

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2154054	(X3) Date Survey Completed 12/19/2018
Name of Provider or Supplier Ear Nose & Throat Associates Of Manatee Pa	Street Address, City, State 8340 Lakewood Ranch Blvd Suite 180, Bradenton, 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 Licensed Practical Nurse (LPN), the facility failed to maintain daily quality control (QC) slide documentation for cytology adequacy testing since testing began in October 2018. Findings included: Review of QC documentation revealed no documentation for the quality of the Hematoxylin and Eosin stains used during cytology adequacy testing. Interview on 12/19/2018 at 10:45 AM with the LPN, confirmed that the quality of the Hematoxylin and Eosin stains for cytology adequacy testing had not been documented.</p>