

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  26D0440645	<b>(X3) Date Survey Completed</b>  12/16/2020
<b>Name of Provider or Supplier</b>  Arthritis Consultants, Inc	<b>Street Address, City, State</b>  522 N New Ballas, Suite 240, Saint Louis, MO	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on the review of procedure manuals for the Coulter AcT diff2 hematology analyzer, patient and background reports and interview with the technical consultant (TC), the laboratory failed to have a policy for hematology troubleshooting for analyzer flags and repeated failed background counts. Findings: 1. Review of the procedure manuals for Coulter AcT diff2 hematology analyzer and patient test reports showed the laboratory must refer to the troubleshooting manual for analyzer flags. The laboratory failed to define in a policy the acceptable criteria and resolution for patient samples when flags occurred on patient results. 2. Review of background counts for the startup of Coulter AcT diff2 hematology analyzer showed multiple attempts at failed background counts to achieve acceptability. The laboratory failed to define in a policy the acceptable criteria and resolution for failed background counts. 3. Interview with the TC on December 16, 2020 at 10:30 AM confirmed the laboratory failed to have a policy for troubleshooting patient result flags, and acceptable criteria and resolution for failed background counts.</p>