Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0038249	01/13/2021
Name of Provider or Supplier	**Street Address, City, State**	
Unitypoint Health Marshalltown	55 Unitypoint Health-Marshalltown, Marshalltown, 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
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of ACL Top 350 coagulation reagent verification records from March 2020, observations of the coagulation analyzer and confirmed by laboratory personnel identifiers #1 and #2 (refer to the Laboratory Personnel Report) at approximately 11:30 am on 01/13/2021, the laboratory failed to program the correct normal patient mean for the current thromboplastin reagent in use (lot N0796941, expiration 07/2021) into the ACL Top 350 coagulation analyzer (SN16110382). The findings include: 1. The laboratory established a normal patient mean of 11.0 seconds for thromboplastin lot number N0796941 (expiration 07/2021) in March 2020 for the ACL Top 350 coagulation analyzer (SN16110382). 2. At the time of the survey, observation of the ACL Top 350 coagulation analyzer (SN16110382) revealed that the laboratory had programmed a normal patient mean of 11.1 seconds into the instrument. 3. Observation of thromboplastin reagent in the laboratory's refrigerator confirmed current use of lot N0796941 (expiration 07/2021). 4. Laboratory personnel identifiers #1 and #2 confirmed that the laboratory did not have the correct established normal patient mean programmed into the coagulation analyzer.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the

	laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of ACL Top 350 calibration records, lack of calibration verification records and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 11:30 am on 01/13/2021, the laboratory failed to perform and document calibration verification every six months on the ACL Top 350 test system for the analyte, D-dimer, for one out of two time periods from 01/01/2020-01/08/2021. The findings include: 1. The laboratory performs D-dimer testing on two ACL Top 350 coagulation instruments: serial number SN17100744 and serial number SN16110382. 2. The ACL Top 350 instrument with serial number SN17100744 has been in use since the last survey on 10/16/2018. The laboratory implemented and began using the ACL Top 350 instrument with serial number SN16110382 in March 2020. 3. The laboratory performed calibrations on new lots of HemosIL D-dimer reagent using 5 levels of calibrator on the following dates: * SN17100744: 02/07 /2020, 05/13/2020 and 01/08/2021 * SN16110382: 05/13/2020 and 01/08/2021 2. At the time of the survey, the laboratory did not have additional calibration or calibration verification records for the time period between 05/13/2020 and 01/08/2021 for either instrument.