

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0886776	(X3) Date Survey Completed 02/07/2020
Name of Provider or Supplier Shore Institute For Reproductive Medicine	Street Address, City, State 475 Route 70, Lakewood, 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
D2100	<p>ENDOCRINOLOGY CFR(s): 493.843(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the General Supervisor (GS), the laboratory failed to participate in American Association of Bioanalysts PT for Q1 of 2019 for Human Chorionic Gonadotropin (HCG) test. The GS confirmed on 2/7/20 at 11:30 am that the laboratory did not participate in event Q1 of 2019 for HCG.</p>
D6016	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;</p>

This STANDARD is not met as evidenced by:
Based on surveyor review of Proficiency Testing (PT) records and interview with the General Supervisor (GS), the Laboratory Director (LD) failed to ensure that PT samples were tested for Human Chorionic Gonadotropin (HCG) in Q1 of 2019 with American Association of Bioanalysts. The GS confirmed on 2/7/20 at 11:31 pm that the LD did not ensure that PT samples were tested.