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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>34D1088969            | <b>(X3) Date Survey Completed</b><br><br>09/09/2019 |
| <b>Name of Provider or Supplier</b><br><br>Piedmont Reproductive Endocrinology Group (Preg)                                | <b>Street Address, City, State</b><br><br>76 Peachtree Road, Suite 210, Asheville, NC |   |
| 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>   |
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| <b>D2009</b>              | <p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b><br/>CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of 2017 and 2018 AAB(American Association of Bioanalysts) Proficiency testing records and interview with TS(Technical Supervisor) 9/9/19, the laboratory failed to ensure attestation statements were signed to document testing of the proficiency samples in the patient workload using the laboratory's routine methods. Findings: Review of 2017 and 2018 AAB proficiency testing records revealed: 1. The laboratory director or designee failed to sign the attestation statements for the following events: a. 2017 S2 event Andrology; b. 2017 Q2 event Chemistry; c. 2017 Q3 event Chemistry; d. 2018 Q1 event Chemistry. During interview at approximately 2:45p.m., the TS stated the attestations had not been signed by previous TS.</p> |
| <b>D5211</b>              | <p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b><br/>CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of laboratory's PT (Proficiency testing) policy, the review of 2018 and 2019 AAB (American Association of Bioanalysts) PT records, and interview with the TS(Technical Supervisor) 9/9/19, the laboratory failed to ensure that all</p>  |

proficiency testing results were evaluated to include corrective action for unacceptable responses. Findings: The laboratory's "Proficiency Testing Performance" policy states under Corrective Actions, " If threshold is not met, investigation of why the results were unacceptable, unsatisfactory, or unsuccessful will be instituted." Under Ungraded PT, the policy states, "Any PT challenges that are done and intended to be graded but were not, will be reviewed with all appropriate staff members when PT answers are released online. Any unsatisfactory results will be investigated and staff members will be re-trained if necessary. An investigation to determine the root cause of the failure to submit PT challenge answers will be started and changes made to the way PT materials are handled will be implemented if necessary." Review of the 2018 and 2019 AAB PT records revealed the laboratory failed to evaluate the PT results for the following: 1.) 2019 S1 Andrology event: result "No data received by AAB." During interview at approximately 2:45pm, the TS confirmed the results had not been evaluated yet. She stated the samples from AAB were not tested. She suspected the PT package from AAB was accidentally discarded by a former lab employee. She confirmed testing personnel(TP#1) completed the PT from the online videos once available from the PT vendor. 2.) 2018 S2 Andrology event: a. 50% score for sperm count. Sample #1: The laboratory reported a result that was out of grading range or incorrect response. Sample #2: The result was not graded because of a lack of participant consensus. b. 20 % score for Sperm morphology/Sperm cell ID. Sample #2: The laboratory reported a result that was an incorrect response. Samples #3, #4, #5: The laboratory did not report a value. During interview, the TS confirmed re-training was given to TP#1 for how to perform testing with pictures online. She confirmed the ungraded PT response was not evaluated. 3.) 2018 Q2 Chemistry event: 0% score for Estradiol with no corrective action documented. The TS confirmed the unacceptable response was not evaluated and corrective action not documented by the previous TS.

**D5785**

**CORRECTIVE ACTIONS**  
CFR(s): 493.1282(b)(3)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.

This STANDARD is not met as evidenced by:  
Based on review of the Tosoh AIA-360 Manufacturer's Operation Manual, review of the 2018 and 2019 Temperature and Humidity logs, and interview with TS(Technical Supervisor) 9/9/19, the laboratory failed to ensure corrective action was taken and documented for humidity readings outside the acceptable limits. Findings: Review of the Tosoh AIA-360 manufacturer's Operation manual revealed operating environment limits of 40-80% room humidity, with no condensation. 1. Review of the 2018 and 2019 temperature and humidity logs revealed room humidity was outside the acceptable limits of 40-80% for the following with no corrective action taken: a. 7 days in February 2018; b. 3 days in March 2018; c. 10 days in October 2018; d. 12 days in November 2018; e. 16 days in December 2018; f. 20 days in January 2019; g. 14 days in February 2019; h. 18 days in March 2019; i. 13 days in April 2019; j. 1 day in May 2019. During interview at approximately 3:30pm, the TS confirmed corrective action was not documented for the out of range humidity readings.

**D6127**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**  
CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's "Personnel Assessment and Competency Testing Policy", review of personnel records, and interview with TS(Technical Supervisor) 9/9/19, the Technical Supervisor failed to evaluate and document a semiannual competency assessment for 1 of 2 TP(Testing Personnel #1.) Findings: The laboratory's "Personnel Assessment and Competency Testing Policy" states, "An initial competency evaluation must be performed following the 6 month probation period with subsequent annual competency evaluation to follow performed by director and/or designee annually. " Review of the personnel records revealed TP#1 was trained 9/14/18. An annual competency assessment was completed for TP#1 on 8/27/19. There was no semiannual competency assessment completed for TP#1 during her first year of testing patient specimens. During interview at approximately 3:30p.m, the TS stated she was unaware a 6-month competency assessment was required during the first year.