| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 14D2158039 | 12/08/2020 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Advanced Fertility Center Of Chicago | 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.

| (X4) ID Prefix Tag | Summary Statement of Deficiencies |
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| **D5221** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(d)<br><br>All proficiency testing evaluation and verification activities must be documented.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review, proficiency testing (PT) reports, and an interview with the laboratory director (LD), the laboratory failed to document verification procedures for the semen analysis testing performed. Findings include: 1. The American Association of Bioanalysts (AAB)-PT program reports for event 2 of 2019, events 1 & 2 of 2020, and laboratory's PT policies and procedures manual were reviewed. 2. The PT policy stated the following under Section IV. Proficiency Testing Review, #B.: "A Proficiency Testing Review form should be filled out for each testing event as record of review and attached directly to the results. 3. The AAB-PT program reports revealed the following: *The laboratory failed to use the PT Review form for 3 out of 3 events; *The PT test results for 3 out of 3 events were not documented; and *The laboratory failed to use the PT Review form to evaluate and document PT failures. 4. Interview with the LD on 12/08/2020 at 12:30 PM confirmed the above findings. |
| **D5415** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(c)<br><br>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.<br><br>This STANDARD is not met as evidenced by: |

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| | Based on direct observation, record review, and an interview with the laboratory director (LD); the laboratory failed to label reagents and solutions used in Semen Analysis for morphology identification. Findings include: 1. The laboratory's procedures manual was reviewed. 2. On 12/08/2020 at 11:00 AM during a tour of the laboratory, the surveyor observed 3 filled blank bottles and a slide staining rack situated on a lab table by a sink. The surveyor was informed that these were the reagents and stains from the Quick III stain kit used to stain slides for semen analysis. The LD continued to explain that the kit's reagents and stains are poured into smaller bottles which remain on the work bench for daily use. 3. The laboratory failed to label the blank bottles containing reagents and stain solutions with the following required information: *Identity and when significant, titer, strength or concentration. *Storage requirements. *Preparation (date opened) and expiration dates. *Other pertinent information required for proper use. 4. The procedures manual failed to include instructions to ensure all reagents and staining solutions are labeled with the required information when in-use for patient testing. 5. Interview with the LD on 12/08/2020 at 11:30 PM confirmed the above findings. |
| **D5447** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(3)(i)(g)<br><br>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review, lack of documentation, and an interview with the laboratory director (LD), the laboratory failed to document all control procedures when performing Semen Analysis each day of testing, affecting 6 out of 6 patients. Findings include: 1. The laboratory procedures manual, the Daily Andrology lists, and patient test logs were reviewed. 2. The laboratory used the "Daily Andrology list" to record the High and Low quality control (QC) bead counts. 3. The patients' test log and Daily Andrology list revealed the QC Beads' lot numbers and expiration dates were not recorded each day of testing for 6 out of 6 patients. 4. Further review of the Daily lists revealed the lot numbers and expiration dates of the QC Beads used were not recorded from May of 2019 through December 2020. 5. The "Semen Analysis" policies and procedures failed to include the documenting of control lot information each day of testing. 6. Interview with the LD on 12/08/2020 at 12:30 PM confirmed the above findings. |
| **D5471** | CONTROL PROCEDURES<br>CFR(s): 493.1256(e)(1)(g)<br><br>(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. |

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| | This STANDARD is not met as evidenced by:<br>Based on record review and an interview with the laboratory director (LD), the laboratory failed to document the lot number of commercially prepared reagents and stains, when opened, as well as graded reactivity, when performing Semen Analysis, affecting 6 out of 6 patients. Findings include: 1. The laboratory procedures manual, Quick III kit package insert, the Daily Andrology lists, and patient test logs were reviewed. 2. The laboratory used the "Daily Andrology list" to record the Semen analysis morphology slide check. 3. The patients test logs and daily andrololgy list revealed the following: *The lot numbers and expiration dates of the staining reagents and solutions were not recorded, and *The laboratory recorded "check marks" as an assessment of the slides' quality for each date of testing for 6 out of 6 patients. 4. Further review of the Daily lists showed the lot information and slide quality assessments had not been documented from May 2019 through December 2020. 5. Review of the package insert under section "TECHNIQUE", the manufacturer provides a stain reactivity color chart as guidance to determine slide stain quality. The laboratory failed to document stain reactivity as instructed by the manufacturer to assess stain quality. 6. The "Semen Analysis" policies and procedures failed to include the documenting of slide quality and the lot information of staining reagents each day of testing. 7. Interview with the LD on 12/08/2020 at 12:30 PM confirmed the above findings. |
| **D6102** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(12)<br><br>The laboratory director must 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.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and an interview with the laboratory director (LD), the LD failed to ensure prior to testing patients' specimens, all personnel have the appropriate training and have demonstrated that they can perform all testing operations reliably to provide and report accurate results, affecting 1(TP2) out of 2 testing personnel (TP). Findings include: 1. The laboratory personnel documents, the Laboratory Personnel Report (CMS 209), and patients' test logs were reviewed. 2. The CMS 209 list 2 TP (TP1 and TP2) performing Semen Analysis. 3. The personnel records and test logs revealed TP2 training was not completed and TP2 was performing semen analysis testing without supervision. 4. The LD failed to complete the training and competency evaluation of TP2 prior to testing patients' specimens. 5. Interview with the LD on 12 /08/2020 at 12:30 PM confirmed the above findings. |