Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0121068	06/20/2018
Name of Provider or Supplier	**Street Address, City, State**	
Allergy & Asthma Of South Jersey	1122 N High Street, Millville, 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
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual and interview with the Laboratory Director (LD), the laboratory failed to establish a written procedure for Biannual Assessment (BA) from 6/16/16 to the date of survey. The LD confirmed on 6/20/18 at 10:00 am that a BA procedure was not established.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values.

	(12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Laboratory Director (LD), the laboratory failed to have a slide retention procedure for Allergic Cell Cytology tests from 6/16/16 to the date of the survey. The LD confirmed on 6/20/18 at 11:45 am the laboratory did not have the above procedure.
D5629	CYTOLOGY CFR(s): 493.1274(c)(5) (c) Control procedures. The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: (c)(5) An annual statistical laboratory evaluation of the number of - (c)(5)(i) Cytology cases examined; (c)(5)(ii) Specimens processed by specimen type; (c)(5)(iii) Patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation); (c)(5)(iv) Gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison; (c)(5)(v) Gynecologic cases where cytology and histology are discrepant; and (c)(5)(vi) Gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and office review of records, the laboratory failed to establish a written procedure which includes an annual statistical evaluation of cytology cases examined from 6/16/16 to the date of the survey. The findings include: 1. The PM did not have a procedure to determine statistics as follows: a. Cytology cases examined b. Specimens processed by specimen type c. Patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation) on the day of the survey. 2. The Office Manager was notified and confirmed via telephone on 6/27/18 at 1:30 pm the laboratory did not have a procedure for annual statistical evaluation.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

	This STANDARD is not met as evidenced by: Based on surveyor review of the Accession Log (AL), Final Report (FR) and interview with the Laboratory Director (LD), the laboratory failed to ensure that test results were accurately and reliably entered on the FR from 6/16/16 to the date of survey. The findings include: 1. A review of 10 patients listed on the AL and the corresponding FR revealed: a. Patient LM - 7/20/17 AL specimen -sputum X 2; FR specimen - nasal b. Patient GSS - 4/11/18 AL specimen - conjunct; FR had no result c. Patient SK - 5/16/18 & 6/6/18 - AL specimen - nasal; FR had no result 2. The LD confirmed on 6/20/18 at 11:30 am that the laboratory did not report results accurately and in a timely manner.
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 Report (FR) and interview with the Laboratory Director (LD), the laboratory failed to ensure that the FR for Allergic Cell Cytology tests included all the required information from 6/16/16 to the date of the survey. The findings include: 1. The FR did not have the name and address of the laboratory where tests were performed. 2. The FR did not have the Test Report date. 3. The LD confirmed on 6/20/18 at 11:30 am that the FR failed to include all the required information.