Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0505492	06/01/2022
Name of Provider or Supplier	**Street Address, City, State**	
Westlake Ivf Andrology/South	4303 A James Casey, Austin, 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 initial survey conducted on June 1, 2022 found the laboratory out of compliance with the following CONDITION LEVEL DEFICIENCIES: D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems;
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 laboratory procedures, personnel records, and in interview with the laboratory director, the laboratory failed to establish written procedures to ensure competency assessment for three of five employees (supervisors and the clinical consultant for hematology). Findings included: 1. Review of the laboratory's written procedures did not include competency assessment for individuals designated as the technical supervisor, general supervisor, and clinical consultant, as required. The supervisors and clinical consultant provided oversight of hematology testing (Sperm Chromatin Dispersion Test - HaloSperm). 2. Review of the technical supervisor, general supervisor, and clinical consultant records included date of employment since 07/2021. The records did not include competency assessment performed and documented based on position responsibilities as defined in Subpart M (493.1351). 3. During an interview on 06/01/2022 at 1:00 pm, the laboratory director confirmed written procedures did not include performing and documenting competency assessments for the technical supervisor, general supervisor, and clinical consultant.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250

	Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on a review of the Centers for Medicaid and Medicare Services (CMS) form 116, laboratory quality control (QC) records, patient testing logs, laboratory documents, instructions for use, and confirmed in interviews the laboratory failed to meet the analytic system requirements in 493.1251 through 493.1283. The findings include: 1. The laboratory failed to establish the test system performance specifications for accuracy, precision, analytical sensitivity, analytical specificity to include interfering substances, reportable range of test results, and reference intervals (normal values) for the Sperm Chromatin Dispersion Test before reporting 66 of 66 patients test results from June 2021 to February 2022. Refer to D5423. 2. The laboratory failed to test staining materials for intended reactivity each day of patient testing for the Halosperm Chromatin Dispersion Test, for 16 of 66 patients tested from June 2021 to February 2022. Refer to D5473.
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 laboratory policy, direct observation, and confirmed in interview, the laboratory failed to follow its own policy for the processing of post vasectomy semen analysis for one of one patient observed 6/1/2022. The findings include: 1. Review of the laboratory policy titled "Semen Analysis", section 11. "Sperm Concentration", point 11.6 stated the following: "All Azoospermic or Post Vasectomy samples must be centrifuged at 300xg for 5 minutes and the pellets examined for the presence of sperm. Note on report." 2. Surveyor observed testing person (TP) 1 process the following post-vasectomy patient at 10:28 hours on 6/1/2022, in the

	laboratory, without centrifuging the liquified semen prior to observing for the presence or absence of sperm: SAJC2022254 3. In an interview at 12:15 hours on 6/1 /2022, in the breakroom, TP1 confirmed that the laboratory did not centrifuge post-vasectomy patient samples as designated by the laboratory policy.
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 surveyor observation, review of instructions for use, laboratory documents, and confirmed in an interview, the laboratory failed to follow the manufacturer's instructions for the preparation of patient slides for the Sperm Chromatin Dispersion Test, for 66 of 66 patients processed from June 2021 to February 2022. The findings include: 1. In a tour of the laboratory at 09:47 hours on 6/1/2022, the surveyor noted that no fume hood, or biosafety cabinet (BSC), was available for use for the processing of specimens. 2. Review of the instructions for use for the halotech halosperm kit, ref HT-HS10, section "safety and the environment" had the following statement: "Work under air removal environment and follow the manufacturer's Material Safey Data regarding safe handling." 3. Review of the instructions for use for the halotech DNA brightfield staining kit, section "Precautions" had the following statement: "Use under fume hood." 4. Review of the laboratory patient specimen log listed 66 patients processed from June 2021 to February 2022 a sampling of 10 patients was as follows: Date - Patient ID 6/24/2021 - DNAJC2021001 6/24/2021 - DNAJC2021002 8/23/2021 - DNAJC2021016 9/13/2021 - DNAJC2021022 10/4 /2021 - DNAJC2021026 10/25/2021 - DNAJC2021033 11/8/2021 - DNAJC2021037 12/13/2021 - DNAJC2021046 1/10/2022 - DNAJC2022003 2/4/2022 - DNAJC2022013 5. In an interview at 11:46 hours, on 6/1/2022, TP1 confirmed the laboratory did not process specimens for the Sperm Chromatin Dispersion Test under a BSC or fume hood.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicaid and Medicare Services (CMS) form

