Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2126070	02/03/2020
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 02/03/2020 found that E-lab of Florida clinical laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of American Academy of Family Physicians (AAFP) proficiency testing (PT) records and interview with laboratory director (LD), the laboratory failed to have attestation signed for 3 out of 3 events reviewed for 2019 for the specialties of Chemistry and Hematology. Findings include: Review of AAFP proficiency records revealed that the laboratory failed to have a signed attestation for: -1st event of 2019 by the testing person (TP) -2nd and 3rd event 2019 by TP and LD. During an interview on 02/03/2020 at 11:30 AM, the LD confirmed that the laboratory failed to have a signed attestation for the events of reference.
D2099	ENDOCRINOLOGY CFR(s): 493.843(b) 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 with laboratory director (LD), the laboratory

	failed to attain 80 % score for T3 Uptake for 1 event out 3 events reviewed in 2019. Findings include: Review of proficiency testing records of American Academy of Family Physicians for 2019, revealed a 0 % score for T3 Uptake for the 3rd event of 2019. During an interview on 02/03/2020 at 11:30 am, the LD, confirmed that the laboratory had a 0 % score for the analyte for the event of reference.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to perform the 6 months competency assessment for 1 out of 1 testing personnel (TP) in 2019. Findings include: Review of personnel files revealed that: TP had the initial competency evaluation on 2/16/2019. There was no documentation of the 6 month competency assessment for the TP later on 2019. During an interview on 02/03/2020 at 12:30 PM, with laboratory director, he confirmed that there was no documentation of the 6 month competency assessment for the TP for the period of reference.
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 record review and interview, the laboratory failed to provide QA forms showing the laboratory was monitoring, assesing and correcting problems from December 2018 to January 2020. Findings include: -Review of Quality Assurance (QA) policy revealed that the laboratory had a Calendar of Annual Review and a QA Monitor monthly form. -No monthly QA forms available to support that the laboratory followed their QA calendar from December 2018 to January 2020. During an interview on 02/03/2020 at 1:30 PM, the laboratory director confirmed that there was no documentation of the QA for the period of reference.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system

	performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview with testing personnel (TP), the laboratory failed to monitor quality control (QC) over time for shifts and trends for 1 out of 1 year reviewed (2019) for the Chemistry Analyzer AU400. Findings include: 1-Review of QC records for the AU 400 analyzer revealed only daily QC. There was no documentation of monitoring the shifts and trends of the QC over time for the QC results for the Chemistry analyzer during 2019. 2-Corrective Action log for the Chemistry Analyzer AU400 reviewed did not have records for: - December of 2018 - January to August 11th and September 20th to December 31st of 2019 -January of 2020 During an interview on 02/03/2020 at 12:30 PM, TP confirmed that there was no documentation of monitoring the shifts and trends of the QC over time and that the Corrective Action log for the Chemistry Analyzer AU400 was missing the days listed above.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patient reports and interview with laboratory director (LD), the laboratory failed to include the correct laboratory address in final patient reports since February 2019. Findings include: Review of final patient reports revealed that the reports failed to have the updated laboratory address since February 2019. During an interview on 02/03/20 at 2:00 p.m., the laboratory director confirmed that the final report did not include the correct laboratory address for the period of reference.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director (LD) failed to ensure that the laboratory follow their written quality assesment (QA) policy. Findings include: Cross Reference D5291. The Anual Calendar Review procedure stated "Review the element(s) assigned for each month. Doccument the review and attach all supporting data and information." During and interview on 02/03/2020 at 2:00 pm, the

	LD confirmed that the laboratory could not provide documentation of the QA review. Therefore the LD did not ensure that the laboratory followed their QA policy.