

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D2299753	(X3) Date Survey Completed 05/12/2026
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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Director (LD), the Laboratory Director failed to attest to the routine integration of proficiency testing (PT) samples into the patient workload using the laboratory's routine methods for four out of four College of American Pathologists (CAP) PT events which included postvasectomy sperm count, automated sperm count, sperm morphology, and sperm count and motility. Findings Include: 1. Review of the laboratory's CMS-209, approved by the LD via signature and date on 03/30/2026, revealed one out of one qualified and listed General Supervisor. 2. Review of the laboratory's 05/05/2026 CAP PT attestation pages found the GS signature for the Director (or designee). 3. Review of the laboratory's "Proficiency Testing Policy" policy and procedure, approved via signature and date by the LD on 02/05/2025, found the following statement: "1. The attestation statement must be signed by the laboratory director or designee and all individuals involved in the testing process." 4. Review of the laboratory's "Lab Director Delegation of Responsibilities" policy and procedure, approved by the LD via signature and date on 02/05/2025, found the following statement: "2. Specific laboratory director functions or responsibilities delegated must be in writing (by name and job title), with records of authorization to perform testing, and the level of supervision required, as applicable." 5. On 05/12/2026, at 11:30 AM, the Inspector requested the LD's PT attestation delegation to the GS in writing from the LD. The LD confirmed he did not delegate specific Laboratory Director functions or responsibilities in writing and was unable to provide the requested documentation.</p>

6. Review of laboratory test records revealed the laboratory performed 189 patient Hematology tests between the CAP PT third event on 11/18/2025 and the CAP PT first event on 05/05/2026.

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES

CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:

Based on a record review and an interview with the Laboratory Director (LD), the laboratory failed to follow written policies and procedures for assessing the competency of one out of one Technical Supervisor (TS) and one out of one General Supervisor (GS) based on the responsibilities of the positions for high-complexity Hematology testing procedures performed. Findings Include: 1. Review of the laboratory's Form CMS-209, approved via signature and date by the Laboratory Director on 03/30/2026 and provided on 05/06/2026, revealed one out of one individual qualified and listed to function as the TS, and one out of one individual qualified and listed to function as the GS for the high complexity hematology testing procedures. 2. Review of all of the laboratory's policies and procedures titled, "QMP. AE.1.0020 Lab Director Delegation of Responsibilities Policy", approved via signature and date by the LD on 02/05/2025, and provided on the date of the inspection, revealed the following statement: "V. Competency Assessment Requirements 1. Documented competency assessment is required for the following named positions: A. Technical Supervisor ...C. General Supervisor 3. Review of the laboratory's 2024, 2025, and 2026 competency assessment documentation did not find any competency assessment documentation based on the responsibilities for the TS and GS. 4. On 05/12/2026 at 10:30 AM, the Inspector requested the laboratory's 2024, 2025, and 2026 TS and GS competency assessment documentation from the LD. The LD confirmed the laboratory did not conduct competency assessments on the TS and GS in 2024, 2025, and 2026, and was unable to provide the requested documentation on the date of the inspection. 5. Review of laboratory test records revealed 792 patient Hematology test results reported between 05/31/2024 and 05/12/2026.