

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D0990335	<b>(X3) Date Survey Completed</b>  02/15/2023
<b>Name of Provider or Supplier</b>  Colon And Rectal Associates Of Texas	<b>Street Address, City, State</b>  1705 Ohio Drive Suite 100, Plano, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	<p>Laboratory representatives were present at the entrance conference. The survey process was discussed. An opportunity for questions and comments was given. The exit conference was held with the laboratory representatives. The laboratory was found to be in substantial compliance for the specialties/subspecialties for which it was surveyed. The standard level deficiencies cited were discussed. The process for submitting the corrections was explained. CMS form 2567 will be emailed from the Texas Health and Human Services Commission, Health Facility Compliance Arlington Group. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Southern Operations Branch-Dallas for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.</p>
<b>D5473</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records submitted at survey, laboratory policy, patient records, and confirmed in interview, the laboratory failed to define and document intended reactivity to ensure predictable staining characteristics of immunohistochemical (IHC) and special stains for 1 of 1 days in April 2022 and 1 of 1 days in August 2022. The findings include: 1. Review of laboratory records</p>

submitted at survey revealed the laboratory evaluated immunohistochemical and special stains. 2. Review of the laboratory policy titled "Stain Quality Control Evaluation" revealed: "1. PURPOSE All laboratories must evaluate the stain quality of the slide received and daily document the recording of the quality. Criteria to evaluate includes: Acceptability criteria is met to ensure predictable staining characteristics, slides are labeled with patient identifiers to ensure positive patient identification and traceability, and feedback to the reference histopathology laboratory where the Technical Component is complete if quality is not acceptable. For hematoxylin and eosin and other routine stains, the patient slide serves as the internal control to ensure adequate staining technique." The policy failed to define the staining characteristics for intended reactivity of the IHC and special stains. The surveyor requested documentation of a policy or quality control log that defined IHC and special stain staining characteristics. None was provided. 3. A random review of patient slides and final reports from April and August 2022 revealed the laboratory did not include for each day of use, documentation of the intended reactivity (quality control) for IHC stains and special stains on the following days patients were tested and reported in 2022: 04/12/2022 Accession #: RA22-011220-TC Stains performed: CMV, GMS, HSV I-II 08/22/2022 Accession #: RA22-012889-TC Stains performed: CMV, AFB, GMS, HSV I-II The surveyor requested documentation of quality control to ensure predictable staining characteristics for the above IHC and special stains. None was provided. 4. During an interview on 02/15/2023 at 12:22 p.m., the Office Manager confirmed the above findings. Key: CMV- Cytomegalovirus AFB- Acid fast bacilli GMS- Grocott's methenamine silver HSV- Herpes simplex virus