

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 14D2158039	<b>(X3) Date Survey Completed</b> 06/26/2024
<b>Name of Provider or Supplier</b> Advanced Fertility Center Of Chicago	<b>Street Address, City, State</b> 4920 N Central Ave - Ste 2c, Chicago, IL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D3037</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation and interview with testing personnel 2 (TP 2); the laboratory failed to retain proficiency testing records for two of two events (Event 1 and Event 2) in 2023. Findings include: 1. Review of the "Advanced Fertility Center of Chicago Reproductive Laboratories Standard Operating Procedure" revealed the following: "III. Quality Assurance / Performance Parameters: A. Technical Staff: ...4. Proficiency testing a. Inter technician proficiency - Participate in AAB proficiency test twice annually. b. Intra technician proficiency for sperm counts, motility, progression and morphology performed twice annually." 2. Review of laboratory records revealed no documentation of the laboratory's "AAB Medical Laboratory Evaluation (AAB) - Event 1" 2023, test sample results. 3. Review of laboratory records revealed no documentation of the laboratory's "AAB Medical Laboratory Evaluation - Event 2" 2023, test sample worksheets or results. 4. On 06/26 /2024, at 11:28 a.m., an interview with TP 2 revealed, "Event 1 was a self-evaluation, not sent out to AAB and Event 2 was also a self- evaluation that was compared to another lab, but they did not receive the results."</p>
<b>D5221</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation and interview with</p>

testing personnel 2 (TP 2); the laboratory failed to document corrective actions for one of one semen analysis proficiency testing (PT) event (Event 2) in 2022. Findings include: 1. Review of laboratory proficiency testing records, "AAB Medical Laboratory Evaluation (AAB) - Embryology, Andrology & Fetal S2 - 10/25/2022" revealed the following information: Sperm Count: Score - 100 Sperm Morphology: Score - 100 Sperm Motility: Score - 50 2. Review of laboratory records and no documentation revealed the laboratory failed to retain AAB corrective action documentation for the Sperm Motility Score - 50 for Event 2, 2022. 3. On 06/26/2024, at 11:20 a.m., an interview with TP 2 revealed, "No corrective action records on file."

**D5401**

**PROCEDURE MANUAL**  
CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:  
Based on review of laboratory records, lack of documentation and interview with testing personnel 2 (TP 2); the laboratory failed to follow the written procedure for reporting general specimen observation of hematology semen specimens for five of five final patient reports reviewed in 2022 through 2024. Findings include: 1. Review of the laboratory's standard operating procedure marked, "Advanced Fertility Center of Chicago ...Reproductive Laboratories - Semen Analysis - PN-LA-AND-105 Version Date: 2018" revealed the following information: "E. Semen Analysis Procedure ...2. Preliminary Semen Observation: ...e. Make note on the report of other observation such as the color of the semen, the presence of gel bodies, etc. ... VIII. Releasing Semen Analysis Report: ...4. Any comments on the worksheet will be typed into the final report. B. Reviewing final semen analysis report. 1. Compare all the information on the worksheet matches the information transfer or type on the report is accurate." 2. Laboratory records revealed five Semen Analysis Final patient reports for review in 2022 through 2024. a) Patient A: Accession Number - 68340, Collection / Report Date: 06/10/2022 b) Patient B: Accession Number - 90801, Collection / Report Date: 10/13/2022 c) Patient C: Accession Number - 123569, Collection / Report Date: 04/25/2023 d) Patient D: Accession Number - 147254, Collection / Report Date: 08/30/2023 e) Patient E: Accession Number - 182541, Collection / Report Date: 05/02/2024 3. Review of laboratory records and lack of documentation revealed the laboratory failed to follow the laboratory's standard operating procedure for reporting general specimen observation for five of five (Patient A through Patient E) final patient reports reviewed in 2022 through 2024. - Patient A: Documented worksheet comments, "Decreased motility may be due to either non-viable or non-motile sperm. Gel bodies observed." Documented final report comments: "Gel bodies present in the sample." Final report comments for Patient A failed to report, "Decreased motility may be due to either non-viable or non-motile sperm." - Patient A through Patient E: No color of semen documented on the worksheets or final reports. Abnormal sperm morphology documented on worksheets; not reported on the final reports. Dilution Factor and Final Mean reported on final reports; not documented on the worksheets. 4. On 06/26/2024, at 12:00 p.m., TP 2 confirmed the above findings.

**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 review of laboratory records, lack of documentation, CMS-209 (Laboratory Personnel Report), and interview with testing personnel (TP 2); the laboratory failed to ensure two of three testing personnel met the qualification requirements for hematology semen analysis testing in 2022 through 2024. (Refer to 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 have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent

stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (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; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:

Based on review of laboratory records, lack of documentation, CMS - 209 (Laboratory Personnel Report), and interview with testing personnel (TP 2); the laboratory failed to ensure two of three testing personnel were qualified for hematology semen analysis testing in 2022 through 2024. Findings Include: 1. Review of the "Advanced Fertility Center of Chicago Reproductive Laboratories Standard Operating Procedure" revealed the following: "III. Quality Assurance / Performance Parameters: A. Technical Staff: 1. Staff must be authorized for performing any semen analysis before undertaking any procedure without direct supervision." 2. Review of the CMS-209 (06/26/2024) and lack of documentation revealed the laboratory failed to retain education transcripts to qualify two (TP 2 and TP 3) of three TP for semen analysis testing in 2022 through 2024. 3. On 06/26/2024, at 9:00 a.m., TP 2 confirmed the above findings.