Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2176055	12/09/2022
Name of Provider or Supplier	**Street Address, City, State**	
Acrm	2006 Brookwood Medical Center Drive, Suite 302, Birmingham, 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
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 (AAB) proficiency test records and an interview with Testing Personnel #3, the Laboratory failed to implement a mechanism to verify the accuracy of Embryology. This was noted for one of four events reviewed in 2021 and 2022. The findings include: 1. A review of the AAB proficiency records revealed the laboratory scored zero percent due to "Failure to participate" on the 2021 Embryology S1 Event. 2. During an interview on December 9, 2022, at 11:27 PM, Testing Personnel #3 confirmed the Embryology Event S1 survey was not submitted due to insufficient staffing in 2021.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by:

	Based on a review of the temperature records, and an interview with Testing Personnel #4, the Laboratory failed to document the room temperature which is required for the Chemistry analyzer Cobas e411. This was noted for 21 days of the 10 months reviewed in 2021. The findings include: 1. A review of the temperature records revealed the room temperature was not documented for the Chemistry Analyzer Cobas e411 for sixteen days in May and five days in August 2021. 2. During an interview on December 9, 2022, at 8:20 AM, Testing Personnel #4 confirmed the previous employee did not document the temperatures above.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of the Chemistry analyzer maintenance records, Andrology maintenance records, and an interview with Testing Personnel #4, the Laboratory failed to: 1) document maintenance on the Chemistry analyzer Cobas e411 for 119 days out of 10 months; 2) document maintenance for Andrology 5 months of 17 months reviewed for 2021 and 2022; This was noted for: 1. A review of the maintenance records revealed the maintenance for the Chemistry analyzer Cobas e411 was not documented, as follows: 1) February 2021; 12 days missed. 2) April 2021; 19 days missed. 3) March, May, June, July 2021; no documentation. 2. A review of the maintenance records revealed the maintenance for Andrology was not documented, as follows: 1) August, November, and December 2021 2) January and February 2022 3. During an interview on December 9, 2022, at 8:20 AM, Testing Personnel #4 confirmed the prior lab employee did not document maintenance.