Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0479301	10/06/2020
Name of Provider or Supplier	**Street Address, City, State**	
Texas Urology Specialist - Dallas Methodist	1411 N Beckley Ave Pav Iii Ste 464, Dallas, TX	

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	Entrance and exit conferences were held with the laboratory representatives. The survey process was discussed, and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the entrance and exit conferences. The laboratory representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in COMPLIANCE with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (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. This STANDARD is not met as evidenced by: Based on review of laboratory records, patient test records, and confirmed in interview, the laboratory failed to document the intended reactivity for Hematoxylin and Eosin (H & E) staining to ensure predictable staining characteristics and failed to document the negative and positive reactivity of quality control slides for

	Hematoxylin and Eosin (H & E) staining on each day of patient testing between January 2019 to June 2020. Findings included: 1. Review of laboratory records revealed that all histology specimens for the laboratory were sent to a reference laboratory for grossing and Hematoxylin and Eosin (H & E) staining. The slides were digitized and shipped back to the laboratory for pathological interpretation. 2. A random review of patient test reports between January 2019 and June 2020 revealed the laboratory failed to document the intended reactivity for Hematoxylin and Eosin (H & E) staining and failed to document the negative and positive reactivity of quality control slides for Hematoxylin and Eosin (H & E) staining on each day of patient testing between January 2019 to June 2020. 3. According to records, the laboratory's annual volume was 2,800 histology tests. 4. The above findings were confirmed by the laboratory director in an interview on 10/06/2020 at 1046 hours.
D5475	CONTROL PROCEDURES CFR(s): 493.1256(e)(3)(g) (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. This STANDARD is not met as evidenced by: Based on review of laboratory records, patient test records, and confirmed in interview, the laboratory failed to document immunohistochemical stains for positive and negative reactivity each time of use between January 2019 and June 2020. Findings included: 1. Review of laboratory records revealed that all histology specimens for the laboratory were sent to a reference laboratory for grossing and immunohistochemical staining. The slides were digitized and shipped back to the laboratory for pathological interpretation. 2. A random review of patient test reports between January 2019 and June 2020 revealed the laboratory failed to document immunohistochemical stains for positive and negative reactivity each time of use between January 2019 and June 2020. 3. The above findings were confirmed by the laboratory director in an interview on 10/06/2020 at 1046 hours.