Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0150319	(X3) Date Survey Completed 01/31/2019
Name of Provider or Supplier Ent And Allergy Associates, Llp	**Street Address, City, State** 163-03 Horace Harding Expressway - 3rd Floor, Fresh Meadows, 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
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 a review of competency procedures, records and an interview with the laboratory testing person, the laboratory failed to have a complete policy/procedure to assess employees competency. Finding Include: At approximately 11:15 am on January 31, 2019, it was confirmed by the laboratory testing person that the laboratory failed to include in their competency procedure direct observation of routine patient test performance (including patient preparation, if applicable, specimen handling, processing, and testing); and the performance of instrument maintenance and function checks.
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 review of quality control records and an interview with the laboratory

	testing person, the laboratory failed to follow their procedure and test external liquid control each day of patient testing. Findings Include: On January 31, 2019, at approximately 11:15 am the laboratory testing person confirmed that the laboratory failed to perform and retain documentation of the external control results for Allergy testing performed on the Hitachi CLA Allergen-Specific IgE Assay on February 8, 14, April 25, May 1, 2, 8 and 9, and August 14, 2018. A total of 155 patient specimens were tested and results released on the above days that controls were not tested.
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 review of QC records, and an interview with the laboratory testing person, the laboratory director failed to ensure that the QC program for allergy testing was maintained to assure the quality of laboratory services. Refer to: Refer to D5449