Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2136521	05/25/2022
Name of Provider or Supplier	**Street Address, City, State**	
Niehs Clinical Research Unit	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manuals, Centers for Medicare & Medicaid Services Laboratory Personnel Report (CMS-209), and an interview with testing person #2 on May 25, 2022, the laboratory director failed to sign and date his approval of all initial laboratory procedures from June 2020 to May 2022. Findings include: 1. Review of personnel competency procedures and the quality assurance manual revealed the laboratory director had not signed and dated any initial procedures from June 20, 2020, through May 25, 2022. 2. During an interview with testing person #2 (CMS-209) at approximately 11:00 AM on May 25, 2022, he stated the laboratory director had not signed and dated any procedures in the Procedure Manual since the laboratory first opened in June 2020.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on a review of personnel training records, Centers for Medicare & Medicaid Services Laboratory Personnel Report (CMS-209), and an interview with testing

	person #2, the technical consultant (TC) failed to assess all six minimum criteria for testing personnel competency assessment required for moderate complexity testing for Endocrinology COVID-19 qualitative antibody testing from June 2020 to May 2022. Findings include: 1. Review of the personnel training records revealed a Competency Evaluation Checklist consisted of for all six minimum criteria for testing personnel competency assessment required for moderate complexity testing for Endocrinology COVID-19 qualitative antibody testing, but the technical consultant did not conduct any required initial, semi-annual, or annual competency evaluations from June 2020 to May 2022. The Competency Evaluation Checklist had zero documented competencies for the following six minimum criteria: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting of test results. c) Review of intermediated test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficency testing samples. f) Assessment of problem solving skills. 2. During an interview with testing person #2 at approximately 9:30 AM on May 25, 2022, confirmed the technical consultant did not assess testing personnel #1 and #2 for all six minimum criteria for testing personnel competency assessments required for moderate complexity testing for Endocrinology COVID-19 qualitative antibody testing for any required initial, semi-annual, or annual competency evaluations from June 2020 to May 2022.