Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D1080172	06/06/2023
Name of Provider or Supplier	**Street Address, City, State**	
Smgmg	1011 Clifton Avenue, Clifton, NJ	

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
D3033	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)(i) In addition, the laboratory must retain records of test system performance specifications that the laboratory establishes or verifies under 493.1253 for the period of time the laboratory uses the test system but no less than 2 years. This STANDARD is not met as evidenced by: Based on the lack of Performance Specifications (PS) and interview with the Testing Personnel (TP), the laboratory failed to retain PS records for the Horiba ABX Micros analyzer used to perform Hematology Testing from 11/14/2019 to the date of survey. The findings include: 1) There were no linearity records. 2) There was no source for normal Patient range. 3) The TP confirmed via email on 6/12/23 at 2:15 pm that all PS records were not retained.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals

	(normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to have a referral procedure for sending specimens to reference laboratories for testing from 1/14/19 to the date of the survey. The TP as listed on CMS form 209 confirmed on 06/06/2023 at 12:00 pm that the PM did not have a referral procedure.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on lack of Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to document the reaction of a control slide for the iron stain used for Histopathology tests from 11/29/17 to the date of the survey. The TP #1 listed on CMS form 209 confirmed on 06/06/2023 at 11:25 am that the laboratory did not document the reaction of a control slide. Note: This is a repeat citation.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Assurance (QA) records and interview with the Testing Personnel (TP), the laboratory director failed to review the laboratory maintained QA program from 07/01/2020 to the date of the survey. The findings include; 1) There was no evidence the laboratory director reviewed monthly QA checklists at the time of survey. 2) The TP confirmed on 06/06/2023 at 12:00 PM there was no evidence the laboratory director reviewd monthly QA checklist records.