

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 41D0083685	(X3) Date Survey Completed 07/13/2022
Name of Provider or Supplier Brown Urology, Inc	Street Address, City, State 2 Dudley St, 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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on record review and staff interview, the laboratory failed to enroll in proficiency testing (PT) for the subspecialty of Bacteriology. Findings include: 1. Record review on 06/14/2022 of the CLIA Application and Survey Summary Report 0096D revealed: a. Gram Stain was not listed for 2021 events 1, 2 and 3 or 2022 event 1. b. A score of zero was reported for Bacteriology 2022 event 1. 2. Record review of the CMS 116 test menu on 06/14/2022 revealed the laboratory performs the above tests. 3. Record review on 06/14/2022 of the laboratory's American Association of Bioanalysts (AAB) PT records revealed: a. The laboratory did not participate in Gram Stain PT in 2021 or 2022. b. The laboratory did not participate in Bacteriology PT in 2022 event 1. 4. Staff interview on 06/14/2022 at 11:30 AM with the Technical Supervisor (TS) confirmed the above findings. The TS stated the person who used to be in charge left and she didn't realize they weren't enrolled until it was too late. 5. Phone interview on 07/13/2022 at 12:10 PM with a representative at AAB confirmed the above findings. The representative stated the laboratory received a score of zero for 2022 event 1 Bacteriology PT because the laboratory had a hold on their account</p>

for nonpayment. By the time the laboratory paid on 03/08/2022, it was too late to participate in 2022 event 1 Bacteriology PT. 6. The laboratory performs 2,000 tests annually in the subspecialty of Bacteriology.

D2007

TESTING OF PROFICIENCY TESTING SAMPLES
CFR(s): 493.801(b)(1)

The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods

This STANDARD is not met as evidenced by:
Based on record review and staff interview, the laboratory failed to test proficiency testing (PT) samples in the same manner as routine patient samples in the subspecialty of Bacteriology. Findings include: 1. Record review on 06/14/2022 of the laboratory's PT worksheet records revealed: a. Bacteriology 2021 event 1: i. 2 of 5 PT samples (PT #2 and PT #4) with growth on the Blood Agar plate (BAP) and no growth on Maconkey (MAC) were gram stained. b. Bacteriology 2021 event 2: i. 1 of 5 PT samples (PT #7) with growth on the BAP and no growth on MAC were gram stained. c. Bacteriology 2021 event 3: i. 1 of 5 PT samples (PT #15) with growth on the BAP and no growth on MAC were gram stained. 2. Record review on 06/14/2022 of the laboratory's PT policy states "Specimens will be treated the same as individual patients." 3. Staff interview with the Technical Supervisor (TS) on 6/14/2022 at 12:20 PM confirmed the above findings. The TS stated, "The laboratory does not routinely perform gram stains to confirm morphology on patient samples." 4. Record Review on 06/14/2022 of the laboratory's 2021 Assurance Scientific PT records revealed: a. Two Molecular PT events (Events 2 and 3) were tested by TP#1 and one Molecular event (Event 1) was tested by TP#2. b. 1 of 3 TP did not participate in Molecular PT. (TP#3) 5. Record Review on 06/14/2022 of the laboratory's 2021 American Associates of Bioanalysts (AAB) PT records revealed: a. Two Bacteriology PT events (Events 1 and 3) were tested by TP #2 and one Bacteriology event (Event 2) was tested by TP#4. b. 1 of 3 TP did not participate in Molecular PT. (TP#3) 6. Record review on 06/14/2022 of the laboratory's PT policy states, "Each Laboratory Technologist will perform Proficiency Testing on a rotational basis." 7. Staff interview with the TS on 6/14/2022 at 12:30 PM confirmed the findings in #4 and #5 above. 8. The laboratory performs 2,000 tests annually in the subspecialty of Bacteriology.

D2026

BACTERIOLOGY
CFR(s): 493.823(d)

(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

This STANDARD is not met as evidenced by:
Based on record review, lack of documentation and staff interview, the laboratory failed to provide training and document corrective action for an unsatisfactory

Proficiency Testing (PT) event in the subspecialty of Bacteriology. Findings Include: 1. Record review on 06/14/2022 of the CLIA Application and Survey Summary Report 0096D revealed the laboratory's Bacteriology 2021 PT event 1 score (75%) was unsatisfactory. 2. Record review on 06/14/2022 of the laboratory's American Association of Bioanalysts (AAB) PT records revealed the laboratory failed to document corrective action for 2021 Bacteriology event 1 unsatisfactory PT score. 3. Staff interview with the Technical Supervisor on 06/14/2022 at 12:45 confirmed the above findings. 4. The laboratory performs 2,000 tests annually in the subspecialty of Bacteriology.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:
Based on surveyor observation, record review and staff interview the laboratory failed to discontinue use of an expired antibiotic disk in the subspecialty of Bacteriology. Findings Include: 1. Surveyor observation of the contents of the laboratory's Bacteriology sensitivity disk dispenser in use on 06/14/2022 at 1:00 PM revealed the antibiotic, Ciprofloxacin (CIP) , lot # 9116506 expired on 05/21/2022. 2. Record review on 06/14/2022 of the laboratory's patient logs for the month of June revealed: a. On 06/01/2022 patient 1135682 was reported with a minimal inhibitory concentration (MIC) of 23 and a sensitivity of S for CIP. b. On 06/01/2022 patient 1016983E was reported with an MIC of 30 and a sensitivity of S for CIP. 3. Staff interview with the Technical Supervisor on 06/14/2022 at 1:00 PM confirmed the above findings. 4. The laboratory performs 2,000 tests annually in the subspecialty of Bacteriology.

D5507

BACTERIOLOGY
CFR(s): 493.1261(b)(c)

(b) For antimicrobial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms. (b)(1) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure. (b)(2) The laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results. (c) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:
Based on record review and staff interview the laboratory failed to run daily Kirby Bauer (KB) antimicrobial susceptibility testing (AST) Quality Controls (QC) in the subspecialty of Bacteriology. Findings include: 1. Record review on 06/14/2022 of the laboratory's KB AST QC records revealed KB AST QC is run weekly. 2. Staff interview on 06/14/2022 at 11:00 AM with the Technical Supervisor (TS) confirmed KB AST QC is not run each day tests are performed. 3. The laboratory performs 2,000 tests annually in the subspecialty of Bacteriology.

D6092

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(4)(iv)

The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

Based on record review, lack of documentation and staff interview, the Laboratory Director failed to have a corrective action plan for unacceptable proficiency testing (PT) results in the subspecialty of Bacteriology. Findings Include: 1. Record review on 06/14/2022 of the CLIA Application and Survey Summary Report 0096D revealed: a. A score of 83% was reported for Bacteriology 2021 events 2 and 3. 2. Record review on 06/14/2022 of the 'University of Male Reproduction Q.A. Occurrence Report' revealed lack of documentation for a corrective action plan for the above unacceptable scores. 3. Staff interview on 06/14/2022 with the Technical Supervisor confirmed the above findings. 4. The laboratory performs 2,000 tests annually in the subspecialty of Bacteriology.