Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0719399	06/01/2022
Name of Provider or Supplier	**Street Address, City, State**	
Corewell Health Dearborn Hospital Hem & Oncology	19725 Allen Rd, Brownstown, 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
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with Testing Personnel #1 (TP1), the laboratory failed to ensure function checks were within established limits before testing and reporting patient Complete Blood Count (CBC) test results from the Beckman Coulter DxH 520 hematology analyzer for 1 (Patient 251573637) of 1 patient CBC test run observed. Findings include: 1. The surveyor observed Testing Personnel #3 (TP3) on 6/1/22 at 9:06 am perform a CBC on Patient 251573637. After sampling the specimen, the analyzer gave an error code stating, "Count Vacuum Error". TP3 requested assistance from TP1. TP1 advised TP3 to use the results from the patient run if they thought it was normal for that patient. 2. A review of the manufacturer's troubleshooting "Event Messages" revealed a section stating, "Count Vacuum Error. Cause: Vacuum Failure occurred during the counting phase in the analysis cycle OR vacuum stability check failed during the counting vacuum. Consequence: Emergency stop occurs. 1. Perform Diluter Reset from the Diagnostics screen. 2. If the problem recurs, contact your Beckman Coulter Representative." 3. A review of the laboratory's "Procedure when CBC Machine is Not Working" policy, established on 9/12/19, revealed a section stating, "At no time should specimen results be given until problem is corrected and machinery and controls are running properly." 4. An interview on 6/1/22 at 9:21 am confirmed the results for Patient 251573637 obtained from the run with the "Count Vacuum Error" were entered into the patient's chart.

D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Consultant (TC), the laboratory failed to ensure quality control results met laboratory-established criteria prior to reporting patient Complete Blood Count (CBC) results for 3 days (1/28/21, 2/1 /21, and 2/2/21) of 10 months of quality control documentation reviewed. Findings include: 1. A review of the laboratory's "Quality Control Data Interpretive Procedure" revealed a section stating, "Do two consecutive results exceed the same limit (either X + 2SD or X-2SD)? Rejection Rule." 2. A review of the laboratory's "Laboratory Quality Control" policy established on 9/12/19 revealed a section stating, "All controls must be within 2 STD." 3. A review of the laboratory's Beckman Coulter DxH 520 hematology analyzer quality control records revealed the following dates when quality control was out of range: a. The low abnormal control for Mean Platelet Volume (MPV) was out of range for three runs on 1/28/21 performed at 7:44 am, 7:47 am, and 7:49 am. b. The low abnormal control for Mean Platelet Volume (MPV) was out of two standard deviations for three runs on 2/1/21 performed at 7:37 am, 7:43 am, and 7:49 am. c. The low abnormal control for Mean Platelet Volume (MPV) was out of two standard deviations for two runs on 2/2/21 performed at 7:36 am and 7:51 am. 4. An interview on 6/1/22 at 12:27 am with the TC revealed 48 patients were tested on the dates listed above and confirmed the laboratory did not ensure quality control was within established acceptability criteria before reporting patient test results.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: . Based on record review and interview with the Technical Consultant, the laboratory failed to ensure Testing Personnel #1, performing the duties of a Technical Consultant had met the qualification requirements at 493.1411. Findings include: 1. The laboratory failed to ensure personnel performing the Technical Consultant duty of peforming personnel competency assessments was qualified. Refer to D6035.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or

	both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Consultant, the laboratory failed to ensure personnel performing the Technical Consultant duty of performing personnel competency assessments was qualified for 1 (Testing Personnel #1) of 2 personnel performing competency assessments. Findings include: 1. A review of the laboratory's personnel competency records revealed Testing Personnel #1 had performed competency assessment for Testing Personnel #2-#12 in 2021 and 2022. 2. A review of the qualifications for Testing Personnel #1 revealed a lack of documentation required to meet the educational requirements of a Technical Consultant. 3. An interview on 6/1/22 at 9:37 am with the Technical Consultant revealed Testing Personnel #1 was not qualified to perform the duties of a Technical Consultant.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: . Based on record review and a lack of documentation, the laboratory failed to ensure testing personnel met the qualification requirements at 493.1423. Findings include: 1. The laboratory failed to ensure testing personnel were qualified. Refer to D6065.

D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: . Based on a lack of documentation and record review, the laboratory failed to ensure testing personnel were qualified for 1 (Testing Personnel #11) of 12 testing personnel listed on the CMS-209 form. Findings include: 1. A review of the laboratory's personnel records revealed a lack of qualification documentation for Testing Personnel #11 listed on the CMS-209 form performing moderate complexity testing. 2. The surveyor requested qualification documentation for Testing Personnel #11 showing they were qualified to perform moderate complexity testing on 6/1/22 at 10: 03 am and it was not made available. 3. The laboratory was provided 7 days to supply documentation and it was not made available.