Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2176055	01/13/2021
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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on a review of the AAB (American Association of Bioanalysts) proficiency testing (PT) records, and interviews with the Technical Consultant, Testing Personnel #2, and the Chief Operating Officer, the laboratory failed to enroll in an approved PT program by providing a valid CLIA Identification Number (ID #) for this location. The surveyor noted Endocrinology proficiency testing performed by this laboratory from September 2018 to the end of 2020 was performed with no CLIA # for two survey events, and CLIA ID #01D2146054 for seven events. The findings include: 1. On 1/13/2021 the surveyor and surveyor-in-training entered the facility to perform a routine Initial Survey for the laboratory. During the initial tour of the laboratory at approximately 9:15 AM, the Technical Consultant stated the laboratory performed a complete semen analysis (including the total count, morphology and motility), and six Endocrinology assays on the Roche Cobas e411 analyzer, SN (Serial Number) 1599-19 (including Thyroid Stimulating Hormone [TSH] and Human Chorionic Gonadotropin [HCG], two regulated assays, and four non-regulated Endocrinology assays) 2. A review of the AAB PT records revealed Endocrinology PT performed on the Cobas e411, SN1599-19 dated 9/10/2018 thru 9/23/2020. The surveyor noted

	records for PT performed on 9/10/2018 and 1/22/2019 had no CLIA ID#. The seven surveys from 5/2/2019 thru all of 2020 had CLIA ID# 01D2146054 (not this laboratory's ID# 01D2176055). 3. During an interview on 1/13/2021 at 10:15 AM, the surveyor requested only PT records for this laboratory (CLIA ID#01D2176055). The Technical Consultant then explained the discrepancy with the CLIA #'s, including the following timeline: - The TC was hired in June 2018 to work in the laboratory after the business entities opened a second location for the Reproductive Medicine practice in the Brookwood Hospital medical complex. No one realized a separate CLIA # was required for the new location. - The laboratory performed Andrology testing (Semen analysis) after the practice was opened, and in August 2018, the Roche Cobas e411 analyzer, SN1599-19 was installed, validated, and used for patient testing performed thereafter. - In September or October 2019 "they" realized one CLIA # cannot be utilized for two locations, so a CMS-116 was submitted for the "new" laboratory. (The CLIA State Agency "Received Date" for the application was 11/12/2019. CLIA ID#2176055 was assigned.) 4. As the interview continued at approximately 10:30 AM, the surveyor asked why CLIA #01D2176055 was not provided to AAB so the laboratory would have been correctly enrolled in 2020. The Technical Consultant stated they forgot to change the CLIA # on the new order. The surveyor explained failing to enroll for PT on regulated analytes under a valid CLIA # for the laboratory (so the PT provider can forward the results to the CLIA State Agency) is a mandatory Condition Deficiency. .
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) 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 This STANDARD is not met as evidenced by: Based on a review of the 2020 AAB (American Association of Bioanalysts) proficiency testing (PT) records, and an interview with the Technical Consultant (also Testing Personnel #1), the surveyor determined the laboratory failed to ensure proficiency testing samples were rotated between all personnel who performed patient testing. This was noted on three of three Endocrinology surveys, and two of two Andrology (Semen Analysis) surveys reviewed. The findings include: 1. A review of AAB attestation statements revealed Testing Personnel #1 had performed all the testing on three of three of the 2020 Endocrinology surveys, and Testing Personnel #2 had performed all testing on two of two of the 2020 Andrology surveys. 2. During an interview on 1/13/2021 at 12:20 PM, the Technical Consultant confirmed she and Testing Personnel #2 both performed Endocrinology and Andrology testing on patient specimens, however they had failed to rotate PT testing to demonstrate proficiency in each specialty in 2020. .
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) 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.

