

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0897210	(X3) Date Survey Completed 11/08/2018
Name of Provider or Supplier Endo Associates Of Staten Island Pllc	Street Address, City, State 360 Edison Street, Staten Island, NY	
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
D5473	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and an interview with the laboratory director, the laboratory did not perform and document the quality control (QC) acceptability of the Hematoxylin and Eosin stain used for histopathology slides: Finding included; It was confirmed with the laboratory director on November 8, 2018, at approximately 1:30 PM that the laboratory failed to perform and document the QC acceptability of the H&E stains from the date of the last survey of November 1, 2016, through the date of this survey. Approximately 3714 patient slides were tested and results reported for H&E stains.</p>
D6093	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of QC records and confirmed in an interview with the laboratory director on November 8, 2018, the laboratory director failed to ensure that the QC</p>

program for histopathology was followed to assure quality laboratory services. Refer to D5473