Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2317268	07/21/2026
Name of Provider or Supplier	**Street Address, City, State**	
Dallas Fertility Center-Baylor, Llc	3900 Junius Street Suite 610, Dallas, 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	An onsite initial certification survey was conducted on 07/21/2026. The laboratory was found to be in compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (b)(7) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of laboratory policy, American Association of Bioanalysts - Medical Laboratory Evaluation (AAB-MLE) proficiency testing(PT) records, and confirmed in interview, the laboratory failed to retain a copy of all andrology PT records for one of one event in 2025 (Event S2) and all endocrinology PT records for one of two events in 2025 (Event M3) and two of two events in 2026 (Event M1 and M2). Findings included: 1. Review of the laboratory's policy "Quality Management Plan" stated: "17. Proficiency Testing ... 17.2.15. Records of external PT must be reviewed and signed by the Laboratory Director or Technical Consultant and must be maintained for a minimum of two years" 2. Review of AAB PT records revealed the laboratory failed to retain a copy the PT test records/raw data for the following events: 2025 Andrology (semen analysis) Event S2 Endocrinology (fertility testing) Event M3 2026 Endocrinology (fertility testing) Events M1 and M2 The laboratory was asked on 07 /21/2026 at 10:37 AM for the proficiency test records/raw data and none was provided. 3. During an interview in the office on 07/21/2026 at 11:17 AM, the laboratory supervisor confirmed the laboratory failed to retain a copy of all andrology PT records for one of one event in 2025 (Event S2) and all endocrinology PT records for one of two events in 2025 (Event M3) and two of two events in 2026 (Event M1 and M2).

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 CMS (Center for Medicare and Medicaid Services) 209 form, laboratory policies, personnel records, and confirmed in staff interview, the laboratory failed to have a policy for performing competency assessments for laboratory consultants and failed to perform competency assessments for one of one clinical consultant/technical consultant/technical supervisor/general supervisor in 2025 and 2026. Findings included: 1. Review of the laboratory's submitted CMS 209 form identified one person who was delegated to the role as clinical consultant, technical consultant, technical supervisor and general supervisor. 2. Review of the laboratory policy titled "Quality Management Plan" stated: " 7. Personnel, Training, and Competency 7.1. The CLIA regulation requires that certain laboratory positions are defined and have specific personnel requirements based upon the testing complexity level. All personnel associated with laboratory activities must meet or exceed CLIA personnel requirements ... 7.4. Competency Evaluations of Personnel 7.4.1. A competency evaluation must be performed for each test a person performs. Evaluations will be performed at six months after initial training was completed, and annually thereafter." The policy failed to include competency assessment requirements for clinical consultants, technical consultants, technical supervisors and general supervisors. 3. A review of personnel records in 2025 and 2026 revealed competency assessments for the laboratory supervisor who was delegated on the CMS 209 form as the clinical consultant/technical consultant/technical supervisor/general supervisor. The competency assessments were performed by a person who was NOT the laboratory director. 4. During an interview on 07/21/2026 at 11:01 AM, the laboratory supervisor stated that the person who completed his competency assessments was another technical supervisor at a sister laboratory, confirming the above findings.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of laboratory policy, American Association of Bioanalysts - Medical Laboratory Evaluation (AAB-MLE) proficiency testing (PT) records, and confirmed in interview, the laboratory failed to document corrective action for one of one unacceptable PT result in 2025 (endocrinology Event M3). Findings included: 1. Review of the laboratory's policy "Quality Management Plan" stated: "17. Proficiency Testing ... 17.2.7 All testing personnel must review the results of PT when returned by the provider. Any corrective action taken in response to incorrect results must also be reviewed. The objective is to instruct testing personnel regarding procedures and potential sources of error, testing problems, or variation in testing results." 2. Review of the laboratory's 2025 AAB-MLE PT records for endocrinology (fertility testing) Event M3 revealed the following: Analyte: Progesterone Sample: 11 Reported value:

	*1.5 Grading Range: 1.9-3.2 * = Out of range or incorrect response No corrective action was documented for this out of range or incorrect response. The laboratory was asked on 07/21/2026 at 10:37 AM for corrective action documentation and none was provided. 3. During an interview in the office on 07/21/2026 at 11:17 AM, the laboratory supervisor confirmed the laboratory failed to document corrective action for one of one unacceptable PT result in 2025 (endocrinology Event M3).
