

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D2122379	(X3) Date Survey Completed 04/17/2019
Name of Provider or Supplier Cleveland Urology Associates - Antenucci	Street Address, City, State 10500 Antenucci Blvd, Suite 101, Garfield Heights, OH	
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 an interview with the Consultant, the laboratory failed to enroll in a Proficiency Testing (PT) program for the subspecialties of general immunology, endocrinology, urinalysis and bacteriology that met the criteria in subpart I of this part for the year of 2018. All 9,250 patients tested at this laboratory have the potential to be affected. Findings include: 1. Review of policies, procedures, and documentation found the lab failed to enroll in a PT program for the subspecialty of general immunology that met the criteria of subpart I for the year of 2018. (Refer to D2003.) 2. Review of policies, procedures, and documentation found the lab failed to enroll in a PT program for the subspecialty of endocrinology that met the criteria of subpart I for the year of 2018. (Refer to D2003.) 3. Review of policies, procedures, and documentation found the lab failed to enroll in a PT program for the subspecialty of urinalysis that met the criteria of subpart I for the year of 2018. (Refer to D2003.) 4. Review of policies, procedures, and documentation found the lab failed to enroll in a PT program for the subspecialty of bacteriology that met the criteria of subpart I for the year of 2018. (Refer to D2003.) 5. The Consultant confirmed, on 4/17/19 at 2:09 pm, that the lab failed to enroll in a PT program for the subspecialties of general</p>

immunology, endocrinology, urinalysis and bacteriology that met the criteria in subpart I. (Refer to D2003)

D2003

ENROLLMENT

CFR(s): 493.801(a)(2)(ii)

For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1)

This STANDARD is not met as evidenced by:

Based on record review and an interview with the Consultant, the laboratory failed to maintain the accuracy of its testing procedures for the analyte Serum Free PSA (prostate-specific antigen) in the subspecialty of general immunology, and the subspecialties endocrinology, urinalysis, and bacteriology at least twice annually for the year of 2018. All 9,250 patients tested at this laboratory have the potential to be affected. Findings include: 1. Review of the laboratory's CMS "Annual Test Volume" form found that the following number of tests in their respective subspecialties were performed in the year of 2018: General Immunology Serum PSA: 1,000 tests Serum Free PSA: 500 tests Endocrinology Serum Testosterone: 750 tests Urinalysis Microscopic Urine Sediment: 5,000 tests Bacteriology Urine Culture Colony Count: 2,000 tests 2. Review of the laboratory's "Policy and Procedure for Method Accuracy Verification (MAV) serum PSA's, serum Free PSA's, serum Testosterone" found the frequency of MAV listed as quarterly as of 1/1/17, and changed to annually as of 5/1/18. 3. Review of the laboratory's "Policy and Procedure for Method Accuracy Verification microscopic urine sediment" found the frequency of MAV listed as quarterly as of 1/17/19, changed to bi-annually as of 12/13/17, and changed to annually as of 11/27/18. 4. Review of the laboratory's "Policy and Procedure for Method Accuracy Verification urine culture colony count" found the frequency of MAV listed as quarterly as of 1/1/17, and changed to annually as of 1/28/18. 5. Review of the laboratory's MAV documentation found the laboratory verified the accuracy of the analyte serum PSA, in the subspecialty of general immunology, twice annually in the year of 2018, in accordance with 493.1236(c)(1). The serum PSA MAV events were listed as: Patient 90924 on 8/20/18 Patient 90267 on 8/20/18. 6. Review of the laboratory's MAV documentation found the laboratory failed to verify the accuracy of the analyte serum Free PSA, in the subspecialty general immunology, at least twice annually. The only serum Free PSA MAV event in 2018 was listed as: Patient 90267 on 8/20/18. 7. Review of the laboratory's MAV documentation found the laboratory failed to verify the accuracy of the analyte serum Testosterone, in the subspecialty endocrinology, at least twice annually. The only serum Testosterone MAV event in 2018 was listed as: Patient 12278 on 8/20/18. 8. Review of the laboratory's MAV documentation found the laboratory failed to verify the accuracy of the analyte microscopic urine sediment, in the subspecialty urinalysis, at least twice annually. The only microscopic urine sediment MAV event in 2018 was listed as: Patient 1 on 12/31/18. 9. Review of the laboratory's MAV documentation found the laboratory failed to verify the accuracy of the analyte urine culture colony count, in the subspecialty bacteriology, at least twice annually. The only urine culture colony count MAV event in 2018 was listed as: Patient 93082 on 8/20/18. 10. An interview with the Consultant confirmed, on 4/17/19 at 2:09 pm, that the laboratory failed to establish and maintain the accuracy for the analyte Serum Free PSA in the

subspecialty of general immunology, and the subspecialties endocrinology, urinalysis, and bacteriology at least twice annually for the year of 2018; thus not complying with 493.1236(c)(1).