

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2085705	(X3) Date Survey Completed 03/11/2019
Name of Provider or Supplier Digestive Disease Associates Of Central Florida Pa	Street Address, City, State 2050 Ashley Oaks Cir Ste 102, Wesley Chapel, FL	
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
D5473	<p>CONTROL PROCEDURES 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 record review and interview with the Laboratory Director, the laboratory failed to perform a negative control for special stain from 11/21/2017 to 03/07/2019 Findings Included: Review of QC (quality control) records found positive controls for Alcian Blue/Periodic Acid Schiff stain. No negative controls were found. Interview with the Laboratory Director on 03/11/2019 at 9:50 AM, confirmed that no negative controls were ran for Alcian Blue/Periodic Acid Schiff staining.</p>
D5601	<p>HISTOPATHOLOGY CFR(s): 493.1273(a)(f)</p> <p>(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the Laboratory Director, the laboratory</p>

failed to perform a negative control for special stains from 11/21/2017 to 03/07/2019. Findings Included: Review of QC (quality control) records found positive controls for cytomegalovirus (CMV), Herpes Simplex Virus (HSV), H. pyloric, Microsatellite Instability (MLH-1, MSH-2, MSH-6, and PMS-2) and CD3 IHC stains. No negative controls were found. Interview on 03/11//19 at 9:50 AM with the Laboratory Director confirmed that no negative controls were ran for IHC staining.