	This STANDARD is not met as evidenced by: Based on a review of the AAB (American Association of Bioanalysts) proficiency testing (PT) records and an interview with the Technical Consultant (also Testing Personnel #1), the Laboratory Director/Designee and Testing Personnel #1 failed to sign the attestation statement for three of three 2020 Endocrinology PT events. The findings include: 1. A review of AAB PT records revealed the attestation statements for the 2020 Q1, Q2 and Q3 Endocrinology PT were not signed by the Laboratory Director or Designee and Testing Personnel #1. 2. During an interview with the Technical Consultant on 01/13/2021 at 12:20 PM, the surveyor reviewed the instructions on the attestation statement which included the statement, "We, the undersigned...", indicating the statement should be physically signed since it is a legal document. The Technical Consultant confirmed they had failed to physically sign because the names of the Laboratory Director and testing personnel were listed on the electronic copies. .
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 a review of the 2020 AAB (American Association of Bioanalysts) proficiency testing (PT) records, and an interview with the Technical Consultant, the surveyor determined the laboratory failed to ensure reviews of returned proficiency testing evaluations were documented on one of three 2020 Endocrinology PT surveys. The findings include: 1. A review of the returned survey results for the AAB 2020 Q2 Endocrinology survey revealed no documentation of review (as indicated by a signature and date). 2. During an interview on 1/13/2021 at 12:20 PM, the Technical Consultant confirmed she always looked at the results, but failed to document her review on that survey. .
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 laboratory menu, a review of the AAB (American Association of Bioanalysts) proficiency testing (PT) records, and interviews with the Technical Consultant, Testing Personnel #2, and the Chief Operating Officer, the laboratory failed to implement a method of accuracy verification for total sperm count (a non-regulated high-complexity test) in 2020. The findings include: 1. On 1/13/2021 the surveyor and surveyor-in-training entered the facility to perform a routine Initial Survey for the laboratory. During the initial tour of the laboratory at approximately 9: 15 AM, the Technical Consultant stated the laboratory performed a complete semen analysis (including the total count, morphology and motility) in the Andrology area, and Endocrinology testing on the Roche Cobas e411 analyzer. 2. A review of the 2020 AAB PT records revealed Sperm Morphology and Motility were performed for the Andrology subspecialty, however total sperm count was not performed. 3. During an

	interview on 1/13/2021 at 1:30 PM, the Technical Consultant and Testing Personnel #2 (by phone) confirmed semen analysis on patients included a total sperm count. The surveyor then asked if the AAB PT survey included total sperm count. Testing Personnel #2 (on the phone) answered, "No, I don't think so." Both personnel confirmed no other method of accuracy verification had been implemented for total sperm count. 4. As the interview continued with the Chief Operating Officer (COO) on 1/13/2021 at 1:45 PM, the surveyor requested the 2020 and 2021 AAB PT orders. A review of the 2021 AAB PT Order revealed the box for Catalog # 3925-4 "Sperm Count, for Quant and Qual." was not checked on the form. The surveyor then requested the 2020 order. The COO provided an email from AAB dated 12/10/2019 which confirmed the Sperm Count survey was not included in the 2020 AAB PT order. .
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 temperature records, a review of the Laboratory Monitoring and Maintenance Policy, a review of the Cobas e411 Operator's Manuals, a review of Cobas PreciControl Universal quality control package inserts, and an interview with the Technical Consultant, the laboratory failed to: 1) monitor and document room temperature and humidity for the area where the Cobas e411 analyzer has been located since the laboratory opened in December 2019; 2) document room humidity four out of thirteen months in the Andrology area; 3) ensure controls were stored as per manufacturer's instructions with "acceptable ranges" for the freezer temperatures consistent with the manufacturer's requirements of -20 +/- 5 degrees Celsius, and 4) document freezer temperatures five out of thirteen months reviewed by the surveyor. The findings include: 1. A review of the temperature records revealed room temperature and humidity were not documented for the area where the Cobas e411 analyzer has been located since December 2019. Also, the temperature records revealed no documentation of Andrology room humidity in June, September, October, and December 2020. A review of the temperature records showed an acceptable range of -15 +/- 5 degrees Celsius for the freezer used for storage of the Cobas PreciControl Universal quality controls (reconstituted). Also, the temperature records revealed from December 2019 to April 2020 freezer temperatures were not documented. 2. A review of the Laboratory Monitoring and Maintenance Policy (page 25) in the Andrology Laboratory Policy and Procedures Manual revealed, "...4. Freezer Temperatures a. Record temperature reading on lab freezer. b. Reading should fall within -10 to -20 degrees Celsius. ... ...6. Room Humidity a. Record room humidity level. b. Humidity should stay between 50 - 70%. ..." 3. A review of the Cobas e411 Operator's Manual page 58 revealed, "Environmental Conditions Temperature Operation: 18 to 32 degrees Celsius Humidity Operation: 20 - 80 % (non-condensing)". 4. A review of the Cobas PreciControl Universal quality control package insert revealed, "Store at 2 - 8 degree Celsius. The lyophilized control serum is stable up to the stated expiration

