Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0663889	11/28/2018
Name of Provider or Supplier	**Street Address, City, State**	
Corewell Health Farmington Hills Hosp	44130 W 12 Mile Road, Novi, 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: . Based on record review and interview, the laboratory failed to enroll in a proficiency testing program for one (1st) of three events in 2018 in the speciality of hematology for the analytes: white blood cell differential, red blood cell count, hematocrit, hemoglobin, white blood cell count, and platelets. Findings include: 1. On November 28, 2018 at 10:25 AM, record review of the CMS database and the American Association of Bioanalysts (AAB) proficiency testing documents revealed there was no documentation to show the laboratory was enrolled in a proficiency testing program for the 1st event of 2018. 2. On November 28, 2018 at 10:25 AM when queried, the office manager stated that proficiency testing enrollment started the 2nd event of 2018. 3. During the interview on November 28, 2018 at 10:25 AM, the office manager confirmed the laboratory was not enrolled in a proficiency testing program for the 1st event of 2018