Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0715825	10/03/2018
Name of Provider or Supplier	**Street Address, City, State**	
University Urology Assoc Of Nj	20 Hospital Dr Suite 15, Toms River, 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
D5629	CYTOLOGY CFR(s): 493.1274(c)(5) (c) Control procedures. The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: (c)(5) An annual statistical laboratory evaluation of the number of - (c)(5)(i) Cytology cases examined; (c)(5)(ii) Specimens processed by specimen type; (c)(5)(iii) Patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation); (c)(5)(iv) Gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison; (c)(5)(v) Gynecologic cases where cytology and histology are discrepant; and (c)(5)(vi) Gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual and interview with the Consultant, the laboratory failed to establish a procedure for documenting an annual statistic for cytology cases examined, Specimens processed by specimen type and Patient cases reported by diagnosis from 10/19/16 to the day of survey. The Consultant confirmed on 10/3/18 at 12:40 PM that the above mention procedure was not established.
D5643	CYTOLOGY CFR(s): 493.1274(d)(2)(iii) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(2)(iii) Nongynecologic slide preparations made using liquid-based slide preparatory techniques that result in cell dispersion over one-half or less of the total available slide may be counted as one-half slide; and (d)(2)

	(iv) Technical supervisors who perform primary screening are not required to include tissue pathology slides and previously examined cytology slides (gynecologic and nongynecologic) in the 100 slide workload limit. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Consultant, the laboratory failed to establish workload limits for personnel reading nongynecology slides from 10/19/16 to the day of survey. The Consultant confirmed on 10/3/18 at 12:15 PM that workload limits were not established.
D5645	CYTOLOGY CFR(s): 493.1274(d)(3) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(3) The laboratory must maintain records of the total number of slides examined by each individual during each 24-hour period and the number of hours spent examining slides in the 24-hour period irrespective of the site or laboratory. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual and interview with the Consultant, the laboratory failed to establish a procedure for maintaining records of total number of slides review in 24 hours from 10/19/16 to the day of survey. The consultant confirmed on 10/3/18 at 12:30 PM that above mention procedure was not established
D6173	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495 The testing personnel are responsible for specimen processing, test performance and for reporting test results. This STANDARD is not met as evidenced by: Based on surveyor review of the Slide Delivery Log (SDL), Test Requisitions (TR), Final Reports and interview with the Laboratory Director, the Testing Personnel (TP) failed to maintain accurate specimen processing from 6/11/18 to the date of survey. The finding includes: 1) Case numbers UU18 - 00601 and 00602 from 6/11/18 were not recorded in the SDL 2) Case numbers UU18 -00659 and 00660 from 6/25/18 were not recorded in the SDL. 2) The LD confirmed on 10/3/18 at 1:00 pm TP failed to record case numbers in the SDL.