Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0858174	08/17/2021
Name of Provider or Supplier	**Street Address, City, State**	
Arms Metro Health Center	712 25th Street North, 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 CMS-116 Clinical Laboratory Improvement Amendments (CLIA) Application for Certification and an interview with the Testing Personnel #3, the laboratory failed to enroll in a proficiency testing (PT) program for Routine Chemistry - Blood Gases (this is a moderate complexity, regulated Chemistry test). The laboratory was previously performing PPMP and waived testing before adding routine chemistry (iSTAT blood gases) in March 2021 (patient testing started in March 2021). The findings include: 1. A review of CMS-116 Clinical Laboratory Improvement Amendments (CLIA) Application for Certification revealed that the laboratory is performing Blood Gases on the iSTAT. 2. During an interview on 08/17 /2021 at 11:45 AM, Testing Personnel #3 confirmed the laboratory is not performing Proficiency Testing and they have not ordered PT for the iSTAT Blood Gases.
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 lack of Wet Prep records and an interview with the Chief Operating Officer, the laboratory failed to verify the accuracy of Vaginal Wet Mount at least twice annually. This was noted from 12/01/2020 to date of survey (08/17/2021). The findings include: 1. A review of the Vaginal Wet Mount records revealed a lack of accuracy verification being performed at least twice annually. 2. During an interview on 08/17/2021 at 12:05 PM, the Chief Operating Officer confirmed accuracy was not verified for Vaginal Wet Mount performed on the Microscope.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on a review of i-STAT records and an interview with Testing Personnel #3, the surveyor determined the laboratory failed to monitor and evaluate the overall quality of i-STAT Blood Gases. This was noted from March 2021 to date of survey (08/17 /2021). The findings include: 1. Refer to D5407. 2. Refer to D5413. 3. Refer to D5431.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of the Procedure Manual and an interview with the Health Informatics and Quality Specialist, the laboratory failed to have a written procedure for Vaginal Wet Mount performed as Provider-Performed Microscopy (PPM). The findings include: 1. A review of the Procedure Manual revealed a lack of written procedures for Vaginal Wet Mount. 2. During an interview on 08/17/2021 at 12:05 PM, the Health Informatics and Quality Specialist confirmed the laboratory did not have a procedure for the test above.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

	This STANDARD is not met as evidenced by: Based on a review of the Procedure Manual and an interview with Testing Personnel #3, the Laboratory Director failed to approve the Procedure being used in the Laboratory by signature. The findings include: 1. A review of the Procedure Manual for the iSTAT System revealed the Laboratory Director did not approve the procedure by signature. 2. During an interview on 08/17/2021 at 12:15 PM, Testing Personnel #3 confirmed the Procedure reviewed during the survey was not signed by the Laboratory Director.
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 Procedure Manual for the i-STAT System, an observation by the surveyor during the walk through of laboratory areas, and an interview with Testing Personnel #3, the laboratory failed to monitor and document room temperature for the room where the i-STAT and cartridges are located. Also, the laboratory kept the cartridges out at room temperature longer than the manufacturer's recommendation. The findings include: 1. A review of the Procedure Manual for the i-STAT System revealed on page 1 "...Cartridges may be stored at room temperature (18 to 30 degrees Celsius or 64 to 86 degrees Fahrenheit) for 14 days. Cartridges should not be returned to the refrigerator once they have been at room temperature, and should not be exposed to temperatures above 30 degrees Celsius (86 degrees Fahrenheit)..." 2. During walk through of the room where the i-STAT is located it was observed by the surveyor there was one box of cartridges on the counter by the i-STAT. 3. During an interview conducted on 08/17/2021 at 11:35 AM, Testing Personnel #3 confirmed that the laboratory had not monitored room temperature in the room where the i-STAT and cartridges are kept. Also, Testing Personnel #3 stated the cartridges are kept at room temperature for two months.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of the iSTAT Electronic Simulator records, a review of the Procedure Manual for the iSTAT System, and an interview with Testing Personnel #3, the laboratory failed to perform and document function checks (Electronic Simulator)