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, quality control records, and confirmed in interview, the laboratory failed to follow their own written policy when performing lot-to-lot conversions for three of three lots of MAS Liquimmune quality control material. Findings included: 1. Review of the laboratory's policy "Quality Management Plan" stated: "14. Lot-to-lot Comparison 14.1. For quantitative tests, verify a new lot by testing both levels of QC and, if stable, three prior patient samples. Ideally, these three samples should be across the linear range of the method and not require dilution. The acceptable range will be the prior result for each sample 2 SD based on the CV of the nearest QC sample ... 14.1.3. Document lot-to-lot verification and store for two years." 2. Review of the laboratory's QC records for 2025 and 2026 revealed the laboratory failed to perform a lot-to-lot conversion for the three current in-use lots of quality control used on the TOSOH analyzer. The laboratory began using the following lots of QC on 09/22/2025: MAS Liquimmune 1, lot # LIA28021A, expiration date: 02/29/2028 MAS Liquimmune 2, lot # LIA28022A, expiration date: 02/29/2028 MAS Liquimmune 3, lot #LIA28023A, expiration date: 02 /29/2028 3. During an interview in the office on 07/21/2026 at 12:45 PM, testing person #2 stated that the laboratory did not perform lot-to-lot conversions for new lots of QC, confirming the laboratory failed to follow their own written policy when performing lot-to-lot conversions for three of three lots of MAS Liquimmune quality control material.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of laboratory policies and confirmed in staff interview, the laboratory failed to ensure five of five laboratory policies were approved, signed, and dated by the laboratory director before use. Findings included: 1. Review of the laboratory's policy manuals revealed the following policies were not approved, signed, or dated by the laboratory director before they began patient testing in January 2025: Quality Management Plan Quality Management Plan II: Quality Control, Quality Assurance, and Quality Improvement Quality Control AIA-360 TOSOH Operator's

	Manual (used as laboratory policy) Incident Management Plan The above listed policies were signed and approved by the technical/general supervisor and NOT the laboratory director. Continued review of the laboratory policies revealed the laboratory director delegated the technical/general supervisor as the laboratory policy designee under the "Laboratory Plan". 2. Further review of the laboratory's policy "Quality Management Plan" stated: "9. Laboratory SOPs 9.1. All laboratory testing must be performed in compliance with DALLAS FERTILITY CENTER BAYLOR Laboratory SOPs. 9.2. The laboratory must have an SOP for each testing procedure performed. SOPs must be initially approved, dated, and signed by the Laboratory Director. 9.3. SOP's will not be initially implemented until all approval signatures have been obtained." 3. During an interview in the office on 07/21/2026 at 11:49 AM, the laboratory supervisor, after a review of records, confirmed the laboratory failed to ensure five of five laboratory policies were approved, signed, and dated by the laboratory director before use.
