

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D1081301	(X3) Date Survey Completed 04/25/2024
Name of Provider or Supplier Fertility Laboratories	Street Address, City, State 42-31 Colden Street Suite 202, Flushing, NY	
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 CLIA exempt-state validation survey was performed on April 25, 2024, by a CMS CLIA federal surveyor. The laboratory was surveyed under 42 CFR part 493 CLIA regulations. The laboratory was found not to be in compliance with standard-level CLIA requirements. The findings were reviewed with the laboratory director during an exit conference at the conclusion of the survey.
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>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</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the Laboratory Director (LD) the laboratory failed to ensure proficiency testing (PT) was rotated among all testing persons (TP) in the specialty of Hematology. Findings include: 1. Record review on 04/25/2024 of the Laboratory Personnel Report (Forms CMS-209) signed by the laboratory director on 04/25/2024 included two TP. 2. Record review on 04/25/2024 of the laboratory's 2022 and 2023 College of American Pathologists (CAP) Semen Analysis Glass Slides and Sperm Count PT records revealed no evidence of PT participation for one (TP #2) of two TP. 3. Interview on 04/25/2024 at 01:00 pm with the LD confirmed the findings above.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or</p>

examining specimens.

This STANDARD is not met as evidenced by:

Based on laboratory written policies and procedures, patient worksheets, and interview with the laboratory director (LD), the laboratory failed to follow written procedures for sperm counts duplicate testing for one of five patients. Findings include: 1. Record review on 04/25/2024 of the laboratory's written policies and procedures titled, "Procedure Manuals" under section, "Standard Operations Procedures for Andrology" stated the following: "2. When sperm counts, motility and concentrations are performed manually: a) Testing shall be performed, in duplicate from one dilution, using two separate counting chambers; b) Forward progression shall be evaluated and graded as a subset of motility; and, c) Acceptable precision limits for duplicate testing shall be defined." "The results of duplicate testing should be averaged. If less than 10% discrepancy is obtained, the results may be reported. If the difference exceeds 10%, the specimen shall be analyzed a third time and the average of the three test results should be reported." 2. Record review on 04/25/2024 of five patient worksheets tested on 10/20/23, 10/21/2023, 10/24/2023, and 10/25/2023 revealed the following for one of five patients: a. 10/24/2024 - Patient #5 worksheet exceeded the 10% difference limit for sperm counts. b. No evidence of a third analysis 3. Interview with the LD on 04/25/2024 at 01:20 pm confirmed the findings above.