Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2115146	04/17/2019
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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on review of competency evaluation forms and policies and interview with the testing personnel, the laboratory failed to follow established competency evaluation policies to include the assessment of problem solving skills. Findings include: 1. The laboratory's established policy titled, "Quality Management", page 5, lists the 6 required elements that are monitored during the performance of competency evaluations including the "Assessment of problem solving skills". 2. The competency evaluation forms reviewed during the survey for two out of two testing personnel for the 1st quarter of 2019 failed to include documentation regarding the assessment of problem solving skills, specifically the testing personnel's ability to identify and correct test system issues when control material fails to meet the laboratory's established performance specifications. 3. The testing personnel confirmed that the assessment of problem solving skills was not evaluated during competency evaluations.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step

	performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual, quality control (QC) records and interview with the facility personnel, the laboratory's procedure manual failed to include information specific to the control procedures performed on the Access 2 analyzer. Findings include: 1. The laboratory performs approximately 3,600 patient tests annually on the Access 2 analyzer in the sub-specialty of Endocrinology. 2. The laboratory's established policy titled, "Quality Management" states on page 6, "Written procedures must be clearly defined for ongoing monitoring of analytic performance including number and frequency of controls, establishment of tolerance limits for control testing and corrective actions based on quality control data". 3. No documentation was presented for review during the survey to indicate the laboratory's quality control policy and procedure included information regarding the special handling of QC reagents. The manufacturer's package insert for the QC specifies that QC reagents must be completely thawed at room temperature (18 to 25 degrees Celsius, whether frozen or refrigerated) and mixed to ensure homogeneity, before use. 4. No documentation was presented for review during the survey to indicate the laboratory's quality control policy and procedure included information regarding the performance of QC samples specific to control limits as established by the laboratory, the criteria to determine acceptable control results and the actions to take when QC values fall outside the laboratory's established performance specifications. 5. The facility personnel confirmed that the laboratory's quality control procedures presented for review during the survey lacked the information indicated above.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of the manufacturer's package insert for Bio-Rad Quality Control (QC) material and interview with the testing personnel, the laboratory failed to follow the manufacturer's instructions for the storage and stability. Findings include: 1. The laboratory uses Bio-Rad Liquichek Immunoassay Plus Controls, Level 1 and Level 3, for the following tests performed on the Access 2 analyzer: Beta hCG, Cortisol,

