Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0985260	02/14/2019
Name of Provider or Supplier	**Street Address, City, State**	
Asthma & Allergy Solutions Inc	858 S White Horse Pike, Hammonton, 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
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 surveyor review of the Competency Assessment (CA) records and interview with the Testing Personnel (TP), the laboratory failed to perform CA correctly on one of one TP from 3/1/17 to the date of survey. The finding includes: 1. The CA did not include how assessment was done and what records were reviewed. 2. The TP confirmed on 2/14/19 at 1:00 am that CA was not done correctly.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H 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 review and evaluate coded PT results obtained from the College of American Pathologists (CAP) for Diagnostic Allergy events performed in the calendar year 2018. The finding include: 1. There was no evaluation documented when the laboratory received an exception code of 20 (No appropriate target/response cannot be graded) and 26 (Educational Challenge) in the calendar year 2018. 2. The TP confirmed on 2/14/19 at 10:30 am that the laboratory did not review and evaluate coded PT results in 2018.

D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on surveyor review of the Final Reports (FR) and interview with the Testing Personnel (TP), the laboratory failed to ensure that the Test Report Date (TRD) was indicated on the FR for allergy tests performed on the HYTEC 288 analyzer from 3/1 /17 to the date of survey. The TP confirmed on 2/14/19 at 10:55 am that the TRD was not on the FR.