Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2240452	07/09/2026
Name of Provider or Supplier	**Street Address, City, State**	
Westlake Ivf Andrology/North	7700 Cat Hollow Dr Suite 105, Round Rock, 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	The Westlake IVF Andrology/North laboratory was found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, CLIA requirements for laboratories as a result of a recertification survey on 07/08 /2026 and recertification is recommended. Standard level deficiencies were cited.
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: I. Based on a review of the laboratory's policies and procedures, laboratory's records, pre-survey paperwork, and interview, the laboratory failed to retain the kit lot number, expiration date, and open date for the Halosperm G2 (Sperm Chromatin Dispersion test) for assessing sperm DNA Fragmentation for two of two years reviewed. Findings follow. A. Review of the laboratory's policy and procedure titled QM/QA and Personnel Policy, adopted 10/09/2025, under Section Four at Reagent Quality Standards stated, "Each reagent will be labeled as to its use, content, date of receipt, opened or prepared, expiration, storage requirements and technologist initials when appropriate. Reagents may not be used past their expiration date and must be discarded." B. The documentation of the kit lot number, expiration date, and open date was requested on July 8, 2026 at 1445 hours but not provided. C. Review of the pre-survey paperwork titled Annual Test Volume & Proficiency Testing Programs Worksheet showed approximately 40 Sperm Chromatin Dispersion tests were performed annually. D. Interview with the General Supervisor (as listed on the CMS Form 209) on July 8, 2026 at 1445 hours in the office confirmed the laboratory did not retain that information. II. Based on review of the laboratory's policies and

	procedures, reagent log, pre-survey paperwork, and interview, the laboratory failed to retain the Eosin/Nigrosin stain lot number, expiration date, received date, and open date used in the Sperm Viability test for two of two years reviewed. Findings follow. A. Review of the laboratory's policy and procedure titled QM/QA and Personnel Policy, adopted 10/09/2025, under Section Four at Reagent Quality Standards stated, "Each reagent will be labeled as to its use, content, date of receipt, opened or prepared, expiration, storage requirements and technologist initials when appropriate. Reagents may not be used past their expiration date and must be discarded." B. The reagent log was requested on July 8, 2026 at 1445 hours but not provided. C. Review of the pre-survey paperwork titled Annual Test Volume & Proficiency Testing Programs Worksheet showed approximately 10 Sperm Viability tests were performed annually. D. Interview with the General Supervisor (as listed on the CMS Form 209) on July 8, 2026 at 1445 hours in the office confirmed the laboratory did not retain that information.
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 evaluations and interview, the laboratory failed to assess competency for one of one clinical consultant, and one of one technical supervisor for two of two years reviewed. Findings follow. A. Review of competency evaluations from 2024 and 2025 showed none for the positions of clinical consultant and technical supervisor for the North location. B.Interview with Technical Supervisor (as listed on the CMS Form 209) on July 8, 2026 at 1210 hours in the office acknowledged the competencies they had were performed at the Westlake location.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) (b)(9) 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 review of the laboratory's policy and procedures, pre-survey paperwork, laboratory records, and interview, the technical supervisor failed to evaluate the competency at least semi-annually during the first year the individual tested patient specimens for one of two new hires that performed Semen Analysis, Sperm Viability, and Sperm Chromatin Dispersion testing. Findings follow. A. Review of the laboratory's policy and procedure titled QM/QA and Personnel Policy, adopted 10/09 /2025, under Section One at Laboratory Positions and Personnel for Andrology Supervisor stated, "2. Perform initial, 6 month, and annual competency assessments for all Andrologists." B. Review of the pre-survey paperwork titled Laboratory Personnel showed testing personnel #3 (as listed on the CMS form 209), was hired 12 /30/2024 (elapsed time: 1 year, 6 months). C. Review of the laboratory records

	showed no semi-annual competency evaluations performed for this location. Competency evaluations were requested on July 8, 2026 at 1210 hours but not provided. D. Interview with the General Supervisor (as listed on the CMS Form 209) on July 8, 2026 at 1210 hours acknowledged the competency evaluations were performed at the Westlake location.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) (b)(9) Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individuals 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 review of the laboratory's policy and procedures, pre-survey paperwork, laboratory records, and interview, the technical supervisor failed to evaluate and document the performance of individuals annually for one of one employees that performed Semen Analysis, Sperm Viability, and Sperm Chromatin Dispersion testing for two of two years reviewed. Findings follow. A. Review of the laboratory's policy and procedure titled QM/QA and Personnel Policy, adopted 10/09/2025, under Section One at Laboratory Positions and Personnel for Andrology Supervisor stated, "2. Perform initial, 6 month, and annual competency assessments for all Andrologists." B. Review of the pre-survey paperwork titled Laboratory Personnel showed testing personnel #1 (as listed on the CMS form 209), was hired 08/29/22 (elapsed time 3 years 10 months). C. Review of the laboratory records showed no annual competency evaluations performed for 2024 and 2025 at the North location. Competency evaluations were requested on July 8, 2026 at 1210 hours but not provided. D. Interview with the General Supervisor (as listed on the CMS Form 209) on July 8, 2026 at 1210 hours acknowledged the competency evaluations were performed at the Westlake location.