	DHEA-S, Estradiol, FSH, LH, Progesterone, and TSH. 2. During the survey, the testing personnel stated that the QC has a 10 day stability once thawed and opened. 3. The manufacturer's package insert for Bio-Rad Liquichek Immunoassay Plus Controls, lot #40970, stated, "Thawed Opened: Once thawed, opened, and stored tightly capped at 2 to 8 degrees Celsius, this product will be stable as follows: All analytes - 14 days, except Estradiol: 5 days...This product should be treated the same as patient specimens and run in accordance with the instructions accompanying the instrument, kit or reagent being used". 4. The laboratory failed to follow the manufacturer's storage and stability requirements for Estradiol. 5. The testing personnel acknowledged that the laboratory was not following the manufacturer's stability requirements for Estradiol.
D5465	CONTROL PROCEDURES CFR(s): 493.1256(d)(8)(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--Test control materials in the same manner as patient specimens. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of Quality Control (QC) records, patient test records, the manufacturer's package insert for QC material and interview with the testing personnel, the laboratory failed to test control materials in the same manner as patient specimens. Findings include: 1. The laboratory performs approximately 3,600 patient tests annually on the Access 2 analyzer in the sub-specialty of Endocrinology. The analytes tested by the laboratory include Beta hCG, Cortisol, DHEA-S, Estradiol, FSH, LH, Progesterone, and TSH. It is the practice of the laboratory to perform two levels, Level 1 and Level 3, of QC material for each analyte tested, each day of patient testing. 2. The manufacturer's package insert for the QC material used by the laboratory states, "This product should be treated the same as patient specimens and run in accordance with the instructions accompanying the instrument, kit, or reagent being used". 3. Review of the laboratory's QC records for testing performed on the Access 2 analyzer revealed that QC material was repeatedly performed until acceptable results were obtained. See D5791 for findings. 4. Review of patient test records and interview with the testing personnel indicate the laboratory would only repeat a patient specimen one time if the initial results were outside of the laboratory's established reference range. 5. The testing personnel acknowledged that the laboratory failed to test control materials in the same manner as patient specimens.
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 laboratory's quality control (QC) policy, lack of QC lot change documentation and interview with the facility personnel, the laboratory (A) failed to verify the criteria for acceptability of quality control materials and (B) failed to verify and accurately input the stated values of a commercially assayed control material for DHEA-S testing. Findings include: 1. The laboratory performs patient testing using the Access 2 endocrinology analyzer. It is the practice of the laboratory to perform 2 levels of QC material each day prior to patient testing. A2. The testing personnel interviewed during the survey stated that the laboratory does not establish a new QC range or mean and instead uses the manufacturer's QC values and inputs those values directly into the instrument. A3. No documentation was presented for review during the survey conducted on April 17, 2019 to indicate the laboratory verified the criteria for acceptability of each lot of control materials used on the Access 2 analyzer from January 2018 through the date of the survey. A4. The testing personnel confirmed that the laboratory failed to verify the criteria for acceptability of control lots that were performed on the analyzer stated above. B1. The laboratory uses Bio-Rad Liquichek Immunoassay Plus Control, Level 1 and Level 3, for QC testing for the analyte, DHEA-S. The current lot of QC material in use at the time of the survey on April 17, 2019 was Lot# 40970 and was put into use on the analyzer on 12/06/2018. B2. The manufacturer's package insert for the DHEA-S QC Level 1 listed the mean and standard deviation (SD) as 64.05 g/dL(mean) with a 4.15 SD. B3. The manufacturer's package insert for the DHEA-S QC Level 3 listed the mean and standard deviation (SD) as 427.4 g/dL(mean) with a 18.64 SD. B4. The testing personnel stated that the QC data manually entered into the analyzer by testing personnel for DHEA-S includes the Mean and SD. The analyzer then calculates an acceptable range based off of these values. B5. The testing personnel confirmed that the QC data for DHEA-S entered into the analyzer at the time of the survey for Level 1 was a mean of 64 g/dL, with a SD of 6.1. For Level 3, the QC data entered was a mean of 478 g/dL and a SD of 41.6. B6. The testing personnel acknowledged that the QC data for DHEA-S entered into the analyzer did not coincide with the stated values listed on the manufacturer's package insert and confirmed that the laboratory failed to verify the manufacturer's stated values of control material.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of Quality Assessment (QA) policies and documentation, Quality Control (QC) records, and interview with the testing personnel, the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified with the repeated unsuccessful performance of QC testing. Findings include: 1. The laboratory performs