	every 8 hours. This was noted from March 2021 (when patient testing started) to August 2021 (date of Survey). The findings include: 1. A review of the Electronic Simulator Log revealed it was performed the following days and passed: 03/09/2021, 03/10/2021, 05/18/2021, 06/17/202, 06/22/2021, 07/07/2021, 07/13/2021, 07/20/2021, 07/27/2021, 08/03/202, and 08/10/2021. 2. A review of the Procedure Manual for the iSTAT System revealed on page 19 "...Verify the performance of each handheld analyzer or Blood Analysis Module in the i-STAT System using the internal or external Electronic Simulator every 24 hours of use, or as needed for regulatory compliance. In the USA, verification is required every 8 hours for blood gases, ..." 3. During an interview on 08/17/2021 at 11:15 AM, Testing Personnel #3 confirmed the Electronic Simulator was being run each week with Quality Control and was not aware it needed to be run every 8 hours with patient testing.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the iSTAT Blood Gases quality control and an interview with the Testing Personnel #3, the laboratory failed run controls at least once a day patient specimens are performed or implement an Individualized Quality Control Plan (IQCP) for iSTAT Blood Gases. This was noted from March 2021 when patient testing started to August 2021 (day of survey). The findings include: 1. A review of the quality control for iSTAT Blood Gases revealed quality control was being performed once a week: 03/29/2021, 04/07/2021, 04/09/2021, 04/12/2021, 04/20/2021, 04/27/2021, 05 /04/2021, 05/10/2021, 05/19/2021, 05/25/2021, 06/01/2021, 06/08/2021, 06/17/2021, 06/22/2021, 06/29/2021, 07/07/2021, 07/13/2021, 07/20/2021, 07/27/2021, 08/03 /2021, and 08/10/2021. 2. During an interview on 08/17/2021 at 11:15 AM, Testing Personnel #3 confirmed the Laboratory was performing Quality Control weekly and an IQCP had not been written for iSTAT Blood Gases. Also, Testing Personnel #3 confirmed patient testing is usually performed 5 days a week.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of validation records for the i-STAT Blood Gases, lack of blood gases Proficiency Testing records, quality control records for the i-STAT Blood Gases, and an interview with Testing Personnel #3, the Laboratory Director failed to fulfill the Laboratory Director's responsibilities. This was noted from March 2021 to the survey date (08/17/2021). The findings include: 1. Refer to D6013. 2. Refer to D6015. 3. Refer to D6020.

D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on a review of the validation records for the iSTAT Blood Gases and interview with Testing Personnel (TP) #3, the surveyor determined the Laboratory Director failed to ensure the validation was reviewed and approved before patient testing started. This was noted for one of one new instruments installed (patient testing started in March of 2021). The findings include: 1. A review of the validation records for the iSTAT Blood Gases revealed the validation was performed March 9-10, 2021 and no indication of a signature of the Laboratory Director. 2. During an interview on 08/17/2021 at 12:15 PM, TP #3 confirmed patient testing started in March of 2021 and the Laboratory Director did not sign the validation as indication of review and approval.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on a lack of Proficiency Testing records and an interview with Testing Personnel #3, the Laboratory Director failed to ensure the laboratory was enrolled in an approved proficiency testing program for Blood Gases. This noted from March 2021 to the survey date (08/17/2021). The findings include: 1. Refer to D2000.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by:

	Based on the i-STAT Blood Gases Quality Control and an interview with Testing Personnel #3, the Laboratory Director failed to ensure at least 2 levels of Quality Control were performed each day of patient testing or implement an IQCP (Individualized Quality Control Plan). This noted from March 2021 to the survey date (08/17/2021). The findings include: 1. Refer to D5447.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on a review of CMS-209 Laboratory Personnel Report and an interview with the Informatics and Quality Specialist, the laboratory failed to have a technical consultant who meets the qualification requirements. The laboratory was previously performing PPMP and waived testing before adding routine chemistry (iSTAT blood gases) in March 2021. The findings include: 1. Refer to D6034.
D6034	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section. This STANDARD is not met as evidenced by: Based on a review of CMS-209 Laboratory Personnel Report and an interview with the Informatics and Quality Specialist, the laboratory failed to have a technical consultant who meets the qualification requirements. The laboratory was previously performing PPMP and waived testing before adding routine chemistry (iSTAT blood gases) in March 2021 (patient testing started in March 2021). The findings include: 1. A review of CMS-209 Laboratory Personnel Report revealed that the laboratory failed to fill the technical consultant position. 2. During an interview on 08/17/2021 at 10:30 AM, the Informatics and Quality Specialist confirmed the current Laboratory Director does not have laboratory experience to qualify as the Technical Consultant and they have not filled the position with a qualified individual.