

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  04D1048934	<b>(X3) Date Survey Completed</b>  12/20/2018
<b>Name of Provider or Supplier</b>  Wrnc Medical Complex Laboratory	<b>Street Address, City, State</b>  195 Hospital Drive, Suite E, Cherokee Village, AR	
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: Through a review of the Laboratory Policy and Procedure Manual, a review of Platelet Poor Plasma Studies for 2016 through 2018, and interviews with laboratory staff, it was determined the laboratory failed to follow written procedures for performing Platelet Poor Plasma Studies twice per year. Survey findings include: A. The Laboratory Policy and Procedure Manual includes a policy that requires the laboratory to perform Platelet Poor Plasma Studies twice per year to insure that the speed and time in which the laboratory centrifuges samples for coagulation are adequate to produce platelet poor plasma (which is the required sample) for coagulation testing. B. Through a review of the Platelet Poor Plasma Studies for 2016, 2017, and 2018 it was determined that Platelet Poor Plasma Studies were performed on 12/14/2016, 9/7/2017, and 10/24/2018 (performed three of five due since December 2016). Studies were documented once per year instead of twice per year as required by the written laboratory procedures. C. During an interview at 10:05 on 12/20/2018, the technical consultant (as listed on the form CMS-209) confirmed the laboratory performed Platelet Poor Plasma Studies once per year instead of twice per year as required by the written procedures.</p>
<b>D5445</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations</p>

Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--  
(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Through a review of the Individualized Quality Control Plan (IQCP) for the GEM 3000, a tour of the laboratory, and interviews with laboratory staff, it was determined the laboratory IQCP for blood gas testing did not include required components and was not completed for the instrument in use for blood gas analysis. Survey findings follow: A. During a review of the IQCP for blood gas testing it was determined the IQCP risk assessment was missing two of the five required components. The IQCP risk assessment did not include risk assessment for Reagents or for the Test System. During the review it was also noted that the IQCP was written for the GEM 3000 blood gas test system although the blood gas test system in use is the GEM 3500. B. During a tour of the laboratory on 12/20/2018 at 09:25, the surveyor observed the GEM 3500 in use for blood gas testing although the IQCP in the laboratory policy and procedure manual was written for the GEM 3000. C. In an interview at 10:05 on 12/20/2018 the technical consultant (as listed on the form CMS-209) confirmed the IQCP was not for the current instrument and did not include Reagent and Test System components of the risk assessment.