Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 36D2299753	**(X3) Date Survey Completed** 05/30/2024
Name of Provider or Supplier Ohio Fertility Providers, Llc	**Street Address, City, State** 10506 Montgomery Rd, Suite 303/305, Cincinnati, 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**
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Director, the Laboratory Director failed to ensure approved policies and procedures related to the laboratory's exposure control, quality management, and proficiency testing were available to all personnel prior to patient testing. This deficient practice had the potential to affect 1,000 out of 1,000 patients tested in the Specialty of Hematology from 02/16/2024 through 05/30/2024. Findings Include: 1. Review of the laboratory's patient logs revealed patient testing started 02/16/2024. 2. Review of the laboratory's policy and procedure manual titled "Ovation Fertility Protocols" found the following MediaLab cover pages electronically signed by the Laboratory Director on 02/28/2024: "SAP. AE.2.001 Ovation Exposure Control Plan" "QMP.AE.1.0015 Quality Management Policy" "QMP.AE.1.0025 Proficiency Testing Policy" 3. The Laboratory Director confirmed the above mentioned policies and procedures were not approved via signature and date before patient testing had begun. The interview occurred on 05/30 /2024 at 2:30 PM.