

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  34D2136521	<b>(X3) Date Survey Completed</b>  05/14/2024
<b>Name of Provider or Supplier</b>  Niehs Clinical Research Unit	<b>Street Address, City, State</b>  Niehs Clinical Research Unit Laboratory, Research Triangle Park, NC	
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>D5435</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(b)(2)</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: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: Based on the observation of the laboratory, review of laboratory procedures, review of laboratory maintenance records and interview with laboratory staff, the laboratory failed to check centrifuge speed and centrifuge timer for years 2022 and 2023. Findings: 1. During the laboratory tour on May 7, 2024, the following were observed: BD Vacutainer SST tubes (tiger top) Four centrifuges: Sorval Legend X1R Serial Numbers 42324473 and 41531470 Sorval Legend RT Serial Numbers 40598926 and 40598925 2. On May 7, 2024, review of the laboratory's Standard Operating Procedure 4.2.1 Basic Blood Processing Procedure for COVID-19 Serological Survey Specimens, Version 1.0, effective 4/25/2022, found the following: "2.2.1 Separation of Serum from Whole Blood There should be one Tiger top SST blood collection tube per study ... After the specimens have clotted, the specimen tubes are placed in the Sorval Legend RT Centrifuge, Sorval Legend X1R Centrifuge or equivalent [sic] and spun at ambient temperature for 10 minutes at 1150 rcf(g) (range 1000-1300g) with the break set to 3 (in Sorval Legend RT centrifuge) or 9/9 (Sorval Legend X1R centrifuge)" 3. Review of laboratory centrifuge maintenance records for 2022 and 2023 on May 7, 2024, found no records of a timer or speed check for the four</p>

centrifuges the laboratory used to centrifuge SST tubes collected for SARS COV-2 IGG testing performed by the laboratory. 4. During interview on May 7, 2024, at 12: 15pm, the laboratory director confirmed the laboratory did not have documentation of timer and speed checks for the four centrifuges used in the laboratory. Key: SST = Serum Separator Tube