Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0675460	04/04/2019
Name of Provider or Supplier	**Street Address, City, State**	
Uams-South Central	1601 West 40th Ave, Pine Bluff, AR	

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
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: . Through a review of the laboratory "Policy and Procedure Manual", observations made during a tour of the laboratory, and interviews with laboratory staff, it was determined the laboratory failed to follow written policies for positive identification of urine specimens. As evidenced by: A. A review of the laboratory policy for labeling urine specimens revealed "Urine cups given to the patient for specimen collection will be labeled with the patients first initial, last name, date of birth and time of collection." B. During a tour of the laboratory, at 0930 on 4/4/2019, the surveyor observed of six urine containers in the laboratory sink. Three of six urine containers were labeled with the patients first and last name only. C. In an interview at 0930 on 4/4/2019, laboratory personnel #3 (as listed on form CMS 209) confirmed the urine containers were not labeled according to laboratory policy.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental

	conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Through a review of the laboratory policy and procedure manual, quality control data for November 2018, January and March 2019, lack of documentation as well as interviews with staff, it was determined the laboratory failed to monitor over time the accuracy and precision of test performance. As evidenced by: A. A review of the laboratory's policy and procedure manual revealed "Shifts and trends should be watched for and corrective actions taken if they occur. B. A review of quality control data (level 1) for November 2018 revealed: Thyroid Stimulating Hormone (TSH) control results were above the mean (18 points) and Free Thyroxin (FT4) control results were above the mean (18 points). A review of quality control data (level 2) for November 2018 revealed: Ferritin control results were below the mean (all points); Prostate Specific Antigen control results were below the mean (all points); TSH control results were above the mean (all points) and FT4 control results were above the mean (14 points). A review of quality control data (level 3) for November 2018 revealed: Ferritin control results were below the mean (all points) and TSH control results were above the mean (all points). C. A review of quality control data (level 2) for January 2019 revealed: FT4 control results were above the mean (16 points); Ferritin control results were below the mean (all points) and PSA control results were below the mean (all points). D. A review of quality control data (level 1) for March 2019 revealed TSH control results were above the mean (18 points): A review of quality control data (level 2) for March 2019 revealed Ferritin control results were below the mean (all points); PSA control results were below the mean (22 points) and TSH control results were above the mean all points: A review of quality control data (level 3) for March 2019 revealed Ferritin control results were below the mean all points; TSH control results were above the mean all points. E. There was no documentation that the laboratory had identified the shifts or trends in test performance or any actions performed to address the shirt or trends. F. In an interview on 4/3/2019 at 1030, laboratory personnel #3 (as listed on form CMS-209) confirmed the laboratory did not evaluate the accuracy and precision over time to meet established criteria of acceptability.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: . Through a review of Liquimmune package inserts, quality control records, lack of documentation, as well as interviews with laboratory staff, it was determined the laboratory failed to establish the criteria for acceptability of control materials for the Siemens Immulite Chemistry Analyzer. As evidence by: A. The laboratory utilizes the Siemens Immulite 1000 to analyze Thyroid Stimulating Hormones (TSH), Free Thyroxin (FT4), Prostate Specific Antigen (PSA) and Ferritin. B. A review of the Liquimmune package insert revealed "Instrument values provided are intended to assist the laboratory in establishing its own means and ranges. Laboratory established means should fall within the assigned ranges." C. The surveyor requested documentation of established ranges for Immunoassay control lot # LIA20041 (level I) LIA20042 (level 2) and LIA20043 (level 3) for analytes TSH, FT4, Ferritin and PSA. None was provided. D. In an interview at 1000 on 4/3/2019, laboratory personnel #3 (as listed on form CMS 209) confirmed the laboratory did not establish their own means and ranges for analytes TSH, FT4, Ferritin and PSA. The laboratory used the manufacturers established mean and range.