

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0109813	(X3) Date Survey Completed 04/02/2019
Name of Provider or Supplier Medical Associates Of Englewood, Pc	Street Address, City, State 15-01 Broadway, Suite # 28, Second Floor, Fair Lawn, 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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with the Office Manager (OM), the laboratory failed to retain the QC Slides for Hematoxylin and Eosin, Immunohistochemistry and Special stains used for Histopathology tests from June 2018 to the date of the survey. The OM confirmed on 4/2/19 at 1:30 pm that the QC slides 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: Based on surveyor review of the Procedure Manual (PM), Histopathology records and interview with the Office Manager (OM), the laboratory failed to follow the Standard Operating Procedure (SOP) Section II-3 from 5/25/17 to the date of a the survey. The finding includes: 1. SOP Section II-3 stated: "When slides with corresponding worksheets are received from the Bio-Reference Laboratory, the receipt date is logged</p>

into the Tissue Accession Log (TAL) worksheet. The accession number on the slides will be matched with pathology requisition form" but the laboratory did not have a TAL worksheet. 2. The OM confirmed on 4/2/19 at 1:45 pm that the laboratory did not follow the written procedure stated above.

D5787

TEST RECORDS
CFR(s): 493.1283(a)

The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:
Based on lack of an Accession Log (AL) and interview with the Office Manager (OM), the laboratory failed to maintain an accurate AL for Histopathology slides received from 5/25/17 to the date of the survey. The findings include: 1. A review of documentation revealed the laboratory did not retain the AL received from the laboratory performing the Technical Component of Histopathology testing. 2. The laboratory did not have a record of: a. The date slides were received b. List of patient names received in the shipment c. The number of slides received 3. The OM confirmed on 4/2/19 at 1:30 pm that the laboratory did not maintain the AL received with the slides.