Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0719399	05/17/2018
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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to rotate the American Association of Bioanalysts (AAB) hematology proficiency testing (PT) samples among all testing personnel who routinely perform patient testing for five (event 3 in 2016, events 1 - 3 in 2017, and event 1 in 2018) of six events reviewed. Findings include: 1. Review of the CMS-209 signed by the laboratory director on May 16, 2018 listed seven testing personnel performing moderately complex hematology testing. 2. On May 17, 2018 at 9:58 AM, review of the final graded AAB hematology proficiency testing documents revealed for five (event 3 in 2016, events 1 - 3 in 2017, and event 1 in 2018) of six events reviewed the same testing personnel (#1) performed and documented all testing. 3. During the interview on May 17, 2018 at 12:45 PM, testing personnel #1 as listed on the CMS-209 confirmed the proficiency testing events were not rotated.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.

	This STANDARD is not met as evidenced by: . Based on record review and interview, the testing personnel failed to attest to the routine integration of the hematology proficiency testing samples into the patient workload for four (events 1-3 in 2017 and event 1 in 2018) of six testing events reviewed. Findings include: 1. On May 17, 2018 at 9:55 AM, record review of the American Association of Bioanalysts (AAB) hematology proficiency testing documents revealed for four (events 1-3 in 2017 and event 1 in 2018) of six testing events the testing personnel did not sign the attestation statement sheets. 2. During the interview on May 17, 2018 at 12:45 PM, testing personnel #1 as listed on the CMS-209 confirmed the attestation statement sheets were not signed by the testing personnel.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to retain 1) the monthly quality control records for the hematology Beckman Coulter AcT 5diff CP analyzer for two (#4 and #6) of nine patient charts audited and 2) the daily background counts for one (#8) of nine patient charts audited for two years. Findings include: 1. On May 17, 2018 at 12:37 PM, record review for two of nine and three of nine patient charts audited revealed the laboratory did not retain the following documentation for two years: a. two of nine patient charts audited (#4 and #6) - did not retain the monthly quality control records for the hematology complete blood cell count testing on the Beckman Coulter AcT 5diff CP analyzer b. one of nine patient charts audited (#8) - did not retain the daily background count for the Beckman Coulter AcT 5diff CP analyzer 2. During the interview on May 17, 2018 at 12:45 PM, testing personnel #1 as listed on the CMS-209 confirmed the above documentation was not retained for two years.
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 record review and interview, the laboratory failed to perform the Beckman Coulter Act 5diff CP hematology analyzer calibration procedures at least every 6

	months for one (1st half in 2017) of four every six months reviewed in 2nd half in 2016, 2017, and the 1st half in 2018. Findings include: 1. On May 17, 2018 at 12:30 PM, record review of the calibration data for the hematology Beckman Coulter AcT 5diff CP hematology analyzer revealed the laboratory did not perform and document the calibration procedure every six months for one (1st half in 2017) of four every six months reviewed. 2. On May 17, 2018 at 12:30 PM when requested, testing personnel #1 as listed on the CMS-209 was not able to provide the surveyor with the documentation to demonstrate the calibrations had been performed every six months. 3. During the interview on May 17, 2018 at 12:45 PM, testing personnel #1 confirmed the calibrations procedures was not performed and documented every six months in 2017.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory director failed to ensure the final graded hematology proficiency testing reports received were reviewed by the appropriate staff for six (2nd and 3rd events in 2016, 1st - 3rd events in 2017, and 1st event in 2018) of six events and 2) no corrective action documented for the 80% score received on the white blood cell count (WBC) for one (2nd event in 2017) of six events reviewed. Findings include: 1. On May 17, 2018 at 10:02 PM, record review of the American Association of Bioanalysts (AAB) proficiency testing reports revealed 1) for six of six events reviewed there was no documentation to ensure the appropriate staff reviewed the final graded proficiency testing reports and 2) no documentation to show corrective action was taken for the 80% score on the WBC as follows: a. 2nd and 3rd events in 2016 - no review by testing personnel b. 1st - 3rd events in 2017 - no review by testing personnel c. 1st event in 2018 - no review by testing personnel d. 80% score 2nd event 2017 - no documentation of corrective action taken 2. During the interview on May 17, 2018 at 10:02 AM, testing personnel #1 as listed on the CMS-209 confirmed testing personnel did not review the final graded proficiency testing reports and there was no documentation of corrective action taken for the 80% WBC score on the 2nd event of 2017.