Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2114140	05/07/2024
Name of Provider or Supplier	**Street Address, City, State**	
Allen Reproductive Center	8080 State Hwy 121 Suite 240, Mckinney, 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 announced survey of the laboratory was conducted on 05/07/2024. The laboratory was found in compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories). STANDARD LEVEL DEFICIENCIES were cited.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of laboratory's proficiency testing (PT) records and staff interview, the laboratory failed to ensure attestation was signed for 1 of 4 PT events reviewed from 2022 and 2023. Findings included: 1. Review of laboratory's 2022 and 2023 PT records revealed the laboratory used Medical Laboratory Evaluation as the PT provider. 2. Further review of the above PT records revealed the laboratory did not have signed attestation for the "Embryology, Andrology and Fetal S2 2023" PT event, 1 of 4 PT events reviewed. 3. In an interview on 05/07/2024 at 1350 hours in the office, the laboratory's Testing Person number one (as indicated on submitted form CMS 209) confirmed the findings.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on review of laboratory's proficiency testing (PT) records and staff interview,

	the laboratory failed to retain PT records for 1 of 4 PT events reviewed from 2022 and 2023. Findings included: 1. Review of laboratory's 2022 and 2023 PT records revealed the laboratory used Medical Laboratory Evaluation as the PT provider. 2. Further review of the above PT records revealed the laboratory did not retain records for the "Embryology, Andrology and Fetal S1 2023" PT event, 1 of 4 PT events reviewed. 3. In an interview on 05/07/2024 at 1350 hours in the office, the laboratory's Testing Person number one (as indicated on submitted form CMS 209) confirmed the findings.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of laboratory's proficiency testing (PT) records and staff interview, the laboratory failed to ensure PT results were evaluated for 3 of 4 PT events reviewed from 2022 and 2023. Findings included: 1. Review of laboratory's 2022 and 2023 PT records revealed the laboratory used Medical Laboratory Evaluation as the PT provider. 2. Further review of the above PT records revealed the laboratory did not have documentation of evaluation of PT results for the following 3 of 4 PT events reviewed: Embryology, Andrology and Fetal S1 2022 Embryology, Andrology and Fetal S2 2022 Embryology, Andrology and Fetal S2 2023 3. In an interview on 05/07 /2024 at 1350 hours in the office, the laboratory's Testing Person number one (as indicated on submitted form CMS 209) confirmed the findings.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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: Based on surveyor's observations, review of manufacturer's instructions, laboratory's temperature records and staff interview, the laboratory failed to follow manufacturer instructions for storage for 3 of 3 supplies stored in the refrigerator. Findings included: 1. Surveyor's observations on 04/07/2024 at 1515 hours in the laboratory revealed the following supplies stored in the refrigerator: a. Vitrolife SpermFreeze Solution b. FUJIFILM Multipurpose Handling Medium-Complete (MHM-C) with Gentamycin and HSA c. FUJIFILM ISolate Sperm Separation Medium Stock Solution d. Testsimplets Slides 2. Review of manufacturer instructions for storage for the above supplies revealed the following storage temperature requirements: a. Vitrolife SpermFreeze Solution - storage temperature 2-8C (Degrees Celsius). b. FUJIFILM MHM-C with Gentamycin and HSA - storage temperature 2-8C. c. FUJIFILM ISolate Spem Separation Medium - storage temperature 2-8C. d.

