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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 31D0681031 | (X3) Date Survey Completed 04/29/2021 |
| Name of Provider or Supplier Shore Institute For Reproductive Medicine, Pc | Street Address, City, State 106 Grand Avenue, Englewood, NJ | |
| 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 |
|---------------------------|--|
| D5211 | <p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), it was revealed that the laboratory failed to review code 20 "No appropriate target/response could not be graded" results obtained for Endocrinology PT performed with the College of American Pathologists (CAP) in 2020. The finding includes: 1. Code 20 results were received for: Y-B 2020 Ligand-Special event 2: Follicle-Stimulating Hormone sample Y-04,through 06, Luteinizing Hormone Y-04,through 06, and Progesterone Y-04,through 06. 2. The TP #1 listed on CMS from 209 confirmed on 4/26/21 at 10:30 am that the laboratory failed to evaluate code 20 PT results.</p> |
| D5433 | <p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.</p> <p>This STANDARD is not met as evidenced by:</p> |

Based on surveyor review of the Maintenance Records (MR) and interview with the Testing Personnel (TP), the laboratory failed to ensure that microscope maintenance was performed for the calendar years 2019, and 2020. The finding includes: 1. The microscope MR stated maintenance was required June 2019. 2. There was no evidence that maintenance was performed from June 2019 to the date of survey. 3. The TP #1 listed on CMS form 209 confirmed on 4/29/21 at 11:30 am that the laboratory did not ensure maintenance was performed.

D5445

CONTROL PROCEDURES

CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on surveyor review Quality Control (QC) records and interview with the Testing Personnel, the laboratory failed to perform and document QC on each day of patient testing for Semen analysis From November 2020 date of the survey. The findings include; 1. QC was not performed on 11/10/20, 12/16/20, 1/11/21, 1/13/21, 1/28/21, and 2/8/21. 2. Six patients were run and reported. 3. The TP #1 listed on CMS form 209 confirmed on 4/29/2021 at 9:45 am that the laboratory did not perform QC on each day of patient testing.