Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0393469	06/09/2021
Name of Provider or Supplier	**Street Address, City, State**	
Associated Physicians, Llp	4410 Regent St 1st Flr, Madison, WI	

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
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 surveyor review of laboratory procedures and interview with the technical consultant, the laboratory did not have a procedure for performing white blood cell differentials. Findings include: 1. Review of laboratory procedures showed no evidence of a written procedure for performing white blood cell differentials. 2. Interview with the technical consultant on June 9, 2021 at 1:24 PM confirmed the laboratory performs white blood cell differentials and confirmed the laboratory does not have a written procedure for this test. This is a repeat deficiency previously cited on January 23, 2013 and April 13, 2011.
D5451	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iii)(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-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256 (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by:

	Based on surveyor review of Rheumatoid Factor (RF) control and patient records and interview with the technical consultant, the laboratory performs RF tests producing titered results when the patient test is positive but does not test a control material with titered reactivity. Findings include: 1. Review of RF Control records for the Rhuemajet RF- Biokit showed the laboratory tests a negative and positive control each day of patient testing. No evidence of a titered control is present. 2. Review of patient records showed the laboratory reported titered results for patient samples when the RF result for the undiluted specimen was positive. 3. Interview with the technical consultant on June 9, 2021 at 11:15 AM confirmed the laboratory did not include a control material with titered reactivity when testing titered patient samples.