Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 36D2132071	**(X3) Date Survey Completed** 06/11/2025
Name of Provider or Supplier Metrohealth Andrology Lab	**Street Address, City, State** 12301 Snow Road, 4th Floor, Parma, 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**
D2001	ENROLLMENT CFR(s): 493.801(a)(1)(2)(i) The laboratory must-- (1) Notify HHS of the approved program or programs in which it chooses to participate to meet proficiency testing requirements of this subpart. (2)(i) Designate the program(s) to be used for each specialty, subspecialty, and analyte or test to determine compliance with this subpart if the laboratory participates in more than one proficiency testing program approved by CMS; and This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Director (LD), the laboratory failed to enroll in a proficiency testing (PT) program for high complexity semen analysis performed in the specialty of Hematology from 05/01/2024 through 06/11/2025. This deficient practice had the potential to affect 128 out of 128 semen analysis patients tested under the specialty of Hematology from 05/01/2024 through 06/11/2025. Findings Include: 1. Review of the procedure manual, signed and dated by the LD on 12/31/2018, failed to find policies and procedures for enrollment in a PT program for semen analysis in the specialty of Hematology. 2. The inspector reviewed semen analysis PT results from 03/10/2023 through 06/11/2025. The inspector failed to find semen analysis PT results for 05/01/2024 through 06/11/2025. 3. The inspector requested semen analysis PT records from 05/01/2024 through 06/11/2025 in the specialty of Hematology from the LD. The LD confirmed the laboratory was not enrolled with an HHS approved PT provider for semen analysis in the specialty of Hematology from 05/01/2024 through 06/11/2025 and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 06/11/2025 at 11:00 AM.
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 record review and an interview with the Laboratory Director (LD), the laboratory failed to follow written policies and procedures to assess the competency of Testing Personnel (TP) #3 for the high complexity semen analysis testing procedures performed in the specialty of Hematology. This deficient practice had the potential to affect 135 out of 135 patient semen analysis tests performed from 01/01/2024 through 12/31/2024. Findings Include: 1. Review of the laboratory's Form CMS-209, approved via signature and date by the Laboratory Director on 06/11/2025 and provided on the date of the inspection found three individuals, qualified and listed as a TP to perform semen analysis testing procedures. 2. Review of the laboratory's "Annual Review Competency Checklist" approved via signature and date by the Laboratory Director on 12/31/2018 and provided on the date of the inspection found the following: "...Procedure...schedule reviews annually..." 3. Review of the laboratory's competency assessment documentation, provided on the date of the inspection, failed to find annual competency assessment records for TP #3 for 2024. 4. The inspector requested 2024 competency records for TP #3 from the LD. An interview with the LD confirmed that the lab failed to perform a 2024 competency assessment for TP #3 and was unable to provide the requested documentation. The interview occurred on 06/11/2025 at 11:00 AM.