Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D2009676	03/03/2020
Name of Provider or Supplier	**Street Address, City, State**	
Illume Fertility	103 Newtown Rd, Ste 1a, Danbury, CT	

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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to ensure an approved laboratory procedure was in place prior to performing tests in the specialty of hematology. Findings include: 1. Review of the laboratory's quality control (QC) records on 3/3/2020 for semen analysis (SA) revealed: (a) The laboratory is using proficiency test (PT) materials received from American Association of Bioanalysts (AAB) as QC materials as of 2/3/2020. (b) A hand written note stating, "QC Accubeads out of service 1/31/2020-AAB PT use begin 2/3/2020." 2. Review of laboratory's SA procedure manual (PN-LA-AND-306) on 3/3/2020 revealed accubeads are being used as QC materials for SA test. 3. Staff interview with the laboratory manager on 3/3/2020 at 11:30 AM confirmed: (a) The laboratory switched the QC materials for SA from Accubeads to AAB PT materials effective 2/3/2020. (b) SA-QC procedure is not updated and/or approved by the laboratory director at the time of the inspection on 3/3/2020. (c) Documentation for staff education and/or training with QC procedure update was not available. 4. The laboratory performs 225 SA tests annually.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)

	(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to demonstrate that it can obtain performance specifications comparable to those established by the manufacturer before introducing an unmodified, FDA-cleared or approved test system. Findings include: 1. Review of the laboratory's validation records for beta human chorionic gonadotropin (b-HCG) test on 3/3/2020 revealed: a. Documentation for verification reportable ranges for b-HCG test not performed. b. The laboratory went live with b-HCG testing on 11/8/2018. c. The above validation data was reviewed and approved by the laboratory director. 2. Staff interview with the laboratory manager (LM) on 3/3/2020 at 9:50 AM confirmed the above findings. The LM further stated he/she is unaware if reportable ranges were verified prior to going live with b-HCG testing. 3. The laboratory performs 8,000 b-HCG tests annually. 4. This is a repeat deficiency.