Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0858174	07/12/2023
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
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of Abbott iStat Blood Gas Quality Control (QC) records, a review of the Individualized Quality Control Plan (IQCP) documents, a review of Patient Log records, and an interview with Testing Personnel #1, the laboratory failed to follow the QC requirements specified by the laboratory's IQCP. This was noted one out of 22 months reviewed. The findings include: 1. A review of the iStat Blood Gas QC records revealed two levels of quality control were run on the following days: 11/1 /2022, 12/1/2022, and 2/17/2023. In January 2023 only the Level 2 control was run on 1/3/2023 with a notation, "No TriControl - Level 1 control on order". 2. A review of the iStat Blood Gas IQCP revealed at least two levels of the Tri-control should be performed each month. 3. A review of the January 2023 Patient Log revealed 14 patient tests were run. 4. During an interview on 7/12/2023 at 1:30 PM, Testing Personnel #1 confirmed the above findings.
D6047	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b(8)(i) The procedures for evaluation of the competency of the staff must include, but are not

	limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. This STANDARD is not met as evidenced by: Based on a review of Personnel records, an interview with Testing Personnel #1, and an interview with the Laboratory Director (also the Technical Consultant), the Technical Consultant failed to assess competency of Testing Personnel by direct observation of routine patient testing. This was noted for two out of two competency assessments reviewed since the date of the last survey, 8/17/2021, to the date of the current survey, 7/12/2023. The findings include: 1. A review of Personnel records revealed a 6 month competency dated 8/2022 and an annual competency dated 10/11 /2022 for Testing Personnel #1. The forms included the six required elements of competency assessment, however, the forms were blank except for a signature from the Technical Consultant. 2. During an interview on 7/12/2023 at 2:00 PM, the Surveyor asked how competency assessments were performed by the Technical Consultant; Testing Personnel #1 explained she discussed how she performed patient testing with the Technical Consultant. Testing Personnel #1 confirmed her competency assessment had not included direct observations of routine patient test performance by the Technical Consultant. 3. During an interview on 7/27/2023 at 1:45 PM, the Laboratory Director/ Technical Consultant confirmed Testing Personnel #1 was not directly observed during assessment of competency.
D6056	CLINICAL CONSULTANT CFR(s): 493.1415 The laboratory must have a clinical consultant who meets the qualification requirements of 493.1417 of this part and provides clinical consultation in accordance with 493.1419 of this part. This CONDITION is not met as evidenced by: Based on a review of Personnel records and interviews with the Laboratory Director and Testing Personnel #1, the laboratory failed to fill the position of Clinical Consultant (CC) with a qualified invidual, as required by CLIA for Moderate Complexity laboratories. This was noted from 2/20/2023 to the date of the current survey, 7/12/2023. The findings include: 1. Refer to D6057.
D6057	CLINICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1417 The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493. 1405(b)(1), (2), or (3)(i); or (b) Be a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine and possess a license to practice medicine, osteopathy or podiatry in the State in which the laboratory is located. This STANDARD is not met as evidenced by: Based on a review of Personnel records and interviews with the Laboratory Director and Testing Personnel #1, the laboratory failed to fill the position of Clinical Consultant (CC) with a qualified individual. This was noted from 2/20/2023 to the

	date of the current survey, 7/12/2023. The findings include: 1. A review of Personnel records revealed educational documents for the Laboratory Director (who also acted as Technical Consultant) and Testing Personnel #1. There were no records available for any additional laboratory personnel on the day of the survey. 2. During an interview with Testing Personnel #1 on 7/12/2023 at 2:00 PM, the Surveyor asked who had assumed the position of Clinical Consultant, after the previous CC left the company. Testing Personnel #1 was unsure of who the current CC was, however, indicated it would be either the Laboratory Director or a Certified Registered Nurse Practioner (CRNP) on staff. The Laboratory Director qualified under 493.1405(b)(5), which does not meet the qualifications required to fill the position as the CC. 3. During an interview on 7/27/2023 at 1:45 PM, The Laboratory Director stated the following: "..I was unaware that they had not hired another doctor. Please let me know if the CRNP qualifies for Clinical Consultant". 4. On 7/28/2023 the Laboratory Personnel Report (Form CMS-209) was forwarded to the surveyor with the name of an individual who is a CRNP. The individual listed did not meet educational and licensing requirements for the Clinical Consultant position.