Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 21D2090924	**(X3) Date Survey Completed** 11/08/2023
Name of Provider or Supplier Assisted Reproductive Technology Lab (Art)	**Street Address, City, State** 10755 Falls Rd Pavilion I, Suite 407, Lutherville, MD	
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**
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of the proficiency testing (PT) records and interview with the laboratory director (LD), the laboratory failed to document the PT samples along with the regular patient workload. Findings: 1. The hematology PT records from 2022 and the first event of 2023 were reviewed for a total of three events. 2. The PT records that were reviewed showed that the results were recorded on the PT worksheet. When interviewed the LD stated that the PT results were only recorded on the PT worksheets and not on the worksheet used in the laboratory to record the patient test results. 3. During the validation survey on 11/08/2023 at 1:45 PM, the LD confirmed that the PT results were not being documented in the same manner as the patients.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) 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 the proficiency testing (PT) records and interview with the laboratory director (LD), the laboratory failed to ensure that the attestation worksheet was printed and signed by the appropriate laboratory personnel. Findings: 1. The hematology PT records from 2022 and the first event of 2023 were reviewed for a total of three events and six modules. 2. The Sperm Count, Motility, Morphology and Viability, SPCD-A, PT records for the first event of 2022 showed that the attestation worksheet had not been signed by the LD and testing person. The SPCD-B PT records for the second event of 2022 showed that the attestation worksheet had not been signed by the LD. 3. During the validation survey on 11/08/2023 at 1:45 PM, the LD confirmed that the attestation worksheet had not been signed by the appropriate laboratory personnel.
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on record and procedure review and interview with the laboratory director (LD), the laboratory did not have documentation that the eyewashes were flushed weekly according to the procedure. Findings: 1. The laboratory's procedure titled "Emergency Equipment: Eyewash, Drenching Hose, and Shower Equipment" stated that "Plumbed eyewashes must be activated weekly, for at least three minutes or until the water runs clear, whichever is longer. The purpose of the weekly activation is to verify proper operation, flush stagnant water from the line, and remove sediment from the flushing water" and that "Emergency Equipment Maintenance Logs will be used to document that eyewashes are activated weekly." 2. During the validation survey on 11/08/2023 at 1:45 PM, the LD confirmed that there were no Emergency Equipment Maintenance Logs documenting weekly flushes of the eyewashes.
D6125	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) results and interview with the technical supervisor (TS)/ laboratory director, the TS failed to ensure that written policies and procedures included the evaluation of the competency of the testing personnel (TP) who perform semen analysis. Findings: 1. The "Laboratory Personnel Report (CLIA)" (CMS-209) listed five testing personnel who performed semen analysis. 2. The hematology PT records from 2022 and the first event of 2023 were reviewed for a

	total of three events. 3. The PT records showed that the samples were tested by 2 to 3 TP. The TS explained that each TP would independently perform the tests and record the results. The TP that was scheduled for that event would submit their results. Once the results were received and evaluated, the results of the other TP would be evaluated and used as part of their competency. 4. The PT summary was documented as reviewed, but the results of the other TP were not evaluated as acceptable or unacceptable. The TS confirmed that there was no documented evaluation of the additional results. 5. During the validation survey on 11/08/2023 at 1:45 PM, the TS confirmed that there were no written procedures defining how the PT samples were being used to evaluate all the TP, how they would be evaluated, and corrective actions to be taken when there were failures.