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: I. Based on review of AIA-360 TOSOH Operator's Manual, environmental records, and confirmed in staff interview, the laboratory failed to monitor the room humidity for 12 of 12 months in 2025 and seven of seven months in 2026 (January-July) to ensure the AIA-360 TOSOH analyzer was operating under the environmental conditions specified by the manufacturer. Findings included: 1. Review of the AIA-360 TOSOH Operator's Manual page 2-1 stated: "Chapter 2: Installation ... 2.1 Operating Environment Make sure to install the system on a level table in an environment free from toxic fumes, dust, vibrations and exposure to direct sunlight. Operate the AIA-360 within the range of conditions specified below. Table 2-1 Operating Environment Conditions ... Humidity: 40 to 80%... Make sure to operate the AIA-360 within the range of conditions specified in the table above in an environment free of moisture from condensation." 2. Review of the laboratory environmental records for 2025 and January through July 2026 revealed the laboratory failed to monitor the room humidity to ensure the AIA-360 TOSOH analyzer was operating under the environmental conditions specified by the manufacturer of 40 to 80% humidity. On 07/21/2026 at 2:32 M in the laboratory, the facility was asked to provide documentation, and none was provided. 3. During an interview in the laboratory on 07/21/2026 at 2:32 PM, the laboratory supervisor, after a review of the records, confirmed the laboratory failed to monitor the room humidity for 12 of 12 months in 2025 and seven of seven months in 2026 (January-July) to ensure the AIA-360 TOSOH analyzer was operating under the environmental conditions specified by the manufacturer. II. Based on review of manufacturers' package inserts, environmental logs and confirmed in staff interview, the laboratory failed to ensure the defined room temperature range did not exceed the manufacturer's

instructions for patient specimen preparation for four of four analytes. Findings included: 1. Review of the BHCG (beta human chorionic gonadotropin) package insert stated: "SPECIMEN COLLECTION AND HANDLING ... 2. When using serum, a venous blood sample is collected aseptically without additives. Store at 18-25C until a clot has formed (usually 15-45 minutes), then centrifuge to obtain the serum specimen for assay." Review of the progesterone package insert stated: "SPECIMEN COLLECTION AND HANDLING ... 2. When using serum, a venous blood sample is collected aseptically without additives. Store at 18-25C until a clot has formed (usually 15-45 minutes), then centrifuge to obtain the serum specimen for assay." Review of the luteinizing hormone package insert stated: "SPECIMEN COLLECTION AND HANDLING ... 2. When using serum, a venous blood sample is collected aseptically without additives. Store at 18-25C until a clot has formed (usually 15-45 minutes), then centrifuge to obtain the serum specimen for assay." Review of the estradiol package insert stated: "SPECIMEN COLLECTION AND HANDLING ... 2. When using serum, a venous blood sample is collected aseptically without additives. Store at 18-25 C until a clot has formed (usually 15-45 minutes), then centrifuge to obtain the serum specimen for assay." 2. Review of the laboratory's environmental log documented on the "DFW Andrology Lab QC" log revealed an acceptable room temperature range of 65 F to 85 F (18 C to 29 C). The laboratory's defined acceptable temperature range of 65 F to 85 F (18 C to 29 C) exceeded the manufacturer's acceptable temperature range of 18 C to 25 C. 3. During an interview in the office on 07/21/2026 at 2:32 PM, the laboratory supervisor, after a review of the records, confirmed the laboratory failed to ensure the defined room temperature range did not exceed the manufacturer's instructions for patient specimen preparation for four of four analytes. Word Key: C- Celsius F- Fahrenheit III. Based on manufacturer's instructions, direct observation, and confirmed in interview, the laboratory failed to follow manufacturer's instructions for the proper storage of unopened quality control (QC) material stored in the refrigerator for four of four bottles of QC material. Findings included: 1. Review of MAS Liquimmune manufacturer's instructions (package insert) stated: "STORAGE AND STABILITY Unopened vials of Liquimmune are stable for 90 days from receipt when stored at 2-8 C. Once opened, vials of Liquimmune are stable for 30 days when stored tightly capped at 2-8C. This product is stable until the expiration date on the box when stored at -25 to -15C. Self-defrosting freezers are not suitable." 