Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D2009676	03/23/2018
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
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to ensure an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements. Findings include: 1. Record review of the laboratory's quality incident (QI) documents dated 11/7/17 on 3/23/18 revealed the following incident had occurred: a) A semen sample was obtained from Patient #1 on 11/7/17 for in-vitro fertilization. b) Paper work attached to above sample included copies photo identification (driver's license) from Patient #1 and Patient #2. 2. Record review of corrective action for the above QI on 3/23/18 revealed: a) The above specimen was discarded due to misidentification. b) Corrective action did not include any investigation or retraining/re-education of testing personnel to avoid recurrence in the future. c) Lack of ongoing mechanism to monitor corrective action is not available. 3. Staff interview with the laboratory manager on 3/23/18 at 1:30 PM confirmed the above findings. 4. The laboratory performs 550 tests annually in the specialty of hematology.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) 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

	examining specimens. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to follow established laboratory procedure for beta-human chorionic gonadotropin (HCG) in the sub-specialty of endocrinology. Findings include: 1. Record review of the Roche Cobas e411 procedure for beta-HCG test on 3/23/18 revealed "sample carry over will be assessed quarterly on the Roche e411 for beta-HCG". 2. Record review of the sample carry over data on 3/23/18 revealed the laboratory failed provide evidence of documentation of sample carry over assessments prior to 2/16/18. The instrument was placed into service in December 2016. 3. Staff interview with the laboratory manager (LM) on 3/23/18 at 12:45 PM confirmed the above findings. The LM stated the laboratory has been performing carry over assessments but the records are not available. 4. The laboratory performs 5400 beta-HCG 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 performance specifications comparable to those established by the manufacturer before introducing an unmodified, FDA-cleared or approved test system. Findings include: 1. Record review of the Roche Cobas e411 (SN# 15A730) analyzer validation data on 3/23/18 revealed: a) The validation data did not include the verification of reportable ranges for the endocrinology tests. b) The above analyzer was placed into service in December 2016. 2. Record review of the laboratory's procedure manual for endocrinology tests revealed: a) Reportable ranges for each analytes were not listed. b) Lack of procedure for steps to be taken when patient samples exceeded analytical limits. 3. Staff interview with the laboratory manager on 3/23/18 at 10:30 AM confirmed the above findings. 4. The laboratory performs 34,268 tests in the sub-specialty of endocrinology.