

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  14D0920474	<b>(X3) Date Survey Completed</b>  01/29/2020
<b>Name of Provider or Supplier</b>  Advanced Reproductive Health Centers Chicago Ivf	<b>Street Address, City, State</b>  10811 W 143rd St Ste 120, Orland Park, 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>D5024</b>	<p>HEMATOLOGY CFR(s): 493.1215</p> <p>If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on review of laboratory records and interview with testing personnel (TP) #1; the laboratory failed to meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493.1281 through 493.1299. Findings Include: 1. The laboratory's control procedures failed to detect errors due to operator performance and monitor the accuracy and precision of test performance over time due to variance in operators for semen analysis testing. See D5441. 2. The laboratory failed to ensure two levels of quality control (QC) materials were ran each day of testing for 2 of 6 patient testing dates reviewed for semen analysis testing. See D5447. 3. The laboratory failed to test the staining material Spermac stain for intended reactivity each day of use for semen analysis testing for 5 of 5 patient testing dates reviewed. See D5473. 4. The laboratory failed evaluate patient testing when Accu-bead controls failed to meet the laboratory's established criteria for 5 of 5 dates identified on quality assurance incident reports. See D5783.</p>
<b>D5441</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1)</p>

Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of laboratory records and interview with testing personnel (TP) #1; the laboratory's control procedures failed to detect errors due to operator performance and monitor the accuracy and precision of test performance over time due to variance in operators for semen analysis testing. Findings include: 1. Review of patient testing found for 1 of 5 patient testing dates reviewed found the daily accu-bead controls were performed by an individual not authorized to perform semen analysis testing based on review of the CMS-209 laboratory personnel report. Patient Identification Test Date QC Log P1 01-24-2020 Performed by a nurse not identified on the CMS-209 2. Review of the January 2020 "Q.C. Log-Accubead Daily Count Log (v. 12.19.02)" identified 5 additional patient testing dates (01-20-20, 01-22-20, 01-23-20, 01-24-20, and 01-27-20) where accu-bead quality controls were performed by individuals not authorized to perform semen analysis testing. 3. Review of the "Semen Specimen Accession Log" for the above mentioned testing dates identified 19 additional patients (P6 through P24) that had semen analysis testing performed when accu-bead quality controls were performed by individuals not authorized to perform semen analysis testing. 4. On survey date 01-29-2020, at 2:10 pm, TP#1 confirmed additional nursing staff performed accu-bead controls on the above mentioned dates but were not authorized to perform semen analysis testing.

**D5447**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(d)(3)(i)(g)

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.

This STANDARD is not met as evidenced by:

Based on review of laboratory records and interview with testing personnel (TP) #1; the laboratory failed to ensure two levels of quality control (QC) materials were ran each day of testing for 2 of 6 patient testing dates reviewed for semen analysis testing. Findings include: 1. Review of patient testing found for 2 of 6 patient testing dates the laboratory failed to perform and document 2 levels of accu-bead controls on the laboratory's quality control log. Patient Identification Test Date QC Log P5 12-13-2019 No QC documented P27 06-21-2019 No QC documented 2. Review of the "Semen Specimens Accession Log" revealed 5 patients' had semen analysis testing performed when the accu-bead controls were not performed and documented (12-13-2019 and 06-21-2019). 3. On survey date 01-29-2020, at 2:10 pm, TP#1 confirmed the laboratory failed to perform and document two levels of accu-bead quality control materials for the dates identified.

**D5473**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(e)(2)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of laboratory records and interview with testing personnel (TP) #1; the laboratory failed to test the staining material Spermac stain for intended reactivity each day of use for semen analysis testing for 5 of 5 patient testing dates reviewed. Findings Include: 1. Review of patient test results for semen analysis found for 5 of 5 testing dates reviewed Spermac stain reactivity was not performed or documented. Patient Identification Test Date P1 01-24-2020 P2 02-16-2018 P3 09-21-2018 P4 03-27-2019 P5 12-13-2019 2. Review of the manufacturer's product insert for Spermac stain found under the section "staining procedure" that the testing personnel should observe the following characteristics: acrosome = dark green nucleus = stained red equatorial region = pale green midpiece and tail = green 3. Review of the patient test volume worksheet found 467 patients were tested for semen analysis in 2019 when no reactivity of Spermac stain was performed and documented. 4. On survey date 01-29-2020, at 2:10 pm, TP#1 confirmed the laboratory failed to test and document staining reactivity for Spermac stain each day of patient testing for semen analysis.

**D5783**

**CORRECTIVE ACTIONS**

CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:

Based on review of laboratory records and interview with testing personnel (TP) #1; the laboratory failed evaluate patient testing when accu-bead controls failed to meet the laboratory's established criteria for 5 of 5 patient testing dates identified in the quality assurance incident reports. Findings Include: 1. Review of the laboratory's "Quality Assurance Incident Reports" (QAIR) identified 4 reports were the laboratory identified that they failed to perform accu-bead controls each day of patient testing for semen analysis. QAIR Date 06-21-2019 April 2019 (4-2-19, 4-16-19) 03-28-2018 April 2018 (4-15-18) 2. Review of the corrective actions taken for 4 of 4 incident reports found the laboratory failed to determine if patient test results were adversely affected by the failure to perform accu-bead quality controls for semen analysis. 3. On survey date 01-29-2020, at 2:10 pm, TP#1 confirmed the laboratory failed to evaluate patient testing on each date when accu-bead controls failed to be performed.