

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 42D1087535	<b>(X3) Date Survey Completed</b> 09/13/2019
<b>Name of Provider or Supplier</b> Children's Group, Pc, The	<b>Street Address, City, State</b> 604 N 5th Street, Hartsville, SC	
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>D5429</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on instrument operator manual review, instrument maintenance record review and testing personnel interview, it was determined that the laboratory failed to document instrument decontamination on the Abbott Emerald hematology instrument for one of thirty days reviewed from April 1, 2018 through April 30, 2018 (April 18, 2018). Findings include: 1. Review of the Abbott Emerald hematology instrument operator's manual on 09/13/2019 at 11:30am revealed that all operators should decontaminate the system prior to shipment or relocation. 2. Review of the April 2018 Abbott Emerald hematology instrument maintenance logs on 09/13/2019 at 11:35am revealed that system decontamination had not been performed prior to the instrument relocation on 04/18/2018. 3. Testing personnel confirmed during an onsite interview on 09/13/2019 at 12:30pm that the instrument decontamination had not been performed for the reviewed time period.</p>