Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D0702790	01/16/2025
Name of Provider or Supplier	**Street Address, City, State**	
Ohio Reproductive Medicine, Llc	535 Reach Blvd, Columbus, OH	

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**
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) (b)The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on record review and an interview with the General Supervisor (GS) #3, the laboratory failed to examine the proficiency test samples in the same manner as patients' specimens. This deficient practice had the potential to affect 10,433 out of 10,433 patients tested under the specialty of Hematology and the subspecialty of Endocrinology from 01/16/2024 through 001/16/2025. Findings Include: 1. Review of the laboratory's policy and procedure titled "Quality Management Policy" approved via signature and date by the Laboratory Director on 01/24/2024 revealed the following statement: "External Proficiency Testing Test samples are run the same way as patient samples." 2. GS #3 stated proficiency samples were ran at the end of the day with no other samples and no distractions. GS #3 also stated the policy and procedure was only referring to the instrument used for testing. The interview occurred on 01/16/2025 at 10:20 AM.