

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0940469	(X3) Date Survey Completed 01/22/2018
Name of Provider or Supplier Pinnacle Urology Pc	Street Address, City, State 133-38 41st Road, Suite 2d, Flushing, 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
D5475	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(3)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (3) Check fluorescent and immunohistochemical stains for positive and negative reactivity each time of use. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on a review of quality control (QC) stain records for histopathology, and an interview with the laboratory director at the time of the survey, the laboratory failed to document the QC test results for the FISH images. Findings Include: The laboratory director confirmed on January 22, 2018 at approximately 11:15 am that the laboratory failed to perform and document the stain quality for the FISH images read from October 2017 through the date of this survey. Approximately 50 patient specimens were tested and reported for FISH testing during that time.</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 a review of QC records and confirmed in an interview with the laboratory director at the time of the survey, the director failed to ensure that the QC program for histopathology was followed to assure the quality of laboratory services. Refer to D5475</p>