Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0501573	08/11/2025
Name of Provider or Supplier	**Street Address, City, State**	
San Antonio Fertility Center Laboratory Inc	7707 Ewing Halsell Drive, Suite 103, San Antonio, 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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) 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. In addition, retain the following: This STANDARD is not met as evidenced by: Based on review of the laboratory's calibration verification records for Human chorionic gonadotropin, Progesterone, Estradiol and Follicle Stimulating Hormone testing performed on the Roche 411 analyzer from January 2024 to January 2025, the laboratory failed to retain instrument printouts for 120 of 120 tests performed. The findings included: 1. A review of the laboratory's calibration verification records from January 2024 to January 2025 for Human chorionic gonadotropin, Progesterone, Estradiol, and Follicle Stimulating Hormone identified the laboratory performed testing in January 2024, July 2024 and January 2025. Each event consisted of 5 levels of standard tested in duplicate for each analyte resulting in 40 test results. Therefore, 120 tests were performed in total for the 3 events. 2. Further review of the calibration verification records determined instrument printouts were not available for review with the calibration verification evaluations for each analyte. 3. General Supervisor number 1 (as listed on Form CMS 209) confirmed the findings in an interview conducted on 08/11/2025 at 1000 hours in the conference room.
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 the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, review of the laboratory's policies, and staff interview, the laboratory failed to have documentation of a policy which required competency assessments of technical supervisors and general supervisors. The findings included: 1. A review of the laboratory's submitted Form CMS 209 determined the laboratory identified 2 technical supervisors and 2 general supervisors. 2. A review of the laboratory's personnel records determined the laboratory had documentation of performing competency assessments for each of the technical supervisors and general supervisors in April 2023. 3. A review of the laboratory's policy determined the laboratory failed to have documentation of a written policy defining the frequency of competency assessments for technical supervisors or general supervisors. 4. General supervisor number 1 (as listed on Form CMS 209) confirmed the findings on 08/11 /2025 at 0945 hours in the conference room.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's test menu, review of the laboratory records, and staff interview, the laboratory failed to have documentation of performing twice annual accuracy assessments in 2023 and 2024 for fructose testing of semen samples. The findings included: 1. A review of the laboratory's test menu determined the facility performed fructose testing on azoospermic samples. 2. The laboratory estimated performing 30 fructose tests annually. 3. The laboratory failed to have documentation of performing twice annual accuracy assessments for fructose testing. 4. General supervisor number 1 (as listed on Form CMS 209) confirmed the findings on 08/11/2025 at 1055 hours in the laboratory.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(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. (d)(10)(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. (d)(10)(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. This STANDARD is not met as evidenced by: Based on review of the laboratory's sperm count quality control records from March 2025 to July 2025 and staff interview, the laboratory failed to have documentation of

	monitoring quality control values over time to detect shifts and trends for 5 of 5 months. The findings included: 1. A review of the laboratory's sperm count quality control records from March 2025 to July 2025 identified the laboratory tested 2 levels of quantitative quality control material on 108 days. 2. Further review of the laboratory's quality control records determined the laboratory did not have a mechanism in place to monitor quality control values over time to detect and shifts or trends. 3. General supervisor number 1 (as listed on Form CMS 209) confirmed the findings in an interview conducted on 08/11/2025 at 1015 hours in the conference room.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratorys and, as applicable, the manufacturers test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instruction for QC-Beads quality control material for sperm counts, review of the laboratory's quality control records from May 2025 to July 2025, and staff interview, the laboratory failed to have documentation of quality control material meeting manufacturer's criteria for acceptability on 108 of 108 test days. The findings included: 1. A review of the manufacturer's instructions for the QC-Beads quality control material (L006020.B effective date: Feb 2024) under the section titled "Manual Counting of QC-Beads" determined: "Count the beads using a standard counting procedure for counting sperm. 1. Invert the bottle several times to resuspend the Hi QC-Beads. 2. Using a pipette, remove the volume recommended for the counting chamber you are using. (If using a hemacytometer, dilute the Hi QC-Beads before counting.). 3. Pipette the bead suspension into the counting chamber. 4. Immediately recap the bottle. 5. Wait about 5 minutes to allow the beads to stop moving and then observe using a microscope. 6. Count at least 200 beads. 7. Calculate the concentration of beads according to the counting chamber manufacturer's instructions. 8. Repeat steps 1 -7 using a fresh aliquot of beads. 9. Compare the two results. If the results are within 10% of each other, then average the two counts. 10. The average count should be within the range of the expected values. If the results are not within this range, then repeat steps 1 - 9. 11. Repeat steps 1 - 10 using the Lo QC- Beads." 2. A review of the laboratory's sperm count quality control results from May 2025 to July 2025 determined the laboratory failed to have documentation of testing the quality control material in duplicate and ensuring both counts were within 10% of each other to meet manufacturer's acceptability on 108 of 108 testing days. 3. General supervisor number 1 (as listed on Form CMS 209) stated the facility testing the quality control material in duplicate, but did not document the results, nor did the facility ensure each pair of results were within 10% of each other to meet the manufacturer's acceptability criteria. This interview was conducted on 08 /11/2025 at 1030 hours in the laboratory and confirmed the findings.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to

	determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's Estradiol quality control records from April 2025, review of the laboratory's quality control policy, review of patient testing results and staff interview, the laboratory failed to have documentation of evaluating patient results tested prior to a quality control failure for 5 of 5 patients. The findings included: 1. A review of the laboratory's Estradiol quality control records from April 2025 determined quality control testing failed on April 17, 2025. Resolution of the failure required recalibration of the test system and subsequent retesting of quality control material. The results were: Estradiol High control Mean: 76.60 Range: +/- 12.70 Test one result: 98.79 Test two result: 99.98 Recalibration performed. Test three result: 72.01 2. The laboratory failed to have documentation of the remediation patients tested since the last successful quality control testing (April 16, 2025). Patient test records determined the following 5 patients required remediation: Patient Identification numbers: 43492 49459 48949 42686 48880 3. A review of the laboratory's quality control procedures determine the laboratory did not include the remediation of patients after quality control failure as part of their procedures. 4. General supervisor number 1 (as listed on Form CMS 209) confirmed the findings on 08/11/2025 at 1015 hours in the conference room.