

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0954290	(X3) Date Survey Completed 10/02/2018
Name of Provider or Supplier Allergy Diagnostic & Treatment Ctr Llc	Street Address, City, State 33 Overlook Road, Summit, 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
D3043	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(7)</p> <p>The laboratory must retain cytology slide preparations for at least 5 years from the date of examination (see 493.1274(f) for proficiency testing exception). The laboratory must retain histopathology slides for at least 10 years from the date of examination. The laboratory must retain pathology specimen blocks for at least 2 years from the date of examination. The laboratory must preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation of the lack of Cytology Slides (CS) and interview with the Testing Personnel (TP), the laboratory failed to retain CS for 5 years from the date of examination from 10/2/18 to the date of the survey. The TP #5 listed on CMS form 209 confirmed on 10/2/18 at 2:00 pm the CS were not retained.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: a. Based on surveyor review of the Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to establish a procedure for microscope maintenance from 10/4/16 to the date of the survey. The TP #5 listed on CMS form 209 confirmed on 10/2/18 at 1:50 pm that the laboratory did not establish the above</p>

procedure. b. Based on surveyor review of the PM and interview with the TP, the laboratory failed to establish a slide retention procedure for Allergic Cell Cytology tests from 10/4/16 to the date of the survey. The TP #5 listed on CMS form 209 confirmed on 10/2/18 at 1:45 pm 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 and interview with the Testing Personnel (TP), the laboratory failed to establish a written procedure which included patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation from 10/4/16 to the date of the survey. The TP #5 listed on CMS form 209 confirmed on 10/2/18 at 1:30 pm the laboratory did not have the above procedure.

D6102

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(12)

The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:
Based on surveyor review of the Personnel Records and interview with the Testing Personnel (TP), the Laboratory Director failed to ensure that two of six TP had appropriate education prior to patient testing from 10/4/16 to the date of survey. The TP #5 listed on CMS form 209 confirmed on 10/2/18 at 1:20 pm that education was not documented.

D6103

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(13)

The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to

process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Procedure Manual and interview with the Testing Personnel (TP), the Laboratory Director failed to establish a Competency Assessment (CA) procedure with the applicable elements for Cytology tests from 10/4/16 to the date of survey. The TP #5 listed on CMS form 209 confirmed on 10/2/18 at 1:30 pm that a CA procedure was not established.