

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  42D1054923	<b>(X3) Date Survey Completed</b>  06/26/2018
<b>Name of Provider or Supplier</b>  Doctors Care North Aiken	<b>Street Address, City, State</b>  1029 York St Ne, Aiken, 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>D5401</b>	<p><b>PROCEDURE MANUAL</b> 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: During an onsite recertification survey on 06/26/2018, based on laboratory procedure manual review, random patient chart review, and confirmation by the laboratory testing personnel, the laboratory failed to follow their written procedures to confirm flagged complete blood count (CBC) results by repeat testing for 1 of 5 patient CBCs reviewed from 2016 to 2018. Findings include: 1. The laboratory procedure manual stated that all CBCs with BD, NM, OM or TM flags are verified by repeat analysis. 2. Random review of patient records revealed the following CBCs which were reported with no repeat analysis documented. a. Patient #3384113, tested 08/14/2017, OM flags on CBC report b. Patient #3606354, tested 08/31/17, OM flags on CBC report c. Patient #D199535, tested 3/2/18, BD flags on CBC report 3. Testing personnel confirmed during interview on 06/26/2018 at 12:00pm, that the laboratory had failed to follow their written procedures to confirm flagged complete blood count (CBC) results.</p>