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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 07D2009671 | (X3) Date Survey Completed 03/25/2019 |
| 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 |
|---------------------------|---|
| D6102 | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12)</p> <p>The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to provide documentation for testing personnel (TP) training records to ensure TP can independently perform and report test results accurately in the specialty of Hematology. Findings include: 1. Record review of TP training and competency records on 3/25/19 revealed: (a) TP#1 hired on 5/15/17 did not have site specific training records prior to testing patient samples. (b) TP#2 hired on 12/17/17 did not have site specific training records prior to testing patient samples. 2. Staff interview with laboratory manager on 3/25/19 at 10:30 AM confirmed the above findings. 3. The laboratory performs 550 high complexity tests annually in the specialty of Hematology.</p> |