

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2146054	(X3) Date Survey Completed 12/01/2020
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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on a review of 2018, 2019, and 2020 American Association of BioAnalysts (AAB) proficiency testing records and an interview with the Technical Supervisor (TS), the laboratory failed to ensure the proficiency testing was not performed by the same individual [Testing Personnel (TP) #2] for all events. This affected five of five testing events, reviewed by the surveyor. The findings are: 1) A review of records from five proficiency testing events in 2018, 2019, and 2020 revealed TP #2 tested all specimens. 2) The laboratory staff indicated on the CMS form #209 (Laboratory Personnel Form) two testing personnel of high- complexity semen analysis. 3) During an interview on 12/01/2020 at 12:14 PM, the TS stated she just noticed TP #2 performed all of the proficiency testing, and the laboratory will begin a rotation with the other testing personnel. The surveyor asked what tests were routinely performed by TP #1. The TS confirmed TP #1 was also trained and competent in semen analysis, the only non-waived test, performed by the laboratory.</p>