	116, the U.S. Food and Drug Administration (FDA) website, laboratory specimen log sheet, and confirmed in interview, the laboratory failed to establish the test system performance specifications for accuracy, precision, analytical sensitivity, analytical specificity to include interfering substances, reportable range of test results, and reference intervals (normal values) for the Sperm Chromatin Dispersion Test before reporting 66 of 66 patients test results from June 2021 to February 2022. The findings include: 1. Review of the CMS-116 section VII. "Non-Waived Testing" test menu lists the "Sperm Chromatin Dispersion Test" by the manufacturer "Fina Biotech". 2. Review of the FDA website medical devices database, did not include the above-listed test, classifying it as a laboratory-developed test (LDT), in which establishment studies were required. Surveyor queried the laboratory director, at 10:45 hours on 6/1 /2022, for documentation of the establishment study, and none was provided. 3. Review of the laboratory patient specimen log titled "James Casey DNA Fragmentation Log" listed 66 patients processed from June 2021 to February 2022 a sampling of 10 patients was as follows: Date - Patient ID 6/24/2021 - DNAJC2021001 6/24/2021 - DNAJC2021002 8/23/2021 - DNAJC2021016 9/13 /2021 - DNAJC2021022 10/4/2021 - DNAJC2021026 10/25/2021 - DNAJC2021033 11/8/2021 - DNAJC2021037 12/13/2021 - DNAJC2021046 1/10/2022 - DNAJC2022003 2/4/2022 - DNAJC2022013 4. In an interview at 10:55 hours on 6/1 /2022, in the conference room, the laboratory director confirmed that establishment studies had not been performed for the Sperm Chromatin Dispersion Test before reporting patient test results.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory policy, quality control records, review of the Center's for Medicare and Medicaid (CMS) form 116, and confirmed in interview, the laboratory failed to test two control materials of different concentrations for the quantitative test, pH, for ten of ten months reviewed from August 2021 to May 2022. The findings include: 1. Review of the laboratory procedure "Semen Analysis" section V. "Procedure", subsection A. "Analysis Preparation" had the following statement: "1. Prior to semen analysis, pH paper accuracy is verified using standard buffer. pH must = 7.2-7.6." 2. Review of the laboratory form titled "Daily Andrology Lab QC" listed only one level of QC ran every day of patient testing for the pH paper column. 3. Review of the CMS form 116, section VII. "Non-Waived testing" lists the estimated total annual volume for the specialty of Hematology at 3,000. 4. In an interview at 11: 43 hours on 6/1/2022, in the laboratory, testing personnel (TP) 1 confirmed that the laboratory only used one level of QC to verify the accuracy of the pH paper.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (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. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory quality control (QC) records, patient testing log, and confirmed in interview, the laboratory failed to test staining materials for intended reactivity each day of patient testing for the Halosperm Chromatin Dispersion Test, for 16 of 66 patients tested from June 2021 to February 2022. The findings include: 1. Review of the laboratory QC records titled "James Casey DNA Fragmentation Log" listed repeat values in the QC column for each patient tested across multiple days. Surveyor queried at 09:52 hours in the conference room, about the repeat values. Testing person (1) stated that they only perform QC each time a new kit for the Sperm Chromatin Dispersion test was opened, and the numbers were transcribed down until the kit was used up. An example of the repeat values in January and February 2022 were as follows: Date: Controls (%Frag/%Normal) 1/10/2022: (13.3/86.7) 1/17/2022: (13.3/86.7) 1/24/2022: (13.3/86.7) 2/4/2022: (15.3/84.7) 2/17/2022: (15.3/84.7) 2. Review of the patient test logs from June 2021 to February 2022 had the following 16 patients ran on days where QC was not performed: October 2021 - 8 Patients 10/18 /2021 - DNAJC2021028 10/18/2021 - DNAJC2021029 10/18/2021 - DNAJC2021030 10/25/2021 - DNAJC2021031 10/25/2021 - DNAJC2021032 10/25/2021 - DNAJC2021033 10/25/2021 - DNAJC2021034 10/25/2021 - DNAJC2021035 November 2021 - 1 Patient 11/1/2021 - DNAJC202102 January 2022 - 4 Patients Date: Specimen ID 1/10/2022 - DNAJC2022003 1/10/2022 - DNAJC2022004 1/10 /2022 - DNAJC2022005 1/10/2022 - DNAJC2022006 February 2022: - 3 Patients 2/7 /2022 - DNAJC2022014 2/7/2022 - DNAJC2022015 2/7/2022 - DNAJC2022016 3. In an interview at 11:00 hours in the conference room, the laboratory director confirmed that the laboratory did not test staining materials for intended reactivity each day of patient testing for the Halosperm Chromatin Dispersion Test.
D5805	TEST REPORT CFR(s): 493.1291(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 a review of patient final reports and confirmed in interview, the laboratory failed to include the address of the laboratory location where the test was performed for four of four patient reports reviewed in April and April 2022. The findings include: 1. Review of a random sampling of patient final reports in April 2022 had the incorrect laboratory address in the header of the patient final report: Test date - Sample ID 4/12/2022 - SAJC202217 4/12/2022 - SAJC2022172 4/11/2022 - SAJC2022169 4/11/2022 - JC2022027 2. In an interview at 10:43 hours on 6/1/2022, in the breakroom, the laboratory director confirmed that the laboratory that the

	address on the final patient report was not the location in which the test was performed.