Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D2193465	09/25/2024
Name of Provider or Supplier	**Street Address, City, State**	
Clemson University Covid - 19 Clia Lab	G35 Sirrine Hall, Clemson, SC	

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 conducted at Clemson REDDI Lab on 09/25/2024 by the South Carolina Department of Public Health (SC DPH). The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. The facility was found to be out of compliance with the standards of the CLIA program. The following STANDARD LEVEL DEFICIENCES were found to be out of compliance.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on lack of documentation and staff interviews, the laboratory failed to review and evaluate the results obtained on proficiency testing twice annually. Thae laboratory failed to establish acceptable criteria for accuracy of tests for which proficiency test (PT) samples are not available. Reviewed (2022, 2023, and 2024) 3 of 3 years. Findings included: 1. Review of policy and procedures titled "Research and Education in Disease Diagnosis and Intervention (REDDI) Lab Individualized Quality Control Plan" lack documentation of accuracy of proficiency tests. 2. Review of instrument comparison and proficiency testing results revealed no documentation of date performed, accuracy, or evaluation of performance. 3. In an interview with the Laboratory Director (LD), Technical Supervisor (TS), testing personnel (TP), and Compliance Coordinator on 09/25/2024 in the conference room at 4:54 pm the above findings were confirmed.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT

	CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on lack of documentation and testing personnel interviews, the laboratory failed to follow quality assessment policies and procedures to monitor, assess, and correct problems identified with pre-analytical, analytical, and post-analytical laboratory systems of Multiplex RT-qPCR for Detection of SARS-Co V-2 in Raw Saliva. Findings included: 1. Review of policy titled "Research and Education in Disease Diagnosis and Intervention (REDDI) Lab Individualized Quality Control Plan" includes a section under quality assessment lists proficiency testing records, patient results, specimen rejection logs, turnaround time reports, records of preventive measures, corrective actions and follow-up, personnel competence records. 2. Review of records reveals a lack of documentation of review of proficiency testing records, patient results, specimen rejection logs, turnaround time reports, records of preventive measures, corrective action and follow-up and risk assessment of pipettes or pipettors. 3. During an interview with LD, TS, and Compliance Coordinator on 09/25/2024 in the conference room at 4:54 pm the above findings were confirmed.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory 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 records review, lack of documentation and staff interviews revealed the laboratory failed to perform and document maintenance as defined by manufacturer with at least the frequency specified by manufacturer. 24 months reviewed. Findings included: 1. Reviews of records revealed the laboratory failed to perform and documented monthly maintenance for Opentron Calibration, Cleaning and Maintenance Log. 2 A review of maintenance logs for Opentron instrumentation revealed no documentation of daily maintenance for three months in 2024 (March, April, and May). No documentation available on the day of the survey. 3. A review of records revealed the lack of documentation for monthly maintenance 10 out of 24 months. 4. In an interview with the LD, TS, GS3, and Compliance Coordinator on 09 /25/2024 in the conference room at 4:54 pm the above findings were confirmed
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) 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. This STANDARD is not met as evidenced by: Based on policy and procedures, records review, and staff interviews, the laboratory failed to write a protocol that ensures equipment, instrument, and test system performance is accurate and reliable. The laboratory failed to perform and document function checks. Findings included: 1. Review of policy titled "Oven Usage" revealed the procedure uses timer for 30 minutes. 2. Review of policy titled "Operating Thermocycler for qPCR" revealed the procedure uses a timer for 1:49:00. 3. Review of policy titled "Validating Mastermix" revealed the procedure uses a timer and centrifuge at 500xG. 4. Review of records reveals laboratory lack verification documentation of timer and centrifuge plate at 500xG. 5. In an interview with LD, TS, GS3, and Compliance Coordinator on 09/25/2024 at 4:54 pm the above findings confirmed.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on policy and procedures review, records review, and staff interviews, the technical supervisor failed to evaluate and document performance of high complexity testing personnel at least semiannually during the first year of hire and before the individual(s) test patients' specimens. 2 out of 7 testing personnel (TP) have been identified as new since the last survey. Reviewed (2022, 2023, and 2024) 3 out 3 years. Findings included: 1. Review of policy titled "Personnel Training and Annual Competency" section III. Procedure Step G. says competency assessments will occur initially and annually. 2. Review of laboratory personnel report CMS 209 revealed 7 TP. 2 out of 7 TP was identified as new since last survey. 3. Review of TP6 and TP7 competency forms reveals lack of documentation as initial and/or semi-annual competency. 4. In an interview with LD, TS, GS3, and Compliance Coordinator on 09 /25/2024 in the conference room at 4:54 pm the above findings confirmed.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on policy and procedures review, records review, and staff interview the technical supervisor failed to evaluate and document performance of high complexity

	testing at least annually. 2 out of 7 testing personnel (TP) have been identified as new since the last survey. Reviewed (2022, 2023, and 2024) 3 out of 3 years. Findings included: 1. Review of policy titled "Personnel Training and Annual Competency" section III. Procedure Step G. says competency assessments will occur initially and annually. 2. Review of laboratory personnel report CMS 209 revealed 7 TP. 2 out of 7 TP was identified as new since last survey. 3. Review of TP2 and TP3 competency forms reveals lack of documentation of annual competency for 2022. 4. In an interview with L D, TS, GS3, and Compliance Coordinator on 09/25/2024 in the conference room at 4:54 pm the above findings confirmed.