Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0129618	10/30/2018
Name of Provider or Supplier	**Street Address, City, State**	
Daniel M Libby Md Pllc	407 E 70 St 3rd Floor, New York, NY	

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
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a lack of Individualized Quality Control Plan (IQCP) procedure and an interview with the technical consultant, the laboratory failed to have in place the Risk Assessment (RA) part of the IQCP procedure for Hitachi CLA Allergy testing. Findings Include: It was confirmed with the technical consultant on October 30, 2018 at approximately 3:30 pm that the laboratory failed to perform the evaluation of the five risk assessment components (Test system, Reagent, Environment and Testing personnel) for all phases of testing on the Hitachi CLA Allergen-Specific IgE Assay test.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on a lack of documentation and an interview with the technical consultant, the laboratory has not performed the external and internal quality control (QC) each day of patient testing. Findings Include: It was confirmed with the technical consultant approximately 3:30 pm that the laboratory failed to performed the external and internal QC for Allergy testing performed for the Hitachi CLA Allergen-Specific IgE Assay each day of patient testing. Approximately 400 patients specimens were tested and results reported from July 2018 through October 2018.
D6020	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 the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a lack of QC records, and confirmed in an interview at the time of this survey with the technical consultant, the laboratory director failed to ensure that the QC program for the Hitachi Allergy testing panel was maintained to assure quality of laboratory services. Refer to: D5449
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 the surveyor's review of the laboratory's policy/procedure manual and an interview with the technical consultant, the laboratory director failed to ensure that the laboratory's quality assessment (QA) policy/procedure was followed. Refer to D5445