

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0462715	(X3) Date Survey Completed 07/31/2024
Name of Provider or Supplier Baton Rouge Urology Group	Street Address, City, State 7777 Hennessy Blvd Suite 2004, Baton Rouge, LA	
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
D2010	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)</p> <p>The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by: A Follow-up survey was performed at Baton Rouge Urology Group, CLIA # 19D0982695, on July 31, 2024. Based on review of laboratory policies and proficiency testing records as well as interview with laboratory personnel, the laboratory failed to test proficiency testing (PT) samples in the same manner as patient testing for two (2) of four (4) events reviewed. Findings: 1. Review of proficiency testing (PT) records revealed multiple testing personnel attested to performing PT samples as follows: a) 2024 Microbiology - 1st Event: - Samples UR-01, UR-02, UR-03, UR-04, and UR-05 - all samples tested by the Technical Consultant, Testing Personnel 3, and Testing Personnel 4. b) 2024 Microbiology - 2nd Event: - Samples UR-06, UR-07, UR-08, UR-09, UR-10 - all samples tested by Testing Personnel 1 and Testing Personnel 5. 2. In interview on July 31, 2024 at 11 a. m., the Technical Consultant stated the laboratory does not routinely test patient samples for microbiology testing multiple times. She stated multiple testing personnel tested the same PT samples for evaluation of competency and all testing was performed before the PT event due date passed. She confirmed the PT samples identified above were tested multiple times as identified above. 3. Further review of PT records revealed testing personnel documented the zone size and interpretation for microbiology susceptibility testing for the following events: a) 2024 Microbiology - 1st Event b) 2024 Microbiology - 2nd Event 4. In interview on July 31, 2024 at 2:41 p. m., the Technical Consultant stated the zone sizes for antibiotic disc susceptibility testing for PT samples were measured with a caliper, but the zone sizes for patient samples were not measured with a caliper and instead were measured with a template provided by the manufacturer Becton Dickinson (BD). She further stated testing</p>

personnel do not document the zone size for patient antibiotic susceptibility testing and only document the interpretation. She confirmed PT samples and patient samples were not tested in the same way for antibiotic susceptibility testing.

_____ A Certification survey was performed at Baton Rouge Urology Group, CLIA ID # 19D9462715 on October 24, 2023.

D6089

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(4)(i)

The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.

This STANDARD is not met as evidenced by:
A Follow-up survey was performed at Baton Rouge Urology Group, CLIA # 19D0982695, on July 31, 2024. Based on record review and interview with personnel, the Laboratory Director failed to ensure proficiency samples are tested as required. Refer to D2010. _____ A Certification survey was performed at Baton Rouge Urology Group, CLIA ID # 19D9462715 on October 24, 2023.