Department of Health & Human Services
Centers for Medicare & Medicaid Services

Form Approved
OMB No. 0938-0391

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	45D1100419	02/25/2021
Name of Provider or Supplier	**Street Address, City, State**	
Rio Grande Urology Pa	3100 Lee Trevino Suite G, El Paso, TX	

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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of laboratory procedures, Alternative proficiency testing records, and staff interview, the laboratory failed to have documentation of performing accuracy assessment twice annually in 2019 and 2020 for the gross analysis of histology specimens. The findings included: 1. Review of the laboratory's procedure titled Alternative Proficiency Testing (Procedure Number QA-2) found " Twice a year a slide set must be prepared by the lab& staff using protocols consistent with all SOPs. The first set will be from tissue received and processed in the lab between January 1 and June 30. The second set will be prepared from tissue received and processed in the laboratory between July 1 and December 31. Each set must be submitted within 60 days of the sampling window closing. Samples cannot be sent for evaluations that have been prepared by another laboratory. Each slide set will include: 1 H&E stained slide from patient material processed within the previous 6 month period. 1 slide stained with a special stain from the special stain menu from the previous 6 month period- special stains chosen for submission will not be repeated until all stains have been part of a previous alternative proficiency submission. 1 slide with stained with and immunhistochemical (IHC) stain from the Lab stain menu from the previous 6 month -period- IHCstains chosen for submission will not be repeated until all stains have been part of a previous alternative proficiency submission." 2. Review of the 2020 Alternative Proficiency testing Score sheets found two of two histotechnicians performing gross analysis of tissue specimens prepared the slides for the alternative proficiency testing. 3. A request for semi annual accuracy assessment of gross analysis of tissue specimens was requested but not provided. 4. Interview of general supervisor 2 listed on the CMS report 209 conducted on February 25, 2021 at 10:54

	AM confirmed that the alternative proficiency testing assessed the accuracy of the slide preparation and staining only. She also confirmed that the laboratory had no other means to assess the accuracy of gross analysis of tissue specimens at least twice each year.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Review of package inserts, prepared specimen slides and interview of facility personnel found the laboratory failed to follow the manufacturer's instructions for including positive tissue controls on the same slide as the patient tissue, when using the Universal DAB Detection kit in preparation of tissues stained on the Ventana Immunostainer. The findings included: 1. Review of the manufacturer's instructions for the ultraView Universal DAB Detection kit (used to identify targets by immunohistochemistry (IHC) in sections of formalin-fixed, paraffin- embedded and frozen tissue) found on page 2 under Positive Tissue Control "Optimal laboratory practice is to include a positive control section on the same slide as the patient tissue. When this practice is employed, identification of a failure to apply primary antibody or other critical reagent to the patient test slide is easily detected. Additionally, positive controls should be selected on the basis of expression of the antigen. Low levels of antigen expression are suggested to prevent false negative results due to insufficient sensitivity. A tissue with weak positive staining is more suitable for optimal quality control and for detecting minor levels of reagent degradation. A positive tissue control must be run with every staining procedure performed. Optimal laboratory practice is to include a positive control section on the same slide as the patient tissue. This practice helps to identify a failure to apply primary antibody or other critical reagent to the patient test slide. a tissue with weak positive staining is more suitable for optimal quality control. The positive tissue components are used to confirm that the antibody was applied and the instrument functioned properly. The tissue may contain both positive and negative staining cells or tissue components and serve as both the positive and negative control tissue. Control tissues should be fresh autopsy, biopsy, or surgical specimens prepared or fixed as soon as possible in a manner identical to the test sections. Such tissues may monitor all steps of the procedure from tissue preparation through staining. Use of a tissue specimen will provide control for all reagents and method steps except fixation and tissue processing. 2. Review of prepared specimen slides from five cases in 2019, 2020 and 2021 found the laboratory did not include a positive tissue control on the patient test slides. 3. Interview of general supervisor 2 on the CMS report 209 conducted on February 25, 2021 at 11:49 AM confirmed the laboratory did not include a positive tissue control on patient test slides. She went on to say the laboratory prepared "a single control slide with each run instead because the pathologist doesn't want it".