2. During a tour of the laboratory on 07/21/2021 at 2:33 PM, the surveyor observed the following quality control material stored in the refrigerator: 1 bottle MAS Liquimmune 1, lot # LIA28021A, expiration date: 02/29/2028, storage -15C to -25C 2 bottles MAS Liquimmune 3, lot #LIA28023A, expiration date: 02/29/2028, storage -15C to -25C 1 bottle MAS Liquimmune 2, lot # LIA28022A, expiration date: 02/29/2028, storage -25 to -15C The laboratory's acceptable temperature range for the refrigerator was 2-8C. The laboratory did NOT document a revised expiration date on the unopened bottles of quality control material. The laboratory failed to ensure the proper storage of unopened bottles of quality control material. 3. During an interview in the laboratory on 07/21/2026 at 2:50 PM, testing person 1 stated that quality control materials were stable according to the expiration date indicated on the bottles, confirming the laboratory failed to follow manufacturer's instructions for the proper storage of unopened quality control (QC) material stored in the refrigerator for four of four bottles of QC material. Word Key: C- Celsius IV. Based on manufacturer's instructions, direct observation, and confirmed in interview, the laboratory failed to follow manufacturer's instructions for the proper storage of opened reagents stored on the counter for six of six reagents. Findings included: 1. Review of MAS Liquimmune manufacturer's instructions (package insert) stated: "STORAGE AND STABILITY Unopened vials of Liquimmune are stable for 90 days from receipt when stored at 2-8

	C. Once opened, vials of Liquimmune are stable for 30 days when stored tightly capped at 2-8C. This product is stable until the expiration date on the box when stored at -25 to -15C. Self-defrosting freezers are not suitable." Review of the ST AIA-PACK HCGII SAMPLE DILUTING SOLUTION manufacturer's instructions stated: "STORAGE AND STABILITY Always store the ST AIA-PACK HCGII SAMPLE DILUTING SOLUTION in an upright position. When stored unopened and refrigerated at 2-8C, the sample diluting solution will remain stable until the expiry date on the label. After opening, the sample diluting solution can be left on-board of the TOSOH AIA System Analyzers (18-25C for a maximum of 3 days (3 x 24 hours). When stored over night [sic] at 2-8C, the sample diluting solution can be used for up to 9 days (9 cycles of 8 hours on board and 16 hours in the refrigerator). The sample diluting solution should not be used 90 days after opening, even if it is sealed and store in the refrigerator." Review of the ST AIA-PACK hsE2 SAMPLE DILUTING SOLUTION manufacturer's instructions stated: "STORAGE AND STABILITY Always store the ST AIA-PACK hsE2 SAMPLE DILUTING SOLUTION in an upright position. When stored unopened and refrigerated at 2-8C, the sample diluting solution will remain stable until the expiry date on the label. After opening, the sample diluting solution can be left on-board of the TOSOH AIA System Analyzers (18-25C) for a maximum of 1 day (24 hours). When stored over night [sic] at 2-8C, the sample diluting solution can be used for up to 3 days (3 cycles of 8 hours on board and 16 hours in the refrigerator). The sample diluting solution should not be used 90 days after opening, even if it is sealed and store in the refrigerator." 2. During a tour of the laboratory on 07/21/2021 at 2:33 PM, the surveyor observed the following quality control material stored on the counter in a basket: 1 opened bottle MAS Liquimmune 1, lot # LIA28021A, expiration date: 02/29/2028, open date 07/14/2026 1 opened bottle MAS Liquimmune 3, lot #LIA28023A, 02/29/2028, open date: 07/08 /2026 1 opened bottle MAS Liquimmune 2, lot # LIA28022A, expiration date: 02/29 /2028, open date: 07/20/2026 1 opened bottle AIA-PACK SUBSTRATE REAGENT II, lot# 1X60039, expiration date: 09/30/2026, open date: 07/17/2026, storage temperature 2-8C 1 opened bottle AIA-PACK BHCG SAMPLE DILUTING SOLUTION, lot# 1X53571, expiration date: 09/30/2026, open date: 07/06/2026, storage temperature 2-8C 1 opened bottle AIA-PACK hsE2 SAMPLE DILUTING SOLUTION, lot# 1852150, expiration date: 07/31/2026, open date: 07/06/2026, storage temperature 2-8C The laboratory failed to ensure the proper storage of opened bottles of reagents. 3. During an interview in the laboratory on 07/21/2026 at 2:50 PM, the laboratory supervisor confirmed the laboratory failed to follow manufacturer's instructions for the proper storage of opened reagents stored on the counter for six of six reagents. Word Key: C- Celsius
