

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2119640	(X3) Date Survey Completed 01/25/2018
Name of Provider or Supplier Frederick P Smith, Md, Pc, Division Of Rcca	Street Address, City, State 5530 Wisconsin Avenue Suite 1640, Chevy Chase, MD	
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
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Based on review of the written procedure manual and interview with the testing person, the laboratory did not have written policies and procedures for identifying and labeling patient hematology specimens utilizing a unique identifier Findings: 1. The laboratory did not have a system in place when two specimens are received that have the same first and last name or date of birth. 2. The laboratory must have polices and procedures in place to process hematology specimens using distinct identifiers in order to distinguish between the specimens. 3. The testing person confirmed that a policy was not available to identify patients when the two specimens have the same first, and last name or date of birth.</p>
D5401	<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>

This STANDARD is not met as evidenced by:

Based on review of the written procedure manual interview with the testing person, and the analyzer consultant, the laboratory did not follow written procedures for performing hematology testing. Findings: 1. Hematology specimens once collected were placed on a mechanical rocker prior to testing. The analyzer consultant stated that when the testing person is busy samples are rocked. 2. The written procedure states to not place samples on a mechanical rocker prior to patient testing. Constant rocking may cause platelet clumping and white cell membrane changes causing false patient result interpretations. 3. The testing person confirmed that hematology samples are rocked prior to performing patient testing.