Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0973809	03/05/2020
Name of Provider or Supplier	**Street Address, City, State**	
Unitypoint Clinic	6520 Se 14th Street, 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
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of the laboratory's AcT Diff 2 Calibration policy, Beckman Coulter AcT Diff 2 calibration records and confirmed by laboratory personnel identifiers #2 and #3 (refer to the Laboratory Personnel Report) at approximately 12:00 pm on 03/05/2020, the laboratory failed to perform calibration procedures every six months on the Beckman Coulter AcT Diff 2 hematology analyzer for two out of two time periods from 09/14/2018- 01/03/2020. The findings include: 1. The laboratory's AcT Diff 2 Calibration policy stated the following: "Calibration must take place under the following circumstances: every 6 months in compliance with CLIA regulations." 2. Calibration records showed the laboratory calibrated the hematology instrument on 09/14/2018, 05/29/2019, and 01/03/2020. 3. At the time of the survey, personnel identifiers #2 and #3 confirmed that the two time periods between calibrations exceeded the six month time frame written in the laboratory's policy.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)

	(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of patient test records, the laboratory's hematology result flag policy and confirmed by laboratory personnel identifiers #2 and #3 (refer to the Laboratory Personnel Report) at approximately 12:00 pm on 03/05/2020, the laboratory failed to perform and document corrective action when hematology equipment failed to meet the laboratory's established operating parameters for one out of one patient (patient identifier A) tested in December 2019. The findings include: 1. Patient identifier A had a complete blood count (CBC) and differential performed on 12/13/2019. 2. The following test results were flagged with an asterisk (*): lymphocyte percentage (LY), monocyte percentage (MO), granulocyte percentage (GR), absolute lymphocyte count (LY #), absolute monocyte count (MO #), and absolute granulocyte count (GR #). 3. The laboratory's hematology result flag policy stated that when results are flagged with an asterisk, the following must be done: "Rock specimen up to 30 minutes and repeat testing. Follow suggested action in Operator Manual (6-88). Send specimen to reference laboratory if you are unable to resolve problem. Notify physician of instrument problem and specimen is being sent to reference laboratory for testing." 4. At the time of the survey, the laboratory did not have additional corrective action documentation for Patient A.