Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2164078	(X3) Date Survey Completed 12/09/2021
Name of Provider or Supplier Nuberty, Inc	**Street Address, City, State** 227 Sandy Springs Place, Bldg 200, Suite 220, Sandy Springs, GA	

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	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on December 9, 2021. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on Proficiency Test(PT) record review and staff interview, the laboratory failed to maintain copies of all records for proficiency testing. The Findings include: 1. PT record review revealed that copies of all PT records were not maintained for Chemistry Event #2 in 2021. The attestation document was not present during the time of the survey. 2. During an interview with the TP #1(CMS 209) on December 9, 2021 at approximately 1:40 PM, in the conference room, confirmed that copies of the Chemistry Event #2 in 2021 was not present during the time of the survey.
D3011	FACILITIES

	CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on the laboratory record review and an interview with the testing personnel (TP), the laboratory failed to establish a written procedure for eyewash maintenance. Findings include: 1. Laboratory record review revealed that the laboratory failed to establish a written procedure for eyewash maintenance. 2. During an interview with the TP#1 (CMS 209 form) on December 9, 2021, in the conference room, at approximately 1:45 PM, confirmed that the laboratory did not establish a written procedure for eyewash maintenance.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on Proficiency Test(PT) records and staff interview, the laboratory failed to document corrective actions for the unacceptable Chemistry analytes. The Findings include: 1. American Proficiency Institute(API) PT records for Chemistry Event #3 2021 failed to document corrective actions for the unacceptable analytes: DHEA-S and Estradiol. 2. During an interview with the Testing Personnel #1 (CMS 209) on December 9, 2021 at approximately 1:50 PM, in the conference room, confirmed that the Testing Personnel and Laboratory Director failed to perform and document corrective actions for the unacceptable analytes.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual and interview with Testing Personnel(TP), the laboratory failed to establish written instructions for sending specimens to an outside reference laboratory for testing. The findings include: 1. The laboratory's procedure manual did not include a written policy and procedure (to include collection, preservation, storage, transport, testing schedule times, and how to obtain additional assistance) for staff to follow when sending specimens to reference laboratories (LabCorp). 2. During an interview on December 9, 2021 at 1:20 PM, the TP #1(CMS 209), confirmed that the laboratory did not have a written policy and procedure for staff to follow when sending specimens to a reference laboratory.

D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of the Proficiency Testing (PT) records and staff interview, the laboratory director (LD) failed to ensure PT results were reviewed and the attestation document was signed. Findings include: 1. Review of PT records for 2021 revealed the laboratory received unacceptable results for the Chemistry analytes: DHEA-S and Estradiol. The LD did not review or sign the attestation statement. 2. During an interview with the Testing Personnel #1(CMS 209) on December 9, 2021 at approximately 1:50 PM, in the conference room, confirmed that the PT results were not reviewed and the attestation statement document was not singed.
D6075	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(6) Each individual performing moderate complexity testing must document all corrective actions taken when test systems deviate from the laboratory's established performance specifications. This STANDARD is not met as evidenced by: Based on Proficiency Test(PT) record review and staff interview, the Testing Personnel(TP) failed to document all corrective actions taken. The Findings include: 1. PT record review revealed that the TP failed to document the corrective actions for the unacceptable results for the Chemistry Event #3 in 2021 for the American Proficiency Institute PT. 2. During an interview with the Testing Personnel #1(CMS 209) on December 9, 2021 at approximately 2:00 PM, in the conference room, confirmed the TP did not document and perform corrective actions for the PT Chemistry analytes.