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 manufacturer's instructions, direct observation, and confirmed in interview, the laboratory failed to have documentation of a revised expiration date for five of five in-use reagents used on the TOSOH analyzer. Findings included: 1. Review of

	MAS Liquimmune manufacturer's instructions (package insert) stated: "STORAGE AND STABILITY ... Once opened, vials of Liquimmune are stable for 30 days when stored tightly capped at 2-8C." Review of the ST AIA-PACK HCGII SAMPLE DILUTING SOLUTION manufacturer's instructions stated: "STORAGE AND STABILITY ... When stored unopened and refrigerated at 2-8C, the sample diluting solution will remain stable until the expiry date on the label. After opening, the sample diluting solution can be left on-board of the TOSOH AIA System Analyzers (18-25C for a maximum of 3 days (3 x 24 hours). When stored over night [sic] at 2-8C, the sample diluting solution can be used for up to 9 days (9 cycles of 8 hours on board and 16 hours in the refrigerator). The sample diluting solution should not be used 90 days after opening, even if it is sealed and store in the refrigerator." Review of the ST AIA-PACK hsE2 SAMPLE DILUTING SOLUTION manufacturer's instructions stated: "STORAGE AND STABILITY ... When stored unopened and refrigerated at 2-8C, the sample diluting solution will remain stable until the expiry date on the label. After opening, the sample diluting solution can be left on-board of the TOSOH AIA System Analyzers (18-25C) for a maximum of 1 day (24 hours). When stored over night [sic] at 2-8C, the sample diluting solution can be used for up to 3 days (3 cycles of 8 hours on board and 16 hours in the refrigerator). The sample diluting solution should not be used 90 days after opening, even if it is sealed and store in the refrigerator." 2. During a tour of the laboratory on 07/21/2021 at 2:33 PM, the surveyor observed the following quality control material stored on the counter in a basket: 1 opened bottle MAS Liquimmune 1, lot # LIA28021A, expiration date: 02/29/2028, open date 07/14/2026 1 opened bottle MAS Liquimmune 3, lot #LIA28023A, 02/29/2028, open date: 07/08/2026 1 opened bottle MAS Liquimmune 2, lot # LIA28022A, expiration date: 02/29/2028, open date: 07/20/2026 1 opened bottle AIA-PACK BHCG SAMPLE DILUTING SOLUTION, lot# 1X53571, expiration date: 09/30/2026, open date: 07/06/2026, storage temperature 2-8C 1 opened bottle AIA-PACK hsE2 SAMPLE DILUTING SOLUTION, lot# 1852150, expiration date: 07/31/2026, open date: 07/06/2026, storage temperature 2-8C The laboratory did NOT document a revised expiration date on the opened bottles of reagents. 3. During an interview in the laboratory on 07/21/2026 at 2:50 PM, the technical supervisor confirmed the laboratory failed to have documentation of a revised expiration date for five of five in-use reagents used on the TOSOH analyzer. Word Key: C- Celsius
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(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 laboratory policy, TOSOH analyzer verification studies, annual volume records, and confirmed in interview, the laboratory failed to ensure verification studies were performed by the laboratory (accuracy, precision and reportable range) for four of four analytes tested on the TOSOH analyzer to demonstrate performance specifications in comparison to those of the manufacturer. Findings included: 1. Review of the laboratory policy titled "Quality Management

