

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2301750	(X3) Date Survey Completed 11/06/2025
Name of Provider or Supplier Cny Fertility, Pllc	Street Address, City, State 6315 North Center Drive, Suite 102, Norfolk, VA	
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 recertification survey was conducted at CNY Fertility on November 6, 2025 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. CNY Fertility was not in compliance with the applicable Conditions and Standards under 42 CFR part 493 CLIA Regulations. Specific deficiencies are as follows:
D2014	<p>TESTING OF PROFICIENCY TESTING SAMPLES</p> <p>(b)(6) 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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's proficiency testing (PT) records, policy and procedures, lack of documentation and interview, the laboratory failed to retain instrument printouts for three of eleven PT events reviewed. Findings include: 1. Review of the laboratory's 2024 and 2025 College of American Pathologists (CAP) PT records revealed the laboratory participates in CAP PT modules General Chemistry /Therapeutic drugs (C), Sex Hormones (Y), and Immunology (S). Review of 11 PT module event documentation (2024 C-C, 2024 C-A, B, & C; 2024 Y-B, 2025 Y-A & B; 2024 S-B & C, and 2025 S-A&B) revealed no instrument printouts retained for the following 3 events: 2025 C-C, 2025 Y-B, and 2025 S-B. 2. Review of the laboratory's proficiency testing policy "Accessioning, analyzing, resulting and reporting PT</p>

samples" (eff. 3/24/25) revealed the statement "retain all associated records". 3. In an exit interview with the technical consultant on November 6, 2025 at 3:30 PM, the findings were confirmed.

D5215

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(b)(2)

The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's proficiency testing (PT) records, policy and procedures, lack of documentation and interview, the laboratory failed to evaluate non-graded sperm motility PT results for three (3) of three (3) events reviewed. Findings include: 1. Review of the laboratory's 2024 and 2025 College of American Pathologists (CAP) PT records for three (3) sperm morphology & motility (SPCD) event modules revealed no documentation of an evaluation or verification of accuracy for the following non-graded sperm motility results: 2024 SPCD-B motility scores included under "Your Grade": "SEE NOTE [26]"; 2024 SPCD-C motility scores included under "Your Grade": "SEE NOTE [26]"; 2025 SPCD-A motility scores included under "Your Grade": "SEE NOTE [26]". Page 1 of the CAP PT results form for each event included "Exception Reason Code [26] = Educational challenge". No evaluation of the non-graded motility results listed above was available for review. 2. Review of the laboratory's Proficiency Testing policy revealed the statement: "If any test is unable to be graded by the PT supplier, perform verification of the test (self assessment)". 3. In an exit interview with the technical consultant on November 6, 2025 at 3:30 PM, the findings were confirmed.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283.

This STANDARD is not met as evidenced by:

Based on a laboratory tour, review of the laboratory's Beckman Coulter Unicel Dxl 600 Quality Control (QC) records, policy and procedures, lack of documentation, and interviews, the laboratory failed to follow their established policy to perform and document Levy-Jennings (LJ) statistical evaluations for Endocrinology QC shifts and trends for seven (7) of 7 months reviewed. The findings include: 1. During a laboratory tour on 11/06/25 at 9:20am, it was noted that the lab utilizes a Beckman Coulter Unicel Dxl 600 analyzer in the Endocrinology room for patient testing. 2. Electronic review of the laboratory's QC records for March 2025 through September 2025 revealed the lab utilizes Bio-Rad Lyphochek Immunoassay Plus Controls (Levels 1, 2, and 3) for Estradiol, Progesterone, Follicle Stimulating Hormone (FSH), human chorionic gonadotropin (hCG), free Triiodothyronine (fT3), free Thyroxine (fT4), luteinizing hormone (LH), testosterone, progesterone, prolactin, and Thyroid

Stimulating Hormone (TSH) testing on the Unicel Dxl 600. 3. Review of the laboratory's "QC Requirements to Release Results" revealed the statement: "View LJ within the Dxl". In a 2:54pm interview, the Technical Consultant (TC) confirmed that the LJ is on analyzer. 4. The surveyor requested to review documentation of the Endocrinology QC LJ review for the 7 months of March through September 2025. The laboratory provided no documentation for review. 5. In an exit interview with the TC on November 6, 2025 at 3:30 PM, the findings were confirmed.