	date. Stability of all the components ... reconstituted control serum: either at -20 +/- 5 degrees Celsius [for]1 month (freeze only once), or at 2 - 8 degrees Celsius [for] 3 days ...". 5. During an interview conducted on 01/13/2021 at 2:30 PM, the Technical Consultant confirmed the laboratory stored aliquots of reconstituted controls in a lab freezer with an acceptable range of -15 +/- 5 degrees Celsius (not at -20 +/- 5 degrees Celsius, as per manufacturer's instructions), and further confirmed the laboratory had failed to document freezer temperatures from December 2019 to April 2020. 6. During a second interview conducted on 01/13/2021 at 03:07 PM, the Technical Consultant confirmed the Room Temperature and Humidity were not being documented for the room where the Cobas e411 analyzer is located. .
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of temperature records, a review of the Laboratory Monitoring and Maintenance Policy, and an interview with the Technical Consultant, the laboratory failed to document corrective action when humidity was documented outside of the laboratory's established acceptable limits. This was noted 39 days out of the 13-month review period. The findings include: 1. A review of temperature logs revealed Humidity for the Andrology Room with an acceptable range of 50 - 70 % was below 50%, as follows: 4 days in December 2019, 10 days in January 2020, 8 days in February 2020, 6 days in March 2020, 1 day in April 2020, 2 days in May 2020, 3 days in July 2020, 3 days in August 2020, and 2 days in November 2020. 2. A review of the Laboratory Monitoring and Maintenance Policy page 25 of the Andrology Laboratory Policy and Procedures Manual revealed, "... 6. Room Humidity a. Record room humidity level. b. Humidity should stay between 50 - 70%.". 3. During an interview conducted on 01/13/2021 at 3:07 PM, the Technical Consultant confirmed the Room Humidity for the Andrology room was outside of the laboratory's established acceptable limits with no documentation of corrective action. .
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a lack of quality assurance documentation and an interview with the

	Technical Consultant, the surveyor determined the laboratory failed to implement and document effective quality assessment reviews to identify and correct problems cited during the survey process in the analytical systems. The findings include: 1. During an interview on 1/13/2021 at 2:30 PM, when asked if the laboratory had any documentation of quality assurance activities. The Technical Consultant explained she did review quality control results, corrective actions, calibrations, maintenance, temperatures, and proficiency testing, however she was unable to provide documentation of periodic quality assurance reviews. 2. In a review of the laboratory processes, the surveyor noted quality assurance problems in the following areas: A) Proficiency Testing a) Failure to enroll for proficiency testing with a valid CLIA Identification Number (ID #) for this location when patient testing began in 2018. (Refer to D2000.) b) Failure to rotate proficiency testing samples between all personnel who performed patient testing. (Refer to D2007.) c) Failure to ensure the Laboratory/Designee and Testing Personnel signed the proficiency testing attestation statements. (Refer to D2009.) d) Failure to document reviews of returned proficiency testing evaluations (Refer to D5211.) e) Failure to implement a method of accuracy verification or order proficiency testing kits for total sperm count (Refer to D5217.) B) Environmental Parameters a) Failure to review the Roche Cobas e411 manufacturer's required environmental parameters for room temperature and humidity, establish acceptable ranges consistent with the manufacturer's instructions and implement documentation of these parameters each day of patient testing. (Refer to D5413.) b) Failure to ensure documentation of corrective action when humidity was documented outside of the laboratory's established acceptable range. (Refer to D5781.) C) Personnel a) Failure to evaluate and document the performance of individuals at least semiannually during the first year of patient testing. (Refer to D6127.) 3. During the exit summation on 1/13/2021 at approximately 4:00 PM, the surveyor reviewed and confirmed the above noted findings with the Technical Consultant, the Chief Operating Officer and Testing Personnel #3. .
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 a review of the personnel records and an interview with the Technical Consultant, the Technical Supervisor failed to evaluate and document the performance of individuals at least semiannually during the first year of patient testing. This was noted on two of three personnel records reviewed by the surveyor. The finding include: 1. A review of the personnel records revealed no documentation of Andrology semiannual competency evaluations for Testing Personnel #1 (who also serves as the Technical Consultant) and Testing Personnel # 2. 2. Initial training for the above personnel was dated 11/06/2019, and the annual competency evaluation was dated 10/20/2020. 3. During an interview conducted on 01/13/2021 at 12:06 PM, the Technical Consultant confirmed the above noted findings. SURVEYOR ID #32558 Licensure and Certification Surveyor