Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D1083426	01/16/2018
Name of Provider or Supplier	**Street Address, City, State**	
Medstar Med Grp Southern Md Llc/ Cancer Rec Ctr	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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on observation of laboratory (lab) procedures and interview with the technical consultant on the day of survey, the lab did not have safety data sheets for chemicals used for lab testing and cleaning. The surveyor requested the safety data sheets, but they were not available in the lab.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory (lab) staff, the lab written policies for conducting competency checks conducted on testing personnel did not include instructions for documenting each process used to determine competency. Findings: 1. The written procedure did not include instructions to review and observe the recording of patient testing records, preventive maintenance records and quality control records to ensure they are conducted and reported in an accurate and reliable

	manner; 2. The lab did not have instructions to conduct and document staff competency based on practical skills used to problem solve; and 3. this was confirmed during interview with the technical consultant on the day of survey.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory (lab) staff, the hematology labs written quality control policies did not have instructions to monitor quality control results to detect immediate failures as indicated by control results (same analyte) not within range (between 2 and 3 standard deviations) on consecutive days of testing. Findings: 1. The written hematology quality control policy did not instruct staff that quality control failures for an analyte (between 2 and 3 standard deviations) occurring on consecutive days of testing, can indicate a quality control failure and needs investigation and corrective actions prior to testing patient samples; and 2. This was confirmed with the technical consultant during interview on the day of survey.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on record review, the director did not have written procedures to ensure primary source verification for credentialing of laboratory (lab) staff. Findings: 1. The technical consultant did not have written procedures for using primary source verification to credential testing personnel; 2. These records can be primary source documents and they can also be from a third party that has been verified by the lab. This verification would be to ensure that the third party has observed primary source records, evaluated them for CLIA and made a determination; and 3. The labs written procedure did not provide names of entities permitted to credential lab staff, because they have been shown to perform primary source verification procedures.