Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	41D1093435	05/05/2021
Name of Provider or Supplier	**Street Address, City, State**	
Brown Urology, Inc	195 Collyer Street, Providence, RI	

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
D5205	COMPLAINT INVESTIGATIONS CFR(s): 493.1233 The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to ensure a system is place to document and investigate complaints. Findings include: 1. Record review of the laboratory procedue manual on 5/5/21 revealed no written policy for the administration of complaints. 2. Interview with the laboratory staff on 5/5/21 at approximately 9:30 AM revealed that there is no written policy for the administration of complaints.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to establish a written policy for patient preparation. Findings include: 1. Record review of the laboratory procedure manual on 5/5/21 revealed no written policy for the preperation of patients

	prior to testing. 2. Interview with the laboratory staff on 5/5/21 at approximately 9:30 AM confirmed this finding.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory director failed to update and sign for changes to the procedure manual. Findings include: 1. Record review of the approved procedure manual revealed a list of reference laboratories including: Johanthan Epstein at Johns Hopkins, Miraca Life Sciences, Louis Herring Clinical Laboratory and "Other Institution/consultant - as deemed appropriate...". 2. Interview with staff on 5/5/21 at approximately 9:00 AM revealed that Platinum Path P4 is the only current reference laboratory used and is not listed.
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 record review and staff interview the laboratory failed to establish policies and procedures to detect errors in the performance of cytologic examinations and reporting of results that include (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; Findings include: 1. A surveyor request for documentation of the cytology annual statistical anaylysis revealed that no data, policy or procedure was available. 2. Interview with the laboratory staff on 5/5/21 at approximately 9:30 AM revealed that the laboratory does not perform an annual anayisis and had not data to provide.
D5633	CYTOLOGY CFR(s): 493.1274(d)(1) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1) The technical supervisor establishes a maximum workload limit for each individual who performs primary screening.

	This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to establish policies and procedures for workload limits. Findings include: 1: Record review of the laboratory procedure manual on 5/5/21 revealed no policies or procedure for workload limits. 2. Interview with the laboratory staff on 5/5/21 at approximately 9:30 AM confirmed the above finding.
D5635	CYTOLOGY CFR(s): 493.1274(d)(1)(i) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1)(i) The workload limit is based on the individual's performance using evaluations of the following: (d)(1)(i)(A) Review of 10 percent of the cases interpreted as negative for the conditions defined in paragraph (e)(1) of this section. (d)(1)(i)(B) Comparison of the individual's interpretation with the technical supervisor's confirmation of patient smears specified in paragraphs (e)(1) and (e)(3) of this section. This STANDARD is not met as evidenced by: See D Tag 5633
D5637	CYTOLOGY CFR(s): 493.1274(d)(1)(ii) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1)(ii) Each individual's workload limit is reassessed at least every 6 months and adjusted when necessary. This STANDARD is not met as evidenced by: See D Tag 5633
D5663	CYTOLOGY CFR(s): 493.1274(f)(4) (f) Record and slide retention. (f)(4) All slides must be retrievable upon request. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory faile to ensure that patient slides were available upon request. Findings include: 1. Record review of the laboratory "Specimen Send Out Log" on 5/5/21 revealed that between 8/3/20 and 2/26 /21, 8 cases with slides sent out had not been returned. 2. Record review of the laboratory manual on 5/5/21 revealed that a periodic review of the send out log should be completed to "ensure retrun of materials" and that "A request will be made for the return of materials which exceed a period of 60 days." 3. Interview with staff on 5/5 /21 at approximately 9:30 AM confirmed that the 8 send outs had not been returned within the 60 day window.