Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 16D0383796	**(X3) Date Survey Completed** 03/30/2021
Name of Provider or Supplier Iowa Clinic - West Lakes, The	**Street Address, City, State** 5950 University Avenue, Suite 181, West Des Moines, IA	
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**
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's Individualized Quality Control Plan (IQCP), quality control (QC) records, and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 1:45 pm on 03/30/2021, the laboratory failed to perform two levels of rupture of membrane (ROM) testing QC monthly for 15 out of 16 months of testing from December 2019- March 2021. The findings include: 1. The laboratory's IQCP for ROM testing performed on the Amnisure test system stated that QC would be performed with each new lot number and shipment of tests and at least monthly. 2. The laboratory received a new lot number/shipment of tests (lot 56305601, expiration 04/11/2022) and performed two levels of QC on 11/13/2019. 3. Personnel identifier #2 stated that the laboratory used the same lot number/shipment of tests from 11/13/2019- 03/30/2021, but did not perform QC on that lot number from December 2019- February 2021. 4. At the time of the survey, personnel identifier #2 confirmed that the laboratory only performed QC with each new lot number and shipment of tests but not at least monthly as stated in the IQCP.

D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of patient test reports, instrument printouts, and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 12:00 pm on 03/30/2021, the laboratory failed to have a system in place to ensure the Triage Meter instrument printouts had the correct date of testing for one out of one date of patient testing in October 2020. The findings include: 1. Review of the final test report for Patient A indicated that D-dimer testing had been collected, performed, and resulted on 10/30/2020. 2. The corresponding instrument printout from the Triage Meter indicated that testing had been performed on 10/29 /2020. 3. Review of Patient A's Electronic Health Record (EHR) showed that Patient A visited the office on 10/30/2020. 4. At the time of the survey, personnel identifier #2 confirmed that Patient A had d-dimer testing performed on 10/30/2020 and that the date of testing on the Triage Meter instrument printout was incorrect and should have been 10/30/2020 also.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of personnel records and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 10:25 am on 03/30/2021, the laboratory director failed to ensure that prior to testing patient specimens, all testing personnel performing moderate complexity testing received the appropriate training for one out of six new testing personnel (identifier #13) hired since the last survey on 04/18/2019. At the time of the survey, personnel identifier #2 confirmed that the laboratory did not have documented training for personnel identifier #13.