

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2006088	(X3) Date Survey Completed 07/23/2025
Name of Provider or Supplier Z Urology	Street Address, City, State 990 N Federal Highway, Pompano Beach, FL	
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
D0000	An announced CLIA recertification survey was conducted at Z UROLOGY on July 23, 2025. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiency:
D5475	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(3)(g)</p> <p>(e)(3) Check fluorescent and immunohistochemical stains for positive and negative reactivity each time of use.</p> <p>This STANDARD is not met as evidenced by: Based on record review and consultant interview, the laboratory failed to document the positive and/or negative control reactivity for the following immunohistochemical (IHC) stains: Cluster of Differentiation 44 cell surface glycoprotein IHC stain (CD44), Nuclear Non-histone Protein IHC stain (KI67), Tumor Suppressor protein IHC stain (P63), Prostate Adenocarcinoma IHC stain (P504S) for four out of six cases reviewed. Findings included: 1-Review of Form CMS-116 (03/240, revealed that the laboratory performed the interpretation of the IHC stains CD44, KI67, P63, P504S. 2- Review of "DAILY QUALITY CONTROL FOR IMMUNOS & SPECIAL STAINS" log for cases read on the following dates: P#1 (12/16/2024), P#2 (01/08/2025), P#3 (02 /13 /2025), P#4 (03/25/2025), P#5 (04/10/2025) and P#6 (05/13/2025), revealed that for cases: P#1, P#2, P#3 (no documentation of the acceptance of the positive and negative controls; P#3 was not documented the reactivity of negative control. Review of patients reports, revealed no documentation of the reactivity of the positive and negative controls. 3- During an interview on 07/23/2015 at 10:30 AM the consultant confirmed that the laboratory failed to document the reactivity of the positive and /or negative controls for the IHC stains reviewed above.</p>