

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D1083426	(X3) Date Survey Completed 02/19/2020
Name of Provider or Supplier Medstar Med Grp Southern Md Llc/ Cancer Rec Ctr	Street Address, City, State 23415 Three Notch Road Suite 2050, California, 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
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> <p>This STANDARD is not met as evidenced by: Based on laboratory procedure manual and record review and interview with the technical consultant (TC), the laboratory did not ensure that the procedure for evaluating internal hematology quality control (QC) accurately reflected the current practice in the laboratory. Findings: 1. The procedure, "Internal CBC Quality Control Using Patient Specimen" states that, "a patient's sample that has been tested in the early morning hours" "will be tested in the late afternoon. The values will be compared with the morning values and the differences must fall within the stated ranges below." 2. During an interview at 1:00 PM, the testing person stated that they "look at" the results of the two runs to determine if the results are acceptable, but that they don't refer to the acceptable ranges listed in the procedure manual; and 3. The laboratory has documentation that the runs were performed, but there is no indication whether the morning and afternoon runs were acceptable. 4. During an interview on 2/14/20 at 2:00 PM, the TC confirmed that testing personnel were not following the approved procedure for evaluating internal hematology QC for acceptability.</p>
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3)</p>

Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on observation and interview with the technical consultant (TC), the laboratory did not ensure that hematology controls were labeled with the date that they expire.

Findings: 1. During a tour of the laboratory at 11:00 AM, it was observed that the opened and in use "Sysmex XN-L Check" hematology controls in the laboratory refrigerator were labeled with the date that they were put in to use but were not labeled with the expiration date. 2. During an interview on 2/14/20 at 11:00 AM, the TC stated that the controls expire 15 days after opening and confirmed that the in-use hematology controls were not labeled with the expiration date.