

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D0249617	(X3) Date Survey Completed 07/17/2019
Name of Provider or Supplier Doctor's Care - Shandon	Street Address, City, State 2601 Rosewood Drive, Columbia, SC	
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
D5429	<p>MAINTENANCE AND FUNCTION CHECKS 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: During an onsite recertification survey on 07/17/2019, based on instrument operator manual review, instrument maintenance record review and testing personnel interview, it was determined that the laboratory failed to document monthly and daily maintenance on the Medonic hematology instrument for seven of seven months reviewed in 2019 (January 2019 through July 2019). Findings include: 1. Review of the Medonic hematology analyzer operator's manual revealed that all operators should routinely perform scheduled maintenance to ensure optimum performance of the instrument including a monthly cleaning and clot prevention and also a daily cleaning of the aspiration and pre-dilute needles. 2. Review of the Medonic hematology analyzer maintenance logs revealed that monthly and daily maintenance had not been documented for seven of seven months reviewed in 2019 (January 2019 through July 2019). 3. Testing personnel confirmed during an onsite interview on 07/17/2019 at 3:30pm that the monthly and daily maintenance had not been performed for the reviewed months.</p>