Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0978674	11/04/2025
Name of Provider or Supplier	**Street Address, City, State**	
Arizona Advanced Reproductive Lab	4518 E Camp Lowell Drive, Tucson, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records for testing performed in the subspecialty of Endocrinology and interview with the technical supervisor (TS-1) on 11/04/25 at 10:30 AM, the laboratory director failed to sign the PT attestation statements for 3 out of 3 PT events during 2025. Findings include: 1. The laboratory performs testing in the subspecialty of Endocrinology with a reported annual test volume of 11,500. 2. The PT attestation statements presented for review for the 1st, 2nd and 3rd testing events of 2025 lacked the signature of the laboratory director. 3. TS-1 interviewed on 11/04/25 at 10:30 AM confirmed that the PT attestation statements indicated above were not signed by the laboratory director.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of accuracy verification documentation for semen morphology testing and interview with the technical supervisor (TS-1) on 11/04/25 at 10:30 AM,

	the laboratory failed to document corrective action for 1 out of 4 semen morphology scores that failed to meet the acceptable criteria for the intra-laboratory technician comparison completed for Quarter 2 of 2025. Findings include: 1. The laboratory performs semen analysis testing in the specialty of Hematology with a reported annual test volume of 500. 2. The "Intra-Laboratory Technician Comparison" document for Quarter 2 of 2025 states, "Acceptable range is a CV of +/- 20% of the mean of all staff results. Acceptable range for morphology is a StdDev of +/- 5% of each staff result." The results were reviewed and signed by the Laboratory Director on 6/09/25 and the comment stated, "All sperm parameters are within AAB acceptable ranges for all andrology techs." 3. The semen morphology score for 1 out of 4 testing personnel (TP-3) was not within the laboratory's acceptable range as follows: - TP-3 scored a 5 for semen morphology, and the mean of all staff results was 9. The semen morphology scores for the other 3 testing personnel included 10, 11 and 8. 4. The laboratory failed to perform and document corrective action for the unacceptable semen morphology results obtained by TP-3 during the Intra-Laboratory Technician Comparison for Quarter 2 - 2025. 5. The TS-1 interviewed on 11/04/25 at 10:30 AM acknowledged that the semen morphology scores obtained by TP-3 during Quarter 2 - 2025 failed to meet the laboratory's acceptable criteria and no corrective action was taken by the laboratory.
D5301	TEST REQUEST CFR(s): 493.1241(a) (a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: Based on lack of test requisition documentation for review and interview with the technical supervisor (TS-1) on 11/04/25 at 12:11 PM, the laboratory failed to have a written or electronic request for endocrinology testing performed on the Tosoh AIA-900 analyzer for three out of three patient records reviewed during the survey. Findings include: 1. No written or electronic request for endocrinology testing was presented for review for three of three patient records reviewed during the survey, patient# 36487 tested on 4/11/24, patient# 33893 tested on 12/10/24 and patient# 36851 tested on 9/17/25. 2. The TS-1 interviewed on 11/04/25 at 12:11 PM confirmed the laboratory failed to have an electronic or written test requisition for endocrinology testing performed by the laboratory on the specimens indicated above. 3. The laboratory performs 11,500 tests annually under the subspecialty of Endocrinology.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) 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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

	This STANDARD is not met as evidenced by: Based on lack of humidity records for review and interview with the technical supervisor (TS-1) on 11/04/25 at 12:23 PM, the laboratory failed to monitor and document the ambient humidity of the room where the Tosoh AIA-900 analyzer is utilized from 1/23/24 through the survey date of 11/04/25. Findings include: 1. The laboratory failed to monitor and record the ambient humidity of the room where the Tosoh AIA-900 analyzer is operated on each day of patient testing that occurred from 1/23/24 through 11/04/25. The laboratory conducts patient testing each day of the week (Monday - Friday) with the exception of holidays. 2. The manufacturer's instructions for the Tosoh AIA-900 analyzer lists the environmental operating requirement for ambient humidity as 40% -80%. 3. The TS-1 interviewed on 11/04/25 at 12:23 PM confirmed the laboratory failed to monitor and document the ambient humidity of the area where the Tosoh AIA-900 analyzer is operated on each day of patient testing that occurred from 1/23/24 through 11/04/25.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on direct observation of 3 coplin jars containing stain reagents used for semen morphology and interview with the technical supervisor (TS-1) on 11/04/25 at 12:28 PM, the laboratory failed to label three out of three coplin jars with the reagent name, lot number and expiration date. Findings include: 1. Direct observation of 3 out of 3 coplin jars containing reagents used to stain slides for semen morphology revealed the laboratory failed to include a label on each jar to indicate the reagent name, lot number and expiration date. 2. Interview with the TS-1 on 11/04/25 at 12:28 PM confirmed the laboratory failed to label the 3 coplin jars with the stain reagent name, lot number and expiration date. 3. The laboratory reports 500 patient results annually under the specialty of Hematology.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on direct observation of Quik-Dip stain reagents used for staining slides to assess semen morphology and interview with the Technical Supervisor (TS-1) on 11 /04/25 at 12:25 PM, the laboratory used 2 out of 3 Quik-Dip stain solutions for patient testing past the expiration dates. Findings include: 1. The laboratory performs semen morphology testing in the specialty of Hematology, with a reported annual test volume of 500. 2. Direct observation of the Quik-Dip stain reagents on 11/04/25 at 12: 25 PM revealed 2 out of 3 stain components utilized by the laboratory were expired as

	follows: - Quik-Dip Stain 2 Solution, lot# 2206308, expiration date 3/06/24 - Quik-Dip Stain 3 Solution, lot# 2206307, expiration date 3/06/24 3. The number of semen morphology tests performed by the laboratory using the expired stain reagents between 3/06/24 and 11/04/25 could not be determined at the time of the survey. 4. The TS-1 interviewed on 11/04/25 at 12:25 PM confirmed the expired Quik-Dip Stain Solutions indicated above were used for patient testing past the manufacturer's expiration date and were in use at the time of the survey.