Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D1088969	11/16/2021
Name of Provider or Supplier	**Street Address, City, State**	
Piedmont Reproductive Endocrinology Group (Preg)	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on the review of laboratory records and absence of documentation 11/16/21, the laboratory failed to retain manufacturer's QC(quality control) assay sheets for endocrinology testing for 2 years. Findings: Review of 2019, 2020, and 2021 laboratory QC records for the Tosoh AIA-360 revealed the laboratory failed to retain the BioRad Lyphocheck Immunoassay Plus control assay sheets for the following lot numbers: 1. Lyphocheck Immunoassay Plus Levels 1, 2, and 3 Control lot # 40370, expiration date: 10/31/21 ; 2. Lyphocheck Immunoassay Plus Levels 1, 2, and 3 Control lot# 40380, expiration date: 8/3/22.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's PT(Proficiency testing) policy, the review of 2019, 2020, and 2021 AAB(American Association of Bioanalysts) PT records and absence of documentation 11/16/21, the laboratory failed to ensure that all proficiency testing results were evaluated to include corrective action for unacceptable responses. Findings: The laboratory's "Proficiency Testing Performance" policy stated under

	Ungraded PT, "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..." Review of 2019, 2020, and 2021 AAB PT records revealed the laboratory failed to evaluate and document corrective action for the following: 1. 2019 S2 Andrology event: Sperm Motility: forward progression Sample #1- ungraded response(lack of participant consensus) was unacceptable and no corrective action documented; 2. 2020 Q1 Chemistry event: Estradiol Sample #1- ungraded response(lack of participant consensus) was unacceptable and no corrective action documented; 3. 2020 S1 Andrology event: Sperm Morphology: Sperm Cell ID Sample #5 - ungraded response(lack of participant consensus) was unacceptable and no corrective action documented; 4. 2020 S2 Andrology event: Sperm Morphology: Sperm Cell ID Sample #10- ungraded response(lack of participant consensus) was unacceptable and no corrective action documented; 5. 2021 S1 Andrology event: Sperm Count Traditional Sample #2- ungraded response(lack of participant consensus) was unacceptable and no corrective action documented. Deficiency previously cited 9/9/19.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of 2019, 2020, and 2021 Tosoh AIA-360 calibrations and calibration verifications, absence of documentation, interview with the TS(technical supervisor)11 /16/21, and email communication with the TS 11/17/21 and 11/18/21, the laboratory failed to perform 1 of 2 calibration verifications in 2019 and failed to perform 2 of 2 calibration verifications in 2020 as required. Findings: 1. Review of the 2019, 2020, and 2021 calibrations revealed the laboratory performs a 2-point calibration for BhCG (Human chorionic gonadotropin) on the Tosoh AIA-360. 2. Review of 2019, 2020, and 2021 calibration verification records revealed the laboratory performed a calibration verification for BhCG on 3/10/21 and again on 10/7/21. There was no documentation that the laboratory had performed the calibration verification that was

	due in November 2019 or the two calibration verifications that were required in 2020. The calibration verifications for BhCG were not performed from May 2019 until again March 2021, a gap of approximately 22 months. 3. During interview at approximately 5pm on 11/16/21, the TS stated the calibration verifications were done but not located during the survey. Email communication with the TS on 11/17/21 and 11/18/21 confirmed the calibration verifications for BhCG were not performed since May 2019. She stated the testing personnel who was there during that time-frame was no longer employed and she was unsure why they were missed.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) 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. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures, review of personnel records, absence of documentation, and interview with the TS(technical supervisor) 11/16/21, the laboratory director failed to ensure that prior to testing patient specimens, that 2 of 3 TP(testing personnel) received the appropriate training and demonstrated that the TP can perform all testing for the Tosoh AIA-360. Findings: Review of laboratory's procedures revealed "Personnel Assessment and Competency Testing Policy" that stated, "The laboratory provides and assures adequate training to all testing personnel to the extent necessary to consistently provide reliable results. This is accomplished through intense training with the final approval by the laboratory director to perform tasks and evaluation of procedures prior to the testing of patient specimens. Each testing person should have personnel file containing the following: Summary of training experience....The director and/or designee will review each testing personnel's performance, training log, and overall knowledge of polices and procedures prior to allowing technician to perform task unsupervised..." Review of the laboratory's procedures also revealed a delegation of responsibilities dated by the laboratory director 6/8/17, that stated, "Any procedural change, staffing, physical and environmental conditions will remain the responsibility of the laboratory director..." Review of personnel records revealed TP#1 was hired in February 2021. Her documented training in March 2021 did not include training for the endocrinology procedures on the Tosoh AIA-360. TP#3 is a float employee from a sister location. Her documented training in May and June 2020 did not include the endocrinology procedures on the Tosoh AIA-360. At approximately 3pm., the TS confirmed there was no documented Tosoh AIA-360 training on file for TP#1 and TP#3.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

	This STANDARD is not met as evidenced by: Based on review of laboratory procedures, review of personnel competency records, and interview with the TS(technical supervisor)11/16/21, the LD(laboratory director) failed to establish competency procedures for evaluating the delegated responsibilities of the TS. Findings: 1. Review of laboratory procedures revealed no procedure for the competency assessment of the TS. Review of the laboratory procedures revealed a delegation of responsibilities by the LD to the TS on 6/8/17. Review of TS competency records revealed no documentation of TS competency assessments for the delegated responsibilities. At approximately 3pm., the TS confirmed there were no competency assessments performed for the responsibilities delegated to her by the LD.