Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2126070	12/14/2021
Name of Provider or Supplier	**Street Address, City, State**	
E-Lab Of Florida	6100 Hollywood Blvd Ste 306, Hollywood, FL	

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 recertification survey conducted on 12/14/2021, found the E-Lab of Florida clinical laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following Condition was not met: D5400 - Analytic Systems.
D2020	BACTERIOLOGY CFR(s): 493.823(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to score at least 80 % in Bacteriology for the second proficiency testing (PT) event in 2020. Findings include: Review of Bacteriology American Association of Bioanalysts (AAB) PT records, revealed a 40 % score in the second event of 2020. During an interview on 12/14/2021 at 1:25 PM, the owner confirmed that the laboratory failed to receive a passing score of at least 80 % in Bacteriology in the second event of 2020.
D2026	BACTERIOLOGY CFR(s): 493.823(d) (1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by:

	Based on lack of records and owner interview, the laboratory failed to have documentation of the corrective action for the failure in 1 out of 6 events reviewed of Bacteriology specialty in Proficiency Testing (PT). Findings include: -Refer to D2020. -No documentation found of the laboratory review, corrective action and training for the failure of reference. During an interview on 12/14/2021 at 1:30 PM, the owner confirmed that the laboratory failed to have documentation of the corrective action for the failure of the second event of Bacteriology in 2020.
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on records review and interview with owner, the laboratory failed to report 6,300 test results to Florida Department of Health (FDOH) from 06/24/2020 to 12/14 /2021. The laboratory failed to report 6,000 out of 26,604 tests to detect SARS CoV-2 virus using Polymerase chain reaction (PCR) test performed from 01/31/2021 to 12/14 /2021, 250 out of 250 tests to detect Immunoglobulin G (IgG) performed from 06/24 /2020 to 12/14/2021 and 50 out of 50 tests to detect Immunoglobulin M (IgM) to SARS-COV-2 from 11/03/2020 to 12/14/2021. Findings include: - Review of tests records revealed that the laboratory started testing with Access SARS-CoV-2 IgG on 06/24/2020, Access SARS-CoV-2 IgM on 11/03/2020 and PCR test for SARS CoV-2 Virus on 01/31/2021. - Review of Electronic Laboratory Reporting Portal Record revealed that the laboratory started using the Electronic Reporting System (ELR) on 03 /15/2021. -Review of reporting records revealed that the laboratory failed to report: a) 250 out of 250 tests to detect SARS-CoV-2 IgG antibodies. b) 50 out of 50 tests to detect SARS-CoV-2 IgM antibodies. c) 6,000 SARS CoV-2 Virus PCR out of the 26,604 tests performed. During an interview on 12/14/2021 at 4:00 PM, the owner confirmed that the laboratory failed to report 250 IgG and 50 IgM tests to FDOH and explained that with PCR they started reporting on 03/15/2021 to the FDOH but them they had a transmission failure that was corrected on 10/24/2021 and they have a pending balance of 6,000 tests to be reported.
D3005	FACILITIES CFR(s): 493.1101(a)(3) Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation. This STANDARD is not met as evidenced by: Based on interview, record review and observation, the laboratory failed to have

	separate reagent prep and sample areas in COVID-19 Polymerase Chain Reaction (PCR) testing. Findings include : During an observation of the molecular area on 12/14 /2021 at 10:30 AM revealed a testing person prepared samples and reagent under the same PCR hood. Review of Lyra Direct SARS-CoV-2 Assay Instructions for Use stated " Proper workflow planning is essential to minimize contamination risk. Always plan laboratory workflow in a uni-directional manner, beginning with pre-amplification and moving through amplification and detection. Do not allow cross movement of personnel or equipment between areas. Keep amplification supplies separate from pre-amplification supplies at all times. Do not use supplies dedicated for reagent or sample preparation for processing target nucleic acid. During an interview on 12/14/2021 at 4:52 PM, the testing personnel confirmed failed to have separate reagent preparation and sample areas in COVID-19 Polymerase Chain Reaction (PCR) testing.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to complete the validation for Lyra Direct SARS-CoV-2 Assay before starting COVID -19 Polymerase Chain Reaction (PCR) patient testing. (See D5421)
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to complete the validation for Lyra Direct SARS-CoV-2 Assay before starting COVID -19 Polymerase Chain Reaction (PCR) patient testing. Findings include: Review of Lyra Direct SARS-CoV-2 Assay manual stated "Instruments Qualification Method for the Lyra Direct SARS-CoV-2 Assay Purpose: This appendix is intended to provide a qualification procedure describing how to test a panel of specimens for use in verifying performance of the Applied Biosystems 7500 Standard, Roche Light Cycler 480, Bio-Rad CFX96 Touch, Thermofisher Quant Studio 7 Pro with the Lyra Direct SARS-CoV-2 Assay by the end user. Qualification of these instruments with the Lyra Direct SARS-CoV-2 Assay (meeting the acceptance criteria listed below) must be achieved prior to usage for

	diagnostic testing." Review of Lyra Direct SARS-CoV-2 Assay validation revealed the instrument qualification method form was not completed with SARS Co-V-2 and PCR Ct values for each panel for Quant Studio 7 Pro-2778720080010 and Quant Studio 7 Pro-2778720050331. The instrument qualification method form was not signed by a laboratory director, technical supervisor or testing personnel. Review of instrument runs revealed the Quant Studio 7 Pro-2778720080010 had been in use since 01/11/2021 and Quant Studio 7 Pro-2778720050331 had been in use since 08/07 /2021. During an interview on 12/14/2021 at 4:52 PM, the testing personnel confirmed the laboratory failed to complete the validation for Lyra Direct SARS-CoV-2 Assay. The testing personnel also stated that 26,604 patients were tested for COVID-19 PCR from 01/31/2021- 12/14/2021.