Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0468136	(X3) Date Survey Completed 04/10/2019
Name of Provider or Supplier Pocahontas Medical Clinic P A	**Street Address, City, State** 2901 Medical Center Drive, Suite 500, Pocahontas, 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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Through observations made during a tour of the laboratory at 10:35 am on 4/9/2019, and interviews with laboratory staff at the time of the tour, it was determined the laboratory failed to follow manufacturer's expiration instructions for the Multistix 10 SG urine dipsticks. Survey findings include: A. During a tour of the laboratory (10:35 am on 4/9/2019) the surveyor observed one container of Multistix 10 SG urine dipsticks (lot # 709087) on the laboratory counter by the microscope. The Multistix 10 SG (lot # 709087) expired on 3/31/2019, nine days prior to the date of the survey. One of six containers of Multistix 10 SG had exceeded the expiration date. B. In an interview at the time of the tour the technical consultant confirmed the container of Multistix 10 SG were currently in use and further confirmed that they had exceeded their expiration date.
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 the BIO-RAD Lyphochek Immunoassay Plus Control package insert, a review of Levey-Jennings Graphs for PSA, TSH, T4 Free, and T3 Total, and through interviews with laboratory staff, it was determined the laboratory failed to calculate target means, as required by the manufacturer, for new lots of quality control material for four of four tests which use BIO-RAD Lyphochek Immunoassay Plus Control as the control material. Survey findings follow: A. BIO-RAD Lyphochek Immunoassay Plus Control package insert states, "It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides." B. Target means listed on the BIO-RAD Lyphochek Immunoassay Plus Control package insert are as follows for Level 2 (lot #40362): PSA 2.44; TSH 5.11; T4 Free 2.88; and T3 Total 2.00. Target means listed for Level 3 (lot # 40363) are: PSA 14.3; TSH 33.1; T4 Free 3.92; and T3 Total 3.25. C. Levey-Jennings Graphs for quality control included the following means for BIO-RAD Lyphochek Immunoassay Plus Control Level 2 which were taken from the package insert instead of calculated by the laboratory: PSA 2.44; TSH 5.11; T4 Free 2.88; T3 Total 2.00. The Graphs also include the following means for Level 3 Control: PSA 14.3; TSH 33.1; T4 Free 3.92 (in use 7/31/2018 through 10/9/2018); and T3 Total 3.25. All means other than T4 Free are documented in use from the date the new control lot was started (7/31/2018) through the date of the survey (4/10/2019). D. In an interview (10:17 on 4/10/2019) the technical consultant (as listed on the form CMS-209) confirmed the laboratory had failed to establish it's own mean and had used the package insert mean for all tests in which the BIO-RAD Lyphochek Immunoassay Plus Control is used as control material.