

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2008505	(X3) Date Survey Completed 08/29/2025
Name of Provider or Supplier Care Fertility	Street Address, City, State 1250 8th Avenue Suite 365, Fort Worth, TX	
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	The facility was found to be out of compliance with CLIA regulations 42 CFR Part 493. CONDITION LEVEL DEFICIENCIES were found to be out of compliance: 493.1487 Testing Personnel, high complexity
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 review of American Association of Bioanalysts (AAB) Medical Laboratory Evaluation proficiency testing (PT) records, and confirmed in interview, the laboratory failed to attest to the routine integration of proficiency samples into the patient workload for two of two Embryology, Andrology and Fetal events in 2024 (Events S1 and S2) and one of one Embryology, Andrology and Fetal event in 2025 (Event S1). Findings included: 1. Review of AAB PT records Embryology, Andrology and Fetal events in 2024 (Events S1 and S2) and 2025 (Event S1): "Attestations The undersigned analyst attests that samples were tested in the same manner as patient samples." 2. Further review of Embryology, Andrology and Fetal PT records for 2024 and 2025 revealed the following: Events S1 2024 the testing analyst and director or director's designee failed to sign the attestation statements. Event S2 2024 the testing analyst failed to sign the attestation statements. Event S1 2025 the testing analyst and director or director's designee failed to sign the attestation statements. 3. During an interview on 08/29/2025 at 10:53 a.m., the Technical Supervisor, after a review of records confirmed the laboratory failed to attest to the routine integration of proficiency samples into the patient workload.</p>
D2015	TESTING OF PROFICIENCY TESTING SAMPLES

CFR(s): 493.801(b)(5)(6)

(b)(7) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

This STANDARD is not met as evidenced by:

Based on review of laboratory policy, American Association of Bioanalysts (AAB) Medical Laboratory Evaluation proficiency testing (PT) records, and confirmed in interview, the laboratory failed to retain a copy of all Embryology, Andrology and Fetal PT records for two of two events in 2024 (Events S1 and S2) and one of one event in 2025 (Event S1). Findings included: 1. Review of the laboratory's policy "Evaluation of AAB Proficiency Testing" stated: "Quality Assurance (QA) programs developed for the Embryology, Andrology and Endocrinology Laboratories to provide a framework whereby each laboratory assures a high quality of accurate, reliable and prompt service to our patients and their physicians. It is the policy of the Center for Assisted Reproduction to monitor and evaluate the ongoing and overall quality of the testing process. Quality control materials will be used to ensure reliability of testing. Proficiency testing through the American Association of Bioanalysts (AAB) is performed throughout the year and reviewed by the Laboratory Director and/or Laboratory Manager and/or Laboratory Supervisor. The first objective of this program is to identify trends and patterns of performance or potential problems. Second, to implement corrective action and follow-up to maintain the desired level of quality. Finally, to assure safety of those performing the tests which requires the handling of biologic specimens. ... All PT results should be retained for two years." 2. Review of AAB PT records revealed the laboratory failed to retain a copy of the following Embryology, Andrology and Fetal PT records for two of two events in 2024 (Events S1 and S2) and one of one event in 2025 (Event S1). AAB original forms Test records Attestation statements 3. During an interview on 08/29/2025 at 10:53 a.m., the Technical Supervisor, after a review of records confirmed the laboratory failed to retain a copy of all Embryology, Andrology and Fetal PT records for two of two events in 2024 (Events S1 and S2) and one of one event in 2025 (Event S1).

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

(b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on review of laboratory policy, laboratory records, personnel records, and confirmed in staff interview, the technical consultant failed to evaluate and document semiannual competency assessments for one of three testing persons (TP-2) responsible for moderate complexity testing in 2024. Findings included: 1. Review of the laboratory's policy "Technical Supervisor Responsibilities" stated: "(9) Evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens." 2. Review of laboratory records revealed the following testing as moderate complexity: IVOS computer assisted semen analyzer (CASA) 3. Review of personnel records revealed a hire date of 04/2023 and documented training on the IVOS CASA analyzer on 05/2023. Further review of the personnel records revealed

	<p>an annual competency assessment performed on 09/26/2024. The technical supervisor failed to evaluate and document a semiannual competency assessment for TP-2 responsible for high complexity in 2023. On 08/29/2025 at 10:53 a.m. in the conference room, the laboratory was asked to provide documentation of the semiannual competency assessment for 2023. None was provided. 4. During an interview on 08/29/2025 at 10:53 a.m. in the conference room, the Technical Supervisor, after a review of the records confirmed the above findings.</p>
<p>D6127</p>	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)</p> <p>(b)(9) Evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policy, laboratory records, personnel records, and confirmed in staff interview, the technical supervisor failed to evaluate and document semiannual competency assessments for one of three testing persons (TP-2) responsible for high complexity testing in 2024. Findings included: 1. Review of the laboratory's policy "Technical Supervisor Responsibilities" stated: "(9) Evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens." 2. Review of laboratory records revealed the following testing as high complexity: Manual semen analysis (sperm counts and motility) 3. Review of personnel records revealed a hire date of 04/2023 and documented training for manual semen analysis (sperm counts and motility) on 06/2023. Further review of the personnel records revealed an annual competency assessment performed on 09/26/2024. The technical supervisor failed to evaluate and document a semiannual competency assessment for TP-2 responsible for high complexity in 2023. On 08/29/2025 at 10:53 a.m. in the conference room, the laboratory was asked to provide documentation of the semiannual competency assessment for 2023. None was provided. 4. During an interview on 08/29/2025 at 10:53 a.m. in the conference room, the Technical Supervisor, after a review of the records confirmed the above findings.</p>
<p>D6168</p>	<p>TESTING PERSONNEL CFR(s): 493.1487</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on review of CMS (Centers for Medicare and Medicaid Services) 209 form, personnel records, and interview with staff, the laboratory failed to ensure one of three testing persons (TP-1) met the requirements to perform high complexity testing. Refer to D6171.</p>
<p>D6171</p>	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b)</p>

(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) (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 review of CMS (Centers for Medicare and Medicaid Services) 209 form, personnel records, and interview with staff, the laboratory failed to ensure one of three testing persons (TP-1) met the requirements to perform high complexity testing. Findings included: 1. Review of the CMS-209 form listed TP-1 as performing high complexity testing. 2. Review of personnel records for TP-1 included college transcripts. The educational documents did not meet the qualifications for serving as a high complexity testing person. 3. During an interview on 08/29/2025 at 10:53 a.m., the Technical Supervisor, after a review of records confirmed the laboratory failed to ensure one of three testing persons met the requirements to perform high complexity testing.