	Plan" stated: "18. New Test Introduction or Modification of Existing Test Procedure 18.1. All new test systems, regardless of complexity, must be validated and/or verified prior to implementation or whenever a significant change is made to an existing test system. The extent of the validation and/or verification process must be approved by the Laboratory Director prior to the test system being put into use for patient samples. 18.1.1. Situations in which a study is required prior to implementation include Introduction of a test not previously performed Change of instrumentation to test the same analyte Change of manufacturer (e.g., change to a different manufacturer of urine dipstick) ... 18.1.4. Non-waived procedures that have received clearance through the FDA require the verification performance of a study which verifies: Analytical accuracy Analytical precision Reportable range" 2. Verification studies for the TOSOH analyzer were evaluated and signed by the technical consultant NOT the laboratory director. Refer to D6013. Further review of the verification studies revealed: " Method Validation Method validation studies confirm a manufacturer's claims for an analyte and are performed upon installation of a new analyzer ... Each laboratory that introduces an unmodified, FDA cleared or approved test system must do the following before reporting patient test results: 1) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: a. Accuracy b. Precision c. Reportable range of test results for the test system. 2) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population." "EP Evaluator Prepared for: Laboratory - DFW Fertility Associates By: CSS - Tosoh Bioscience The verification studies included accuracy, precision and reportable range for the Beta HCG (human chorionic gonadotropin), estradiol, progesterone and luteinizing hormone analytes that were performed by the vendor NOT the laboratory. 3. Review of the laboratory's annual test volume submitted on the date of the survey revealed 1,792 tests performed on the TOSOH analyzer. 4. During an interview in the office on 07/21/2026 at 11:58 AM, testing person 2 stated that the verification studies (accuracy, precision and reportable range) were performed by the TOSOH analyzer vendor NOT laboratory personnel. This confirmed that the laboratory failed to ensure verification studies were performed by the laboratory for four of four analytes tested on the TOSOH analyzer to demonstrate performance specifications in comparison to those of the manufacturer.
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 laboratory policy, TOSOH analyzer quality control (QC) records, and staff interview, the laboratory failed to verify the criteria for acceptability of all control materials for three of three lot numbers in 2025. Findings included: 1. Review of the laboratory's policy "Quality Management Plan" stated: "13. Quality Control

	13.1. DA LLA S FERTILITY CENTER-BA YLOR Laboratory must establish and maintain a QC system that ensures accurate reporting of results and optimal specimen integrity and identification throughout the testing process. The QC policy and procedure described in this section will in general be the basis for quality control in the laboratory ... 13.1.3. Target values will either be specified by the manufacturer and contained in the package insert provided with the QC material or determined by the laboratory through repetitive testing ... If the manufacturer's target values will be used for a quantitative test, verification of a new lot will be done by replicate testing of the material five times and ensuring that the values fall within the mean +/- 2 SD as determined by the CV of the closest in-use QC material [sic] ... 13.2. Frequency of QC testing volume 13.2.1. QC must be performed on all new shipments of test reagents, controls, or kits, regardless of whether the new material is the same lot number as those currently in use, before they are placed into service. 13.2.2. QC must be performed prior to patient testing, as directed by the test SOP or by the sectional QC SOP or IQCP." 2. Review of QC records tested on the TOSOH analyzer revealed the following QC lot numbers were placed into service and the laboratory failed to verify new quality control lot against the manufacturer's assay ranges for the control levels 1, 2, and 3 in 2025: MAS Liquimmune 1, lot # LIA28021A, expiration date: 02 /29/2028 MAS Liquimmune 2, lot # LIA28022A, expiration date: 02/29/2028 MAS Liquimmune 3, lot #LIA28023A, expiration date: 02/29/2028 The laboratory began using the above lots of QC on 09/22/2025. The analytes tested on these lots were: Beta HCG (human chorionic gonadotropin), estradiol, progesterone and luteinizing hormone. 3. During an interview in the office on 07/21/2026 at 12:45 PM, testing person #2 stated that the laboratory did not verify the acceptability criteria for QC before placing a new lot into use, confirming the laboratory failed to verify the criteria for acceptability of all control materials for three of three lot numbers in 2025.