

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  07D0973463	<b>(X3) Date Survey Completed</b>  09/02/2025
<b>Name of Provider or Supplier</b>  Illume Fertility	<b>Street Address, City, State</b>  761 Main Ave, Ste 200, Norwalk, CT	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2105</b>	<p>ENDOCRINOLOGY CFR(s): 493.843(e)</p> <p>(e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to document remedial action when unacceptable proficiency testing (PT) scores were obtained for two consecutive PT events in the subspecialty of endocrinology. Findings include: 1. Record review on 09/02/2025 of the 'Centers for Medicare &amp; Medicaid Services (CMS) Casper Report 0155D' revealed the laboratory obtained an unacceptable PT score for the following analyte: 0540 Estradiol, 2025 Event 1 and 2, score: 80%. 2. Record review on 09/02/2025 of the laboratory's proficiency testing 'American Association of Bioanalysts - Medical Laboratory Evaluation (AAB-MLE)' form revealed the following: a. AAB-MLE M1 2025: Endocrinology 1 i. 'Analyte: Estradiol' ii. 'Method: Roche Elecsys' iii. 'Instrument: Roche Cobas 6000, 8000' iv. 'Score: 80' v. 'Specimen: 3' vi. 'Reported Value: *32' vii. 'Grading Range: 13.0 - 24.0' b. AAB-MLE M2 2025: Endocrinology 1 i. 'Analyte: Estradiol' ii. 'Method: Roche Elecsys' iii. 'Instrument: Roche Cobas 6000, 8000' iv. 'Score: 80' v. 'Specimen: 10' vi. 'Reported Value: *28' vii. 'Grading Range: 14.0 - 26.0' 3. Record review on 09/02/2025 of the laboratory's PT binder revealed lack of documentation of corrective action for the above unacceptable PT scores listed in 2(a) and (b). 4. Record review on 09/02/2025 of the laboratory's 'General Standard Operating Procedures: Proficiency Testing' revealed 'All Unacceptable testing results must be investigated, and corrective</p>

actions must be initiated immediately. There must be prompt corrective response to unacceptable proficiency testing results. The results should be thoroughly investigated; a proficiency testing review form should be filled out and attached directly to the results'. 5. Staff interview on 09/02/2025 at 12:15 PM with the laboratory's technical supervisor and general supervisor confirmed the above findings. 6. The laboratory performs 50,000 tests annually in the subspecialty of endocrinology.