Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2222216	08/23/2023
Name of Provider or Supplier	**Street Address, City, State**	
Corewell Health Beaumont Troy Hosp Hem &	44199 Dequindre Road Suite G-10, Troy, MI	

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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: . Based on observation and interview with Testing Personnel (TP) #3 and the Technical Consultant (TC), the laboratory testing personnel failed to wear gloves while performing patient testing for 1 of 1 surveyor observations. Findings include: 1. An observation by the surveyor on 8/23/2023 at 10:57 am revealed 1 testing personnel performing a CBC (Complete Blood Count) in the laboratory without wearing gloves. 2. When TP3 was queried on 8/23/2023 at 10:57 am if not wearing gloves was a normal practice TP3 replied "no." 3. An interview on 8/23/2023 at 11:00 am the TC confirmed testing personnel had not been wearing gloves while performing CBC testing in the laboratory.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

	This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Consultant (TC), the laboratory failed to document corrective action for the hematology controls that did not meet acceptability for 1 (1/09/2023) of 8 days patient's complete blood cell counts (CBC) and quality control were reviewed. Findings include: 1. A record review of the monthly "QC File Report" revealed for 2 of 3 levels of controls run on 1/09/2023 for the DxH500 CBC analyzer the controls failed acceptability and no documentation of corrective action was taken as follows: a. low control lot #214311 1. Neutrophil (NE) % had an "H" flag - not repeated 2. Neutrophil absolute (NE#) had an "H" flag - not repeated b. normal control lot #214312 1. Neutrophil (NE) % had an "H" flag - not repeated 2. Neutrophil absolute (NE#) had an "H" flag - not repeated c. high control lot #214313 1. No control was run on 1/09/2023. 2. A record review revealed 1 patient (93313232) was run on the analyzer and resulted into the laboratory information system (LIS) when all 3 controls were not within acceptable criteria. 3. An interview on 8/23/2023 at 11:51 am, the TC confirmed that 1 patient was run on the analyzer and resulted into the LIS when the 3 levels of controls were not acceptable.
D5800	POSTANALYTIC SYSTEMS CFR(s): 493.1290 Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in 493.1291 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 postanalytic systems and correct identified problems as specified in 493. 1299 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: . The laboratory failed to meet applicable postanalytic system requirements. Findings include: 1. The laboratory failed to ensure the results manually entered in the laboratory information system (LIS) for the patient portal was accurately transcribed for the complete blood cell count. Refer to D5801.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Consultant (TC), the laboratory failed to ensure the results manually entered in the laboratory information system (LIS) for the patient portal was accurately transcribed for the complete blood cell count (CBC) for 5 of 8 patient reports reviewed from May 2022 to August 23, 2023. Findings include: 1. A record review for 5 of 8 patient charts reviewed revealed

	the manually transcribed CBC results did not compare to the patient's instrument printout from the analyzer as follows: a. 1819599 i. Absolute lymphocytes 1. manual entry- no result entered 2. instrument printout - 0.56 ii. Absolute monocytes 1. manual entry - no result entered 2. instrument printout - 0.38 iii. Absolute granulocytes 1. manual entry - no result entered 2. instrument printout - 3.39 iv. Monocytes 1. manual entry - no result entered 2. instrument printout - 8.38 v. Granulocytes 1. manual entry - 3.39 2. instrument printout - 74.00 b. 5086541 i. Absolute lymphocytes 1. manual entry - no result entered 2. instrument printout - 0.73 ii. Absolute monocytes 1. manual entry - no result entered 2. instrument printout - 0.30 iii. Absolute granulocytes 1. manual entry - no result entered 2. instrument printout - 2.74 iv. Monocytes 1. manual entry - no result entered 2. instrument printout - 7.24 v. Granulocytes 1. manual entry - 2.74 2. instrument printout - 66.88 c. 3314996 i. Absolute lymphocytes 1. manual entry - no result entered 2. instrument printout - 0.65 ii. Absolute monocytes 1. manual entry - no result entered 2. instrument printout - 0.20 iii. Absolute granulocytes 1. manual entry - no result entered 2. instrument printout - 1.75 iv. Monocytes 1. manual entry - no result entered 2. instrument printout - 7.47 v. Granulocytes 1. manual entry - 1.75 2. instrument printout - 65.32 d. 8247781 i. Absolute lymphocytes 1. manual entry - 7.33 2. instrument printout - 0.50 e. 93313232 i. RDW- CV 1. manual entry - 2.75 2. instrument printout - 19.5 ii. Absolute lymphocytes 1. manual entry - 33.21 2. instrument printout - 0.46 2. An interview on 8/23/2023 at 11:51 am, the TC confirmed the CBC results were transcribed incorrectly into the LIS system.