

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2146054	(X3) Date Survey Completed 09/26/2018
Name of Provider or Supplier Alabama Center For Reproductive Medicine, Pllc	Street Address, City, State One Independence Plaza, Suite 810, Homewood, AL	
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
D6093	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's policy and procedure manual, a lack of documentation of quality control, a review of maintenance/temperature logs, a review of the Certificate of Analysis from Vitrolife for the MicroCell, and interviews with the Laboratory Director and Testing Personnel #2 (TP #2), the surveyor determined the Laboratory Director failed to establish a quality control program to ensure monitoring of quality control for semen analysis counts (using the MicroCell) and manual Diff Quik staining for sperm morphology were performed at least each day of patient testing, in the absence of development of an IQCP (Individualized Quality Control Plan). This affected the semen analysis testing, performed by the laboratory. The findings include: 1. During the tour of the laboratory at 10:10 AM on 9/26/18, the surveyor inquired of the test menu and what observations were made when a semen analysis was performed. TP #2 stated the volume of specimen, pH, appearance, viscosity, motility, sperm count, using the MicroCell slides, and a manual Diff Quik stain, used to observe the sperm morphology (the head, mid-section and tail) were included in a semen analysis. 2. At 10:15 AM, when asked about the quality control of the MicroCell, the Laboratory Director stated the laboratory performed a monthly intra-laboratory technician comparison, using a patient's specimen. According to the Laboratory Director and TP #2, the quality control of the Diff Quik stain consisted of checking for contamination (bacteria) once per week. The Laboratory Director stated the quality of the stain was not monitored by the laboratory. Additionally, the Laboratory Director stated there was no manufacturer's requirements for stain quality control. At 10:20 AM, the surveyor asked if the laboratory had established any IQCPs</p>

for quality control testing. The Laboratory Director responded the laboratory's IQCP was an internal quality control plan and was inclusive of the semen analysis and IVF as a whole. See regulatory language at 493.1256 Control Practices 3. The laboratory's policy and procedure manual included the following: Principle: To analyze semen for use in IVF (Invitro-fertilization) procedures or as a diagnostic/prognostic tool in evaluating fertility. Microscopic Examination: Reticle and MicroCell (are) designed for determining sperm number and motility. 5) Morphology: Manually estimate the percentage of normal sperm by viewing at least 10 fields or 100 sperm. A morphology smear using Diff Quik stain should be made for every semen analysis. 6) Debris: normal and abnormal categorization could be epithelial cells, protein clumps and microorganisms 4. A review of the policy and procedure manual revealed a procedure for the Morphology Stain (dated 1/30/2018 and signed by the Laboratory Director), which included the following instructions: "G. Morphology Stain 1. Principle: To assess the number of normal sperm using Kruger Strict morphology guidelines. ...6. Procedure: ...d. Stain for 5 to 7 dips (10 seconds) in the red stain (Stain A). e. Stain for 5 to 7 dips (10 seconds) in the blue stain (Stain B). f. Rinse under running tap water. g. Allow slide to air dry, aided by a hair dryer. i. Observe staining under microscope using oil immersion. j. Evaluate single sperm cells in a microscope field (1000X). k. Evaluate a total of 100 cells in 4 different areas of the slide using the following guidelines: 1. Cell clumps and cell clusters should be ignored. 2. Check each cell for tail and midpiece defects before evaluating the sperm head. 3. Immature cells are not counted as spermatozoa. 4. Loose sperm heads are counted as abnormal forms. 5. Free tails are not counted as spermatozoa. 6. Pinheads are counted as abnormal forms. 7. Acrosome - tends to stain light and not take up much stain 8. Nucleus - stains blue 9. Midpiece and tail - appears blue ..." 10 and 11. Details the observations of the abnormal and normal sperm in regards to shape, length, width, acrosome, midpiece and tail #9, Procedure notes included a part b, which indicated: "A stained slide should be transparent with only a very slight hint of blue. If the stained slide is not of acceptable quality, examine stains for bacterial contamination and/or expiration date. Consider replacing stains." Part d indicated, "To avoid stain contamination or inadequate staining resulting in false positive diagnosis of bacteriospermia or other inaccuracies, all three staining solutions should be examined for cloudiness, presence of foreign bodies, or other signs or improper staining daily and must be replaced every two weeks. This should be documented on the daily/weekly/periodically Andrology quality control sheet." 5. The laboratory's policy and procedure manual included the following: "5.0 Quality Control (dated 1/30/2018 and signed by the Laboratory Director) ...A detailed Quality Control program specific for the techniques in use (e. g. semen analysis, identification of oocytes) is described in each section. ...Normal and abnormal instrument and procedure quality control readings are recorded in the appropriate logs... For assays where no control specimens are tested (semen analysis, viability etc.), additional procedures (see Quality Assurance section and specific procedures) have been established to ensure the accuracy of patient test results..." 6. A review of the maintenance/temperature logs revealed a section for weekly checks which included the morphology stain. This section was marked with a check mark for February 2018 - August 2018. See the interview with TP #2 at 2:00 PM on 9/26/18. 7. In an interview on 9/26/18 at 2:00PM, TP #2 explained the check marks for the weekly morphology stain as the laboratory staff's check for contamination. When the surveyor asked what quality control was performed on reagents when received, TP #2 responded the received date, lot number and expiration dates were documented in the reagent control system (electronic accounting). TP #2 also stated a gross check of the reagent was performed but was not documented. 8. A review of the supply log, during this interview, revealed a shipment of MicroCell slides and Camco Stain Pak were received on 2/12/18; but no visual inspections were documented. 9. During the same

interview, the surveyor asked the testing personnel what expectations the staff had of the stain used for the sperm morphology. TP #2 stated that although the sperm stained purplish in color, the elements (head, tail and mid-piece) expected to be seen on a slide were not color dependent; but the stain was used to determine the normalcy of the sperm and reported as a percentage. 10. During this interview on 9/26/18 at 2:00PM, the Laboratory Director again stated the quality control of the MicroCell consisted on the monthly intra-laboratory technician comparisons. 11. A review of the Vitrolife Certificate of Analysis for the MicroCell (lot 17103121, expiration date of 10/31/2020) included Quality Control Testing Procedures, performed by the manufacturer, included chamber depth verification, visual inspection, microscopic inspection and capillary action loading pattern. Patricia Watson, BS, MT (ASCP) Licensure and Certification Supervisor