Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0669887	10/15/2019
Name of Provider or Supplier	**Street Address, City, State**	
Allergy & Pediatric Assoc Of Jersey Shore	315 West Main Street, Suite A, Freehold, 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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Laboratory Director (LD), the laboratory failed to ensure that Testing Personnel (TP) who performed Bacteriology Tests participated in the College of American Pathologists PT events in the calendar years 2018 and 2019. The finding includes: 1. A review of all PT event revealed that two out of 18 TP performed PT events in 2018 and 2019. 2. The LD confirmed on 10/15/19 at 10:30 pm that PT events were not rotated between TP.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the surveyor review of the Quality Control (QC) records and interview with

	the Testing Personnel (TP), the laboratory failed to check each new lot number and shipment of culture media for sterility from 10/5/17 to the date of the survey. The TP #12 list on CMS form 209 confirmed on 10/15/19 at 11:00 am the laboratory did not perform sterility on culture media.