Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0984708	02/22/2024
Name of Provider or Supplier	**Street Address, City, State**	
Arkansas Urology P A	1300 Centerview Drive, Room 1099/1106 A/B, Little Rock, 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
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 policies and procedures for quality control, a review of the BioRad Control manufacturer's requirements for assigment of values, and a review of the Beckman Coulter DX 600 and Vitros 5600 quality control (QC) documentation, as well as interviews with laboratory staff, it was determined the laboratory failed to use statistical parameters to calculate criteria for acceptability of QC for ten of ten tests reviewed in which BioRad Controls were the quality control material used. Survey findings include: A) A review of the laboratory policies and procedures determined the policies and procedures stated "control ranges may be used if assayed controls are based on instrument utilized in clinic and package insert does not instruct other wise" if the manufacturer's package insert requires the laboratory to determine its own mean and acceptable range the policy and procedure states "minimum of 20 samples performed on each analyte per control, mean and standard deviation must be

	calculated on data". . B) The manufacturer's package inserts for Biorad Multiqual Liquid Assayed control lot# 45890, Biorad Urine Chemistry control lot # 8870, Biorad Specialty Immunoassay controls lot # 64960 quality control instructions for use state, "It is recommended that each laboratory establish its own mean and acceptable ranges and use those provided only as guides" with footnotes on the assay sheets provided for the controls stating "the assigned values were determined using the reagent and/or instrument manufacturer's protocol and may not represent + or - 3SD ranges". C) Through a review of quality control documentation for for ten analytes recorded in January 2023, May 2023, and August 2023, the surveyor observed the mean and acceptable quality control ranges the laboratory employed were identical to the mean and ranges provided by the manufacturer of Biorad Multiqual Assayed control lot # 45890 for the analytes of Albumin (ALB), Serum Glutamic Pyruvate Transaminase (ALT), Carbon Dioxide (CO2) High Density Lipoprotein Cholesterol (HDL) Sodium (Na) and Total Protein (TProt) , and the analyte for urine creatinine (Ur Creat) was identical to that provided by the manufacturer of Biorad Urine Chemistry control lot # 8871 and the analyte of Prostatic Specific Antigen (PSA) was identical to that provided by the manufacturer of Biorad Specialty Immunoassay control lot # 97400. D) In an interview, at 3:45 on 2 /21/24, laboratory employee #4 (as listed on the form CMS-209) stated "we set acceptable ranges from the package inserts" and further explained this was accomplished by entering the range from the manufacturer's package insert into the Orchard laboratory information system.