approximately 3,600 patient tests annually on the Access 2 analyzer in the sub-specialty of Endocrinology. The analytes tested by the laboratory include Beta hCG, Cortisol, DHEA-S, Estradiol, FSH, LH, Progesterone, and TSH. It is the practice of the laboratory to perform two levels, Level 1 and Level 3, of QC material for each analyte tested, each day of patient testing. 2. The General Operating Policy presented for review during the survey stated, "Malfunctions in laboratory equipment, procedures or quality control failures including the monitoring that falls outside of tolerance limits must be documented using remedial action forms and reported immediately to the Lab Director. Corrective action must be planned, documented, and executed before continuing with laboratory operations". 3. QC records (QC lot# 40970) were reviewed from January 2, 2019 through April 16, 2019. During that time period the laboratory performed patient testing on approximately 55 days. On 37 of those 55 days, the initial QC results for LH, Progesterone, FSH, Beta hCG, Estradiol and/or Cortisol were outside of the laboratory's acceptable range and the QC was re-run by the testing personnel at least one time and sometimes up to six times before acceptable values were obtained. Examples of unacceptable QC performance for either level (1 or 3) were as follows: QC for LH was out of range initially and re-run on 16 out of 55 testing days; QC for Progesterone was out of range initially and re-run on 12 out of 55 testing days; and QC for Beta hCG was performed 5 times on 02/15 /19, 6 times on 2/22/19, 4 times on 03/13/19, 5 times on 3/18//19, and 6 times on 3/20 /19 before acceptable results were obtained. 4. No documentation of corrective action, or a remedial action form as outlined in the General Operating Policy referenced above, was presented for review to indicate the laboratory investigated, identified and resolved the problems associated with repeated unsuccessful QC performance and immediately notified the Laboratory Director. 5. The CMS-209 Laboratory Personnel Form submitted during the survey revealed that the Laboratory Director is also listed as the Clinical Consultant and the Technical Consultant. During the survey the testing personnel stated that the Laboratory Director/Technical Consultant is responsible for reviewing monthly QC charts and graphs for any shifts or trends in QC values. 6. The QC graph (control lot# 40963) presented for review for Beta hCG from 07/01/18 through 09/30/18 revealed the Laboratory Director reviewed the data and commented, "6 occasions, controls needed to be re-run. Re-runs were completed and acceptable. Patient samples could be released at that time. Continue to monitor hCG into the 4th quarter of 2018". The document was signed and dated by the Laboratory Director on 04/08/19. The print date of the document was 04/03/19. No other documentation was presented for review during the survey to indicate the Laboratory Director reviewed and assessed QC results in a timely manner, or was notified of QC failures as they occurred so that the laboratory could immediately implement corrective action processes. 7. The "IVF Phoenix Lab Quality Assurance Review Checklist" presented for review during the survey contains eight areas of testing that are annually monitored by the laboratory, including but not limited to, review of QC procedures (two levels of QC performed each day of patient testing, QC is run in the same manner as patient specimen and reagents used for testing have not exceeded their expiration date) and ensuring that QC was performed according to written procedure without deviation. The form states, "Initials of the Laboratory Director indicate Compliance, a check indicates non-compliance". The QA checklists reviewed during the survey revealed the Laboratory Director's initials by each monitored area thus indicating compliance. No other QA documentation was presented for review to indicate the laboratory identified issues associated with QC results and resolved the problem. 8. The testing personnel confirmed that the laboratory failed to follow its established policy and document corrective action for QC results that fall outside of the laboratory's acceptable range, failed to identify and correct QC results that were routinely trending out of range, and failed to identify and correct issues associated

	with QC results during the annual QA review.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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 the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on the number of deficient practices related to Quality Control (QC) identified during the survey, the laboratory director failed to maintain the QC program to assure the quality of laboratory services provided. See D5403, D5411, D5465, D5469 and D5791 for findings.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: The Condition of Technical Consultant was found to be not met based on the failure of the laboratory to have a Technical Consultant who provides technical oversight as evidenced by: D6043 - failure to resolve technical problems and ensure remedial actions were taken whenever the results of QC testing were outside of the laboratory's established performance specifications; D6052 - failure to assess problem solving skills during the evaluation of the testing personnel's competency; and D6053 - failure to evaluate and document the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tested patient specimens.
D6043	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(5) (b) The technical consultant is responsible for-- (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications; This STANDARD is not met as evidenced by: Based on review of Quality Control (QC) records, Quality Assessment (QA) records and interview with the testing personnel, the Technical Consultant failed to resolve technical problems and ensure remedial actions were taken whenever the results of QC testing were outside of the laboratory's established performance specifications. See D5791 for findings

D6052	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(vi) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills. This STANDARD is not met as evidenced by: Based on review of competency evaluation forms and interview with the testing personnel, the procedures for evaluation of the competency of laboratory staff failed to include the assessment of problem solving skills. Findings include: 1. The competency evaluation forms reviewed during the survey for two out of two testing personnel for the 1st quarter of 2019 failed to include documentation regarding the assessment of problem solving skills, specifically the testing personnel's ability to identify and correct test system failures and/or issues. 2. The testing personnel confirmed that the assessment of problem solving skills was not evaluated during competency evaluations.
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 lack of performance evaluation documentation and interview with the facility personnel, the technical consultant failed to evaluate and document the performance of one testing personnel, at least semiannually during the first year the individual tested patient specimens. Findings include: 1. No semiannual competency evaluation documentation was presented for review for one testing personnel who began patient testing in November 2017. 2. The facility personnel confirmed that the laboratory did not have documentation of a semiannual competency evaluation for the testing personnel indicated above.