Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2299741	09/10/2026
Name of Provider or Supplier	**Street Address, City, State**	
Derbala Institute For Reproductive Immunology	20480 Vernier Road, Harper Woods, MI	

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
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 interview with the Technical Supervisor (TS) and General Supervisor (GS), the laboratory failed to follow its established competency assessment process to ensure competency policy was assessed and documented annually for 1 (TP1) of 5 testing personnel reviewed (TP1). Findings include: 1. Review of the CMS-209 form identified TP1 as Testing Personnel for high-complexity testing. 2. Review of the laboratory's Competency Assessment form revealed that competency re-evaluation is to be "performed after one year post-hire and annually thereafter." 3. Record review of competency assessment documentation for TP1 revealed competency assessments dated March 11, 2024, September 15, 2024, and March 17, 2025. Documentation of a competency assessment for TP1 for 2026 was requested; none was provided. 4. During an interview on September 10, 2026, at 4:15 PM, the TS and GS confirmed that a competency assessment had not been completed for TP1 in 2026.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3)

	Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: . Based on observation and interview with the Technical Supervisor (TS) and General Supervisor (GS), the laboratory failed to ensure 3 of 4 temperature-monitoring devices were calibrated. Findings include: 1. During a tour of the laboratory on September 10, 2026, at 10:25 AM, the surveyor observed three temperature-monitoring devices with expired calibration dates: a. In the Main Laboratory, a Traceable brand thermometer used to monitor the Panasonic refrigerator had a calibration due date of March 13, 2026. b. In the Main Laboratory, a Traceable brand thermometer used to monitor room temperatures had a calibration due date of March 13, 2026. c. In the Culture Room, a Traceable brand temperature-monitoring device used with the water bath had a calibration expiration date of February 2026. 2. During interviews on September 10, 2026, at 11:06 AM, the TS and GS confirmed the expired calibrations for the temperature-monitoring devices.