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (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. This STANDARD is not met as evidenced by: Based on review of manufacturer package inserts, laboratory policies, laboratory quality control records, patient records, laboratory records, and confirmed in staff interview, the laboratory failed to define for each day of use, test staining materials for intended reactivity to ensure the predictable staining characteristics for the HEMA 3 stain quality control (QC) for six of six days in 2026 (July random sampling). Findings included: 1. Review of the HEMA 3 Stain Set package insert stated: "Quality Control: Validate results based on product performance." "Results: Spermatozoa Nucleus Stain Dark Blue" 2. Review of the laboratory policy titled "ANDRO-SOP-04 Morphology Staining" page 18 stated: "9. Procedure Notes a. Perform a morphology stain with every semen analysis. b. A stained slide should be transparent with only a very slight hint of blue. If the stained slide is not of acceptable quality, examine the slide for bacterial contamination and/or an expiration date. Consider replacing the stains. c. Do not allow stains to hinder slide identification. The patient's name and the date of the procedure should be easily identifiable after staining. d. To avoid staining contamination or inadequate staining resulting in false positive diagnosis of bacteriospermia or other inaccuracies, all three staining solutions should be examined f cloudiness, presence of foreign bodies, or other signs of improper staining daily and

	must be replaced every seven days. This should be documented on the daily/weekly /periodic Andrology quality control sheet." The above-mentioned laboratory policy failed to define the intended reactivity for HEMA 3 stain to ensure predictable staining characteristics. 3. A random review in July 2026 of the laboratory's "DFW Andrology Lab QC" log revealed the following: The log listed the following categories as part of the quality control criteria: Reactivity Stain Contamination Stain Acceptable Stain Change Under each category there were boxes where each day stain quality was documented with "Y" or "N" to indicate if the categories were "yes" or "no". The log did not specify if "Reactivity" and "Stain Acceptable" were indicated for the HEMA 3 stain intended reactivity to ensure predictable staining characteristics. The following patients were reported on dates (random sampling) where "Reactivity" was documented with "N" and "Stain Acceptable" was documented with "Y": 07/07 /2026 Patient ID: 82591 07/09/2026 Patient IDs: 79196, 82150, 83450, 84696 07/13 /2026 Patient ID: 69778 07/14/2026 Patient IDs: 85466, 84298, 85106 07/15/2026 Patient ID: 85846 07/16/2026 Patient ID: 85563 4. According to laboratory records, the laboratory's annual volume was 250 semen analysis tests. 5. During an interview in the office on 07/21/2026 at 2:40 PM, the laboratory supervisor, after a review of records, confirmed the laboratory failed to define for each day of use, test staining materials for intended reactivity to ensure the predictable staining characteristics for the HEMA 3 stain quality control (QC) for six of six days in 2026 (July random sampling).
D5805	TEST REPORT CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patient records and confirmed in interview, the laboratory failed to include the testing facility address on 10 of 10 patient final reports in 2026 (random review July). Findings included: 1. Random review of patient records from July 2026 revealed the following ten patient final reports which did not include the testing facility address: Test report: luteinizing hormone Date: 07/01/2026 Patient ID: 66090 Date: 07/06/2026 Patient ID: 82927 Test report: Beta Human Chorionic Gonadotropin Date: 07/01/2026 Patient ID: 66090 Date: 07/02/2026 Patient ID: 73094 Test report: Estradiol Date: 07/01/2026 Patient ID: 66090 Date: 07/02/2026 Patient ID: 73094 Date: 07/06/2026 Patient ID: 82927 Test report: Progesterone Date: 07/01/2026 Patient ID: 66090 Date: 07/02/2026 Patient ID: 73094 Date: 07/06/2026 Patient ID: 82927 2. During an interview in the office on 07/21/2026 at 3:30 PM, the laboratory supervisor, after a review of records, confirmed the laboratory failed to include the testing facility address on 10 of 10 patient final reports in 2026 (random review July).
