Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 01D2257031	**(X3) Date Survey Completed** 09/25/2025
Name of Provider or Supplier Alabama Center For Reproductive Medicine, Pllc	**Street Address, City, State** 7209 Copperfield Dr, Montgomery, 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**
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on reviews of the American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) Proficiency Testing (PT) records for the sperm count analysis, the performance evaluation records and an interview with the Testing Personnel (TP), the laboratory had not successfully participated and implemented effective corrective actions in the PT program, for the specialty and test in which the laboratory is certified under CLIA. The surveyor noted three of the four AAB-MLE PT events reviewed from the date of the last survey, 10-17-2023 to the date of the current survey, 09-25-2025 had unsatisfactory scores. The findings include: 1. A review of the AAB-MLE PT records revealed the following PT performance

	evaluation scores: A) 2023 Embryology-Andrology Fetal S2 Event-50 Percent B) 2024 Embryology-Andrology Fetal S2 Event-50 Percent C) 2025 Embryology-Andrology Fetal S2 Event-50 Percent 2. Further review of the AAB-MLE PT performance evaluation records revealed the laboratory had reviewed videos and sperm count protocol for the unsuccessful PT performance, but unsatisfactory PT scores continued from 2023, 2024, and 2025 on the sperm count analysis. 3. TP confirmed the above findings during the exit conference on 9-25-2022 at 12:26 PM.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a review of the American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) Proficiency Testing (PT) records, and an interview with the Testing Personnel (TP), the laboratory failed to implement a mechanism to verify the accuracy of the sperm count analysis, a non-regulated analyte. The surveyor noted three out of four PT events had unsuccessful PT performance evaluations from the date of the last survey, 10-17-2023 to the date of the current survey, 09-25-2025. The findings include: 1. A review of the AAB-MLE PT records from 2023-2025 revealed the sperm count analysis PT scores of 50 percent for the following events: A) 2023 Embryology-Andrology Fetal S2 Event B) 2024 Embryology-Andrology Fetal S2 Event C) 2025 Embryology-Andrology Fetal S2 Event 2. The TP confirmed the above findings during the exit conference on 09-25-2025 at 12:26 PM.