

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2154054	(X3) Date Survey Completed 08/15/2022
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
D0000	An announced CLIA recertification survey was conducted at Ear Nose & Throat Associates of Manatee PA on 08/15/2022. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the Office Manager, the laboratory failed to document annual competency on 2 (#C and #D) Testing Personnel out of 6 Testing Personnel (#A-#F) reviewed for 1 (2021) out of 2 years (2020 and 2021) reviewed. Findings Included: Review of Form CMS-209, Laboratory Personnel Report, signed by the Laboratory Director on 8/15/22 revealed Staff #C and #D held the positions of Clinical Consultant and Testing Personnel. Review of personnel files for Testing Person #C and #D revealed the last competency evaluations on file were from October of 2020. The files revealed no evidence of annual competency evaluations for Testing Person #C or #D in 2021. Review of the laboratory's policy and procedure (signed as reviewed by the Laboratory Director on 10/03/2021) revealed no policy for competency evaluations. Interview on 08/15/2021 at 4:00 PM with the Office Manager confirmed that there was no documentation of competency evaluations in 2021 for Testing Personnel #C and #D.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p>

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 record review and interview with the Office Manager, the laboratory failed to verify the accuracy of Fine Needle Aspirate cell adequacy at least twice a year for 2 of 2 years (2020-2022) reviewed. Findings Included: Review of the policy titled "Quality Control - Peer Review for Cytopathologists" (signed as reviewed by the Laboratory Director on 10/01/2021) revealed "Every six (6) months the laboratory director will review the files for a past 6-month time period. If any specimen results are questionable, the Laboratory director will discuss the patient with the provider in question. If there are a number of inadequate results coming from a specific lab, the Laboratory Director will discuss these results with the cytopathologist at that particular facility, and the provider performing the biopsy. The Laboratory Director will monitor reports biannually, and will, biannually, select slides for evaluation, on at least two (2) patients, on each provider performing biopsies." Review of quality control documents revealed no peer review for cytopathologists for 2020, 2021, or 2022. Interview on 08/15/2022 at 5:30 PM with the Office Manager revealed there was no documentation of the peer reviews.