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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 08D0962971 | (X3) Date Survey Completed 01/11/2022 |
| Name of Provider or Supplier Delaware Institute For Reproductive Medicine | Street Address, City, State 909 Lakeview Avenue, Milford, DE | |
| 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 |
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| D0000 | A Recertification Survey was conducted at approximately 9:00 am on January 11, 2022 at Delaware Institute for Reproductive Medicine. The laboratory was surveyed according to 42 CFR part 493 CLIA requirements. Specific deficiencies are as follows: |
| D6050 | <p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iv)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to direct observation of performance of instrument maintenance and function checks.</p> <p>This STANDARD is not met as evidenced by: based on record review and interview. The laboratory failed to address two of six elements of a competency assessment program in their Standard Operating Procedure (SOP). Findings include: 1. At approximately 10:30 am on January 11, 2020 during record review it was determined the Competency of Personnel Procedure included four required elements of competency assessment: "Direct observations of routine patient testing including patient preparation, specimen handling, processing and testing; Monitoring the recording and reporting of test results; Review of quality control records, proficiency testing results, and preventive maintenance records: Assessment of problem solving/troubleshooting skills". However, "Direct observations of performance of instrument maintenance and function checks", and "Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples" were not addressed in the SOP. 3. TC2 confirmed in an interview at approximately 10:40 am, that the competency assessment SOP did not address "Direct observations of performance of performance of instrument maintenance and function checks", and "Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples".</p> |