

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0690940	(X3) Date Survey Completed 06/25/2026
Name of Provider or Supplier Reproductive Specialty Center	Street Address, City, State 2350 N Lake Dr Ste 303, Milwaukee, WI	
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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on surveyor observation of one of one container of reagent strips for urinalysis in the clinic, review of the manufacturer's instructions for use, and interview with testing personnel (Staff A), the laboratory used expired Siemens Multistix 10SG reagent strips for patient testing performed after October 31, 2024. Findings include: 1. Observation on June 25, 2026, at 11:40 AM of the single container of Siemens Multistix 10SG reagent strips showed the container label showed the strips were from lot 305036 and the expiration date was 2024-10-31 (October 31, 2024). The container was not labeled with the date the container was opened. 2. Review of the Siemens instructions for use for the 10SG reagent strips showed the procedure included, "Check the expiration date on the Reagent Strip bottle. If the date has passed, discard and get a new bottle" and, "Record the opening date on the label." 3. Interview with Staff A on June 25, 2026, at 11:45 AM confirmed personnel used the expired reagent strips for a patient test on June 24, 2026, and confirmed there were no other reagent strips available for use in the clinic that were not past the expiration date.
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 surveyor review of competence evaluation records and interview with testing personnel (Staff A), records were not available showing the director evaluated the competency of the personnel performing responsibilities in four of four roles other than testing personnel. Findings include: 1. Review of competence evaluation records showed no evidence the laboratory director evaluated personnel assigned clinical consultant, technical consultant, technical supervisor, or general supervisor responsibilities to ensure personnel were competent in performing their assigned responsibilities. 2. Interview with Staff A on June 25, 2026, at 10:45 AM confirmed documentation was not available showing evaluation of competence in completing the assigned roles of clinical consultant, technical consultant, technical supervisor, and general supervisor.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor observation of stains in the laboratory and interview with testing personnel (Staff A), testing personnel used four of four stains in the laboratory when the stain reagents had exceeded their expiration dates in 2025. Findings include: 1a. Observation in the laboratory on June 25, 2026, at 11:10 AM revealed a Hemacolor Stain Set, Lot 3241 with an expiration date of 2025-02-28 (February 28, 2025). The kit included three staining reagents: methanol fixative, eosin stain, and thiazine stain. 1b. Observation of the 0.5% Eosin Y Solution in the laboratory on June 25, 2026, at 11:15 AM revealed the stain lot number was SLCR5130 with an expiration date of 2025-03-01 (March 1, 2025). 2. Interview with Staff A on June 25, 2026, at 11:40 AM confirmed personnel used the four stain reagents for patient testing after February and March 2025, after the stain reagents exceeded their expiration dates.
D6080	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(c) (c) The laboratory director must: (c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and (c)(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with testing personnel (Staff A), the laboratory director was not on site in the last six months. Three of three documented visits occurred prior to November 11, 2025. Findings include: 1. Review of records documenting onsite visits by the laboratory director showed they performed director responsibilities during three visits to the laboratory in 2025 on April 25, September 1, and November 11. The laboratory had no documentation showing the

director made an onsite visit after November 11, 2025. 2. Interview with Staff A on June 25, 2026, at 12:10 PM confirmed the director had not been onsite in the last six months.