

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D1084000	<b>(X3) Date Survey Completed</b>  02/23/2022
<b>Name of Provider or Supplier</b>  Ear Nose & Throat Associates Of Manatee Pa	<b>Street Address, City, State</b>  701 Manatee Ave W Ste 202, Bradenton, FL	
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>	An announced CLIA recertification survey was conducted at Ear, Nose, & Throat Associates of Manatee PA on 02/23/22. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
<b>D5217</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(c)(1)</p> <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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the Licensed Practical Nurse (LPN), the laboratory failed to verify the accuracy of thyroid fine needle aspiration (FNA) adequacy assessment testing twice a year for 6 out of 6 Testing Personnel (#A - #F) for 2 out of 2 years (2020 - 2021) reviewed. Findings Included: Upon review of the policy for peer review, titled "Policy for Determination of Adequacy" adopted on 4/15 /21 and most recently signed and reviewed by the laboratory director on 10/1/21 revealed: Determination of Adequacy: Every six months the laboratory director will review the first 5 specimens of the month, for a total of 30 patients to determine adequacy. Record review revealed no peer review records for Testing Personnel, #A, #B, #C, #D, #E, and #F, for 2020 and 2021. On 02/23/22 at 10:35 AM, the LPN stated that the outside laboratory reviewed referred patient slides for diagnosis and not adequacy. The LPN confirmed that the peer review had not been performed for Testing Personnel, #A -#F, for 2020 or 2021.</p>