

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0943390	(X3) Date Survey Completed 08/05/2026
Name of Provider or Supplier Advanced Reproductive Laboratory, Lp	Street Address, City, State 7501 Las Colinas Blvd Suite 200a, Irving, 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 validation survey was conducted on 08/05/2026. The laboratory was found to be in compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
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: D5417 Based on direct observation, review of patient records, and confirmed in interview, the laboratory failed to ensure five of five Hydrion test paper rolls did not exceed their expiration date prior to performing 822 of 822 semen analysis from July 16, 2025, through August 5, 2026. Findings included: 1. During a tour of the andrology laboratory on 08/05/2026 at 12:50 PM, the surveyor observed the following: Stored under the fume hood: 1 opened Hydrion pH paper roll currently in use for the performance of semen analysis; lot #220822; expiration date: Jul 15, 2025 Stored in a laboratory drawer: 4 closed boxes of Hydrion pH paper roll; lot #220822; expiration date: Jul 15, 2025 2. Review of patient records identified 822 patients who had pH testing performed as part of their semen analysis work up from July 16, 2025, through August 5, 2026 using the expired pH paper. The following is a random sampling of those patients: Test Date: 11/17/2025 Patient ID: 1496-25 Result: 6.8 12 /08/2025 Patient ID: 1583-25 Result: 7.2 01/22/2026 Patient ID: 0076-26 Result: 7.0 Patient ID: 0076-26 Result: 7.0 02/03/2026 Patient ID: 0118-26 Result: 7.0 03/03 /2026 Patient ID: 0275-26 Result: 7.2 03/18/2026 Patient ID: 0353-26 Result: 7.2 04 /22/2026 Patient ID: 0539-26 Result: 7.2 The laboratory failed to ensure Hydrion pH paper did not exceed its expiration date prior to patient testing. 3. During an interview, in the laboratory, on 08/05/2026 at 12:57 PM, the laboratory manager, after a review

of records, confirmed the laboratory failed to ensure five of five Hydrion test paper rolls did not exceed their expiration date prior to performing 822 of 822 semen analysis from July 16, 2025, through August 5, 2026.