

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D1084000	<b>(X3) Date Survey Completed</b>  10/16/2019
<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 10/16/19. 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>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview with the Laboratory Manager the laboratory failed to record the temperature where specimens were stored for 6 months. Findings Included: Observation, during a tour of the laboratory on 10/16/19 at 9:00 AM, revealed a small refrigerator with patient specimens. Closer observation revealed no thermometer in the refrigerator. Review of temperature charts revealed no temperatures were recorded for the small refrigerator. On 10/16/19 at 10:20 AM, the Laboratory Manager reported that the refrigerator had been in service for 6 months and confirmed that the temperatures had not been recorded.</p>
<b>D5429</b>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory</p>

must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on record review and interview with the Laboratory Manager the laboratory failed to document daily microscope cleaning and failed to have preventative maintenance documented since 01/17/18. Findings Included: Review of the Microscope Cleaning Log revealed the following instructions: Please wipe down the microscope face plate at the end of each day that it has been used and replace the cover. Then log in the date and your initials. Review of Microscope Cleaning Log entries revealed the cleaning was performed 08/10/18, 12/06/18, and 09/24/19. Review of the "...Stain Adequacy Chart" revealed testing was performed on 79 days in 2019 and no log was present to indicate how many days testing was performed in 2018. Review of maintenance records revealed no documentation of a yearly preventative maintenance performed on the microscope. Interview on 10/16/19 at 10:40 AM with the Laboratory Manager confirmed that the daily microscope cleaning was not documented and that the microscope preventative maintenance had not been performed.