealed the laboratory failed to have academic credentials to qualify TP-2. 3. No documentation was presented for review during the survey to indicate the laboratory had the diploma and corresponding transcripts for TP-2 evaluated by a foreign transcript evaluation agency to ensure the equivalent education requirements. 4. Interview with laboratory director on 7/16/24 at 10:00 AM confirmed the laboratory failed to provide the required documentation to qualify TP-2 for high complexity testing.