	Testsimplets Slides - storage temperature 2-30C. 3. Review of laboratory's temperature records revealed the laboratory defined acceptable refrigerator temperature range as 1-10C. 4. Further review of random temperature records for 2023 and 2024 revealed the following days refrigerator temperature was out of manufacturer requirements for storage of the above supplies: Date: Temperature (C): 04/12/2023 1.0 04/13/2023 1.0 04/17/2023 1.7 04/18/2023 1.1 04/26/2023 1.0 04/28 /2023 1.0 05/02/2023 1.9 05/05/2023 1.6 05/15/2023 1.1 05/16/2023 1.2 05/25/2023 1.0 05/26/2023 1.0 01/24/2024 1.0 01/30/2024 1.0 02/02/2024 1.0 02/06/2024 1.2 02 /09/2024 1.7 02/15/2024 1.8 02/19/2024 1.2 02/22/2024 1.0 02/27/2024 1.0 03/04 /2024 1.0 03/06/2024 1.4 03/08/2024 1.0 03/14/2024 1.6 03/15/2024 1.0 03/18/2024 1.9 03/21/2024 1.0 03/29/2024 1.1 5. In an interview on 05/07/2024 at 1520 hours in the office, the laboratory's Testing Person number one (as indicated on submitted form CMS 209) confirmed the findings.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: Based on surveyor's observations and staff interview, the laboratory failed to ensure laboratory supplies were not used beyond expiration dates for 2 of 2 expired supplies observed. Findings included: 1. Surveyors observations on 05/07/2024 at 1315 hours in the laboratory reveled the following expired supplies in use sitting on the countertop next to the microscope: a. Steri-Prox 6% - used for disinfection of countertops and equipment. Lot: 21-SPER-114024 Expiration: 01-Mar-2023 b. Testsimplets - slides for differential blood cell counts. Lot: 19773 Expiration: 2023-11 2. In an interview on 05/07/2024 at 1315 hours in the laboratory, the Testing Person number one (as indicated on submitted form CMS 209) confirmed the findings.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on surveyor's observations, review of manufacturer's instructions for use, laboratory's policies/procedures, equipment maintenance records and staff interview, the laboratory failed to define and document microscope maintenance for 2 of 2 microscopes in use. Findings included: 1. Surveyor's observations on 05/07/2024 at 1305 hours in the laboratory revealed 2 microscopes in use: a. VanGuard Microscope Serial Number (SN): 017588 b. Nikon Eclipse E200 SN: 613079 2. The laboratory was asked to provide manufacturer's instructions for use for the above microscopes so

	maintenance requirements could be ascertained and no such documents were available for review prior to survey exit. 3. Review of laboratory's policies/procedures revealed there were no protocols in place defining microscope maintenance requirements /frequency to ensure microscope's proper function. 4. Review of laboratory's microscope maintenance records revealed the only documentation of microscope maintenance was the annual preventive maintenance record. 5. In an interview on 05 /07/2024 at 1510 hours in the laboratory, the Testing Person number one (as indicated on submitted form CMS 209) stated that the microscopes are cleaned all the time, but that there is no documentation of the process. This confirmed the findings.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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's quality control (QC) records, policies/procedures and staff interview, the laboratory director failed to ensure over time quality control (Levey-Jennings plots) review was maintained for one of one laboratory's testing platform, Sperm Analysis. Findings included: 1. Review of laboratory's QC records for 2022, 2023 and 2024 revealed the laboratory failed to document review of over time QC since April 2022. The last Levey-Jennings QC plot review was documented on 04/19/2022. 2. Review of laboratory's policies/procedures revealed there were no protocols in place specifying frequency and/or requirements for over time QC review to ensure there were no shifts or trends in QC that needed to be addressed. 3. In an interview on 05/07/2024 at 1510 hours in the office, the laboratory's Testing Person number one (as indicated on submitted form CMS 209) confirmed the findings.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the 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's Quality Assurance (QA) records and Quarterly QA Checklists, policies/procedures and staff interview, the laboratory director failed to ensure QA review was maintained for one of one laboratory's testing platform, Sperm Analysis. Findings included: 1. Review of laboratory's QA records for 2022, 2023 and 2024 revealed the laboratory failed to document review of QA since April 2022. The last Quarterly QA Checklists' review was documented on 04/18/2022. 2. Review of laboratory's policies/procedures revealed there were no written protocols/policies in place specifying frequency and/or requirements for QA review. 3. In an interview on 05/07/2024 at 1510 hours in the office, the laboratory's Testing Person number one (as indicated on submitted form CMS 209) confirmed the findings.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)

	The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's 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 laboratory's personnel records, policies/procedures and staff interview, the laboratory's technical consultant failed to ensure annual competency assessments were documented for 2 of 3 testing personnel employed by the laboratory. Findings included: 1. Review of laboratory's personnel records revealed there was no documentation of annual competency assessment for 2 of 3 testing personnel (TP) as follows: a. TP number 1 had no competency assessment documented for 2022 and 2023. Competency Assessments were documented in September 2021 and April 2024. b. TP number 2 had no competency assessment documented for 2023. Competency Assessments were documented December 2022 and February 2024. 2. Review of laboratory's policies/procedures revealed there were no written protocols in place delineating frequency and/or requirements for testing personnel competency assessment. 3. In an interview on 05/07/2024 at 1425 hours in the office, the laboratory's Testing Person number one (as indicated on submitted form CMS 209) confirmed the findings.