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1)

	(e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on review of laboratory policies, AIA-360 TOSOH Operator's Manual, manufacturers' package inserts, direct observation, environmental records, annual volume records, and confirmed in staff interview the laboratory director failed to meet the requirements for the preanalytical and analytical systems, as evidenced by: 1. The laboratory failed to monitor the room humidity for 12 of 12 months in 2025 and seven of seven months in 2026 (January-July) to ensure the AIA-360 TOSOH analyzer was operating under the environmental conditions specified by the manufacturer. Refer to D5413-I. 2. The laboratory failed to ensure the defined room temperature range did not exceed the manufacturer's instructions for patient specimen preparation for four of four analytes. Refer to D5413-II. 3. The laboratory failed to follow manufacturer's instructions for the proper storage of unopened quality control (QC) material stored in the refrigerator for four of four bottles of QC material. Refer to D5413-III. 4. The laboratory failed to follow manufacturer's instructions for the proper storage of opened reagents stored on the counter for six of six reagents. Refer to D5413-IV. 5. The laboratory failed to have documentation of a revised expiration date for five of five in-use reagents used on the TOSOH analyzer. Refer to D5415.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on review of laboratory policy, TOSOH analyzer verification studies, Centers for Medicare and Medicaid (CMS) 209 form, and interview with staff, the laboratory director failed to ensure verification studies were complete, reviewed and approved for four of four analytes tested on the TOSOH analyzer. Findings included: 1. Review of the laboratory policy titled "Quality Management Plan" stated: "18. New Test Introduction or Modification of Existing Test Procedure 18.1. All new test systems, regardless of complexity, must be validated and/or verified prior to implementation or whenever a significant change is made to an existing test system. The extent of the validation and/or verification process must be approved by the Laboratory Director prior to the test system being put into use for patient samples. 2. The laboratory provided verification studies of the TOSOH analyzer performance specifications from 04/01/2026. The accuracy, precision and reportable range data from the TOSOH analyzer were not reviewed and signed by the laboratory director for the following analytes: Beta HCG (human chorionic gonadotropin), estradiol, progesterone and luteinizing hormone analytes. The verification studies were signed by the technical consultant, as listed on the CMS-209 form, NOT the laboratory director. 3. During an interview in the office on 07/21/2026 at 11:49 AM, the laboratory supervisor, after a review of the records, confirmed the laboratory director failed to ensure verification studies were complete, reviewed and approved for four of four analytes tested on the TOSOH analyzer.

D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on review of laboratory policies, TOSOH analyzer quality control (QC) records, and confirmed in staff interview the laboratory director failed to ensure a quality control program was established and maintained as evidenced by: 1. The laboratory failed to follow its own written policy when performing lot-to-lot conversions for three of three lots of MAS Liquimmune quality control material. Refer to D5401. 2. The laboratory failed to verify the criteria for acceptability of all control materials for three of three lot numbers in 2025. Refer to D5469.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. The technical consultant is not required to be onsite at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide consultation, as specified in paragraph (a) of this section. This STANDARD is not met as evidenced by: Based on review of laboratory policies, AIA-360 TOSOH Operator's Manual, manufacturers' package inserts, direct observation, environmental records, and confirmed in staff interview the technical consultant failed to provide technical and scientific oversight, as evidenced by: 1. The laboratory failed to monitor the room humidity for 12 of 12 months in 2025 and seven of seven months in 2026 (January-July) to ensure the AIA-360 TOSOH analyzer was operating under the environmental conditions specified by the manufacturer. Refer to D5413-I. 2. The laboratory failed to ensure the defined room temperature range did not exceed the manufacturer's instructions for patient specimen preparation for four of four analytes. Refer to D5413-II. 3. The laboratory failed to follow manufacturer's instructions for the proper storage of unopened quality control (QC) material stored in the refrigerator for four of four bottles of QC material. Refer to D5413-III. 4. The laboratory failed to follow manufacturer's instructions for the proper storage of opened reagents stored on the counter for six of six reagents. Refer to D5413-IV. 5. The laboratory failed to have documentation of a revised expiration date for five of five in-use reagents used on the TOSOH analyzer. Refer to D5415.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

	This STANDARD is not met as evidenced by: Based on review of laboratory policies, TOSOH analyzer quality control (QC) records, and confirmed in staff interview the technical consultant failed to ensure a quality control program was developed and followed as evidenced by: 1. The laboratory failed to follow its own written policy when performing lot-to-lot conversions for three of three lots of MAS Liquimmune quality control material. Refer to D5401. 2. The laboratory failed to verify the criteria for acceptability of all control materials for three of three lot numbers in 2025. Refer to D5469.