Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D1080172	11/14/2019
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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on the lack of Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to enroll in an approved PT program for Manual Differential (MD) tests from 11/29/17 to the date of survey. The TP #1 listed on CMS form 209 confirmed on 11/14/19 at 1:00 pm the laboratory was not enrolled in PT testing for MD.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to verify the accuracy and reliability of Bone Marrow smear tests twice a year from 11/29/17 to the date of survey. The TP

	#1 listed on CMS form 209 confirmed on 11/14/19 at 2:00 pm that the laboratory did not verify the accuracy of above mentioned tests.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) 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) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor review of Manufactures Package Insert, observation of the Quality Control material, and interview with the Testing Personnel (TP), the laboratory failed to put a new expiration date on Hematology Control material used on the Horiba ABX Micros 60 on the date of the survey. The TP #1 listed on CMS form 209 confirmed on 11/14/19 at 1:10 pm the laboratory failed to put a new expiration date on the control material.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on surveyor review of the laboratory records, procedure manual and interview with the Testing Personnel (TP), the laboratory failed to establish a maintenance protocol for the Microscope when protocols were not provided by the manufacturer from 11/29/17 to the date of the survey. The TP #1 listed on CMS form 209 confirmed on 11/14/19 at 1:30 pm that the laboratory did not establish a maintenance protocol.
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 11/14/19 at 1:25 pm that the laboratory did not document the reaction of a control slide.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on lack of an Accession Log (AL) and interview with the Testing Personnel (TP), the laboratory failed to maintain an Accession Log (AL) for Hematology peripheral smears and Bone Marrow smear tests from 11/29/17 to the date of survey. The TP #1 listed on CMS form 209 confirmed on 11/14/19 at 2:15 pm that the laboratory did not maintain an AL for the above mentioned tests.
D5803	TEST REPORT CFR(s): 493.1291(b) Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request. This STANDARD is not met as evidenced by: Based on the surveyor review of the Test Reports (TR) and interview with the Testing Personnel (TP), the laboratory failed to have a TR for Manual Differential (MD) tests from 11/17/17 to the date of the survey. The TP #1 listed on CMS form 209 confirmed on 11/14/19 at 2:10 pm that MD tests did not have a TR.
D6074	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(5) Each individual performing moderate complexity testing must be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the technical consultant, clinical consultant or director. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with the Testing Personnel (TP), the TP failed to identify problems that may affect test performance by not reviewing and evaluating trends and/or shifts for tests performed on the Horiba ABX Micros 60 analyzer from 11/29/17 to the date of the survey. The TP #1 listed on CMS form 209 confirmed on 11/14/19 at 1:45 pm that trends and shifts were not reviewed.

D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on surveyor review of the laboratory Procedure Manual and interview with the Testing Personnel (TP), the Laboratory Director failed to ensure a Quality Assurance (QA) program was established to assure quality of laboratory services provided from 11/29/17 to the date of the survey. The TP #1 listed on CMS form 209 confirmed on 11/14/19 at 1:45 pm that a QA program was not established.