

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2113635	(X3) Date Survey Completed 06/28/2022
Name of Provider or Supplier Physiology Unit, Niaid	Street Address, City, State 12735 Twinbrook Parkway, Room 3w-35, Rockville, MD	
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 performed at the National Institute of Allergy and Infectious Diseases (NIAID): Physiology Unit on June 28, 2022, by the CMS Philadelphia CLIA Branch Location federal surveyor. The laboratory was surveyed under 42 CFR part 493 CLIA regulations. The specific deficiencies are as follows:
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on record review, observations and staff interviews the laboratory failed to perform and document preventative maintenance on 6 of 6 pipettes utilized for CLIA-only testing. Findings include: 1. On 06/28/2022 at approximately 10:30 am during a review of the preventative maintenance records, the documentation revealed the laboratory failed to perform preventative maintenance annually for the following pipettes: a.Pipetman P2 L b.Pipetman P10 L c.Pipetman P20 L d.Pipetman P200 L e. Pipetman P1000 L f.Poseidon Genesse Scientific P20 L 2. The preventative maintenance record specifies the maintenance interval for the pipettes as yearly, the maintenance was last documented on 08/20/2019. 3. At approximately 11:00 am, during a tour of the pre-PCR section of the laboratory, the surveyor requested the pipettes utilized in the CLIA-only PCR hood. The contractor label on the pipettes</p>

confirmed the last calibration date of 08/20/2019. 4. During the exit interview, the laboratory director and clinical consultant confirmed the above findings.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on a review of policy and procedures, lack of documentation, and staff interviews the laboratory director (LD) failed to document the responsibilities and duties of laboratory staff including the laboratory director, clinical consultant, and testing personnel. Findings include: 1. On 06/28/2022 at approximately 11:15 am during a review of the laboratory policy and procedures the surveyor requested the responsibility and duties documentation for each individual involved in the various phases of testing. 2. The clinical consultant stated "one could argue the duties are implied throughout the QA plan" and failed to provide the document requested. 3. During the exit interview, the LD confirmed the laboratory does not have documentation for the above finding.