Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D1000952	03/12/2026
Name of Provider or Supplier	**Street Address, City, State**	
Randy S Morris, Md, Sc	3 N Washington St, Naperville, IL	

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
D0000	A recertification survey was conducted on 03/12/2026. The laboratory was found to be out of compliance with the CLIA regulations (42 CFR Part 493) for the following condition-level deficiencies: D6168 - 42 C.F.R. 493.1487 Condition: Laboratories performing high complexity testing; testing personnel
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of laboratory records, American Association of Bioanalysts-Medical Laboratory Evaluation (AAB-MLE) proficiency testing (PT) records, lack of documentation, and interview with the laboratory director (LD); the laboratory failed to perform biannual method accuracy evaluations for one of three semen analysis measurements performed, sperm motility, in the specialty of hematology from 2024 through the date of survey, 03/12/2026. Findings include: 1. Review of laboratory records revealed the laboratory performed semen analysis measurements including sperm count, sperm motility, and sperm morphology in the specialty of hematology. 2. Review of AAB-MLE PT records revealed the laboratory lacked biannual method accuracy evaluations for the semen analysis measurement of sperm motility. 3. Interviews with the LD on 03/12/2026, at 10:09 am, confirmed the laboratory failed to perform biannual method accuracy evaluations for one of three semen analysis measurements performed, sperm motility, in the specialty of hematology from 2024 through the date of survey, 03/12/2026.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12)

	(e)(12) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results; This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, and interview with the laboratory director (LD); the LD failed to ensure that three of four testing personnel (TP) were qualified to perform the high complexity semen analysis measurements of sperm count and sperm motility in the specialty of hematology from 2024 through the date of testing, 03/12/2026. Findings include: 1. Review of laboratory policies and procedures revealed the policy titled, "Laboratory Director", which stated, under "Personnel Duties", "Ensure that prior to testing patient specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results". 2. Review of laboratory personnel competency records revealed all four TP had competencies completed for semen analysis testing, including sperm count and sperm motility, from 2024 through the date of survey, 03/12/2026. 3. Review of laboratory personnel records revealed three of four TP (TP #2, TP #3, and TP #4) lacked the educational qualifications to perform high complexity testing (see D6171). 4. Interview with the LD on 03/12/2026, at 10:42 am, confirmed the LD failed to ensure that three of four TP were qualified to perform the high complexity semen analysis measurements of sperm count and sperm motility in the specialty of hematology from 2024 through the date of testing, 03/12/2026.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on direct observation, review of laboratory records, lack of documentation, and interview with the laboratory director (LD); the laboratory failed to ensure three of four testing personnel (TP) were qualified for high complexity semen analysis measurements of sperm count and sperm motility testing in the specialty of hematology (see D6171).
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; or (b)(2)(i) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(2)(ii) Be qualified under the requirements of 493.1443(b)(3) or 493.1449(c)(4) or (5); or (b)(3)(i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution or (b)(3)(ii) Have education and training

	equivalent to that specified in paragraph (b)(2)(i) of this section that includes (b)(3)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either (b)(3)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(3)(ii)(A)(2) 24 semester hours of science courses that include (b)(3)(ii)(A)(2)(i) 6 semester hours of chemistry; (b)(3)(ii)(A)(2)(ii) 6 semester hours of biology; and (b)(3)(ii)(A)(2)(iii) 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(3)(ii)(B) Have laboratory training that includes: (b)(3)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or (b)(3)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or (b)(4) Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(5) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(6) For blood gas analysis (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section; or (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution. (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (f) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory records, lack of documentation, and interview with the laboratory director (LD); the laboratory failed to ensure three of four testing personnel (TP) were qualified for high complexity semen analysis measurements of sperm count and sperm motility testing in the specialty of hematology. Findings include: 1. Upon a tour of the laboratory on 03/12/2026, at 10:42 am, the surveyor observed semen analysis testing being performed utilizing a Hamilton Thorne (HT) Computer Assisted Sperm Analysis (CASA) CEROS II System (Serial Number: 7310). 2. Review of laboratory personnel records revealed three of four TP (TP #2, TP #3, and TP #4) lacked the educational qualifications to perform high complexity semen analysis testing on the HT CASA CEROS II System. 3. Interview with the LD on 03/12/2026, at 12:20 pm, confirmed the laboratory failed to ensure three of four TP were qualified for high complexity semen analysis testing in the specialty of hematology.