

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D2009671	(X3) Date Survey Completed 04/06/2021
Name of Provider or Supplier Illume Fertility	Street Address, City, State 260 Long Ridge Rd, Entrance B, Stamford, 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
D6117	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4)</p> <p>The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to ensure the correct quality control (QC) ranges for sperm motility were maintained and within acceptable limits prior to reporting patient test results in the specialty of Hematology. Findings include: 1. Record review on 4/6/2021 of the American Association of Bioanalysts (AAB) 'S2 Andrology & Embryology' Proficiency Testing (PT) 2019 Evaluation form revealed the sperm motility acceptable range for specimen #7 was '64-107'. 2. Record review on 4/6/2021 of the laboratory's QC binder and 'Daily Count, Morphology, Motility QC' monthly logs for the period January 2020 through April 2021 revealed the following: a. AAB PT Event S2 2019 specimens were used as quality control material and labeled as Specimen 'A' and Specimen 'B'. b. The motility acceptable ranges were handwritten on the top of each monthly log sheet. c. The motility acceptable range for Specimen 'B' was written as '64-107' for the months of January through May 2020. d. The motility acceptable range for Specimen 'B' was incorrectly written as '64-167' for the months June 2020 through April 2021. e. Specimen 'B' Motility was above the acceptable limit of 107 as follows: i. 9 of 9 days in December 2020. ii. 1 of 10 days in January 2021. iii. 1 of 13 days in March 2021. f. The AAB Event 2 2019 evaluation form depicting the acceptable motility ranges was not in the QC binder. g. The daily QC logs were reviewed and signed by the general supervisor #1 (GS#1) monthly. 3. Staff interview with GS#1 on 4/6/2021 at 10:52 AM confirmed the following: a. Specimen #7 from the AAB Event 2 2019 was Specimen 'B' used for</p>

QC as indicated on the QC log. b. The handwritten numbers of 64-107 changed in June 2020 to 64-167 and may have been due to the number being copied incorrectly from the prior month. c. The AAB Event 2 2019 evaluation form was not available in the QC binder for reference. d. The motility for specimen 'B' was out of range as indicated in 2e above with no corrective actions and patient results reported. f. GS#1 did not realize the numbers had been changed nor confirmed the acceptable ranges against the official AAB form.