

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 14D2046862	<b>(X3) Date Survey Completed</b> 02/20/2019
<b>Name of Provider or Supplier</b> Fertility Babies	<b>Street Address, City, State</b> 14434 John Humphrey, 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>D2015</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the technical supervisor (TS); the laboratory failed to retain attestation statements for 4 of 4 events in 2017 through 2018 for semen analysis. Findings Include: 1. Review of the American Association of Bioanalysts (AAB) records from 2017 through 2018 found the laboratory failed to retain attestation statements for semen analysis testing for 4 of 4 proficiency testing (PT) events. 2. On survey date 2-20-2019, at 2:45 pm, the TS confirmed the laboratory failed to retain attestation statement documents for 4 of 4 PT events.</p>
<b>D2128</b>	<p>HEMATOLOGY CFR(s): 493.851(e)</p> <p>(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a</p>

proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

This STANDARD is not met as evidenced by:

Based on review of laboratory records and interview with the laboratory technical supervisor (TS); the laboratory failed to perform corrective actions for unsatisfactory semen analysis proficiency testing (PT) performance in 2018 for 1 of 2 events. Findings Include: 1. Review of the laboratory's policy and procedure manual identified the policy, "Proficiency Testing (PT)", which stated the following on page 21: "Every proficiency test failure will be investigated following the Proficiency Test Failure Investigation Checklist and followed up by the laboratory director." 2. Review of American Association of Bioanalysts (AAB) PT documentation identified the laboratory failed to achieve a satisfactory score for sperm counts in event 1 of 2018 with an analyte score of 50%. 3. Review of PT documentation identified the laboratory director signed off on the PT Evaluation form for AAB PT event 1 of 2018, on 6-11-2018, however no corrective action was documented. 4. On survey date 02-20-2019, at 2:45 pm, the TS confirmed that no corrective actions had been taken for the sperm count analyte failure in event 1 of 2018.

**D5417**

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT  
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on direct observations, laboratory records, and interview with the technical supervisor (TS); the laboratory failed to monitor testing supplies by using expired reagents for semen analysis testing in 2017 through the date of survey (2-20-2019) in 2019. Findings Include: 1. Direct observation of testing supplies during the tour of laboratory facility with the TS on February 20, 2019, at 11:46 am, identified the Accu-beads used for semen analysis quality control testing which expired on 12/2017. a. Accu-beads, Lot # 121713181, Expiration Date: 12/2017 b. Accu-beads, Lot # 121713181, Expiration Date: 12/2017 2. Direct observation of testing supplies during a tour of the laboratory facility with the TS on February 20, 2019, at 2:07 pm, identified the andrology staining kit used for semen analysis testing had expired in 03 /2017. a. STAT III Andrology Stain, Lot#85317,85318, 85319, Expiration Date: 3 /2017 3. Review of the laboratory testing accession log for 2018 through the date of survey (02-20-2019) found 8 of 8 patients were tested when Accu-beads and STAT III Andrology stain reagents were expired. 4. On survey date 2-20-2019, at 2:45 pm, the above findings were confirmed by the TS.

**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 interviews with the technical supervisor (TS); the laboratory failed to test staining material for intended reactivity each day of use for semen analysis testing for 5 of 5 patient test dates reviewed. Findings Include: 1. Review of the laboratory policy and procedure manual identified the procedure, "Stain Quality Criteria", which states observations of stain quality should be recorded on the stain quality control sheet. 2. Interview with the TS on 2-20-2019, at 12:30 pm, confirmed the laboratory does not have a stain quality control sheet to document staining quality. 3. Review of patient test results for semen analysis found for 5 of 5 patient test dates reviewed STAT III Andrology Stain reactivity was not performed or documented. Patient Identification Test Date P1 02-09-2019 P2 12-28-2018 P3 04-10-2018 P4 10-27-2017 P5 07-22-2017 4. On 2-20-2019, at 2:45 pm, the TS confirmed the above findings that staining quality is not documented as acceptable for patient testing as described in the laboratory procedure.

**D5481**

**CONTROL PROCEDURES**

CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (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 the technical supervisor (TS); the laboratory failed to ensure two levels of quality control (QC) materials were acceptable prior to reporting patient test results for semen analysis testing for 3 of 7 test dates reviewed. Findings Include: 1. Review of the laboratory policy and procedure manual identified the policy, "Description of the Internal and External Quality Control (QC) System Currently in Use in the Andrology Laboratory", which states, "Results are recorded on the Accu-bead Counts Log form. The control results should be verified for acceptability prior to reporting results." 2. Review of quality control records for semen analysis testing found Accu-beads quality control results were outside the manufacturer's acceptable range for 3 of 7 dates reviewed when patient testing was performed for sperm counts. Date Control Range Result 04-10-2018 15.5-20.5 M/ml 15 M/ml 07-08-2017 15.5-20.5 M/ml 15 M/ml 10-06-2018 15.5-20.5 M/ml 15 M/ml 3. Review of patient test records for the above mentioned dates found 3 patients were tested for semen analysis when quality control values were outside the manufacturer's acceptable range and the laboratory's quality control acceptance procedure was not followed. 4. Interview with the TS on 02-20-2019, at 2:45 pm, confirmed quality control results were outside the acceptable range for sperm count quality control testing for the above mentioned dates when patient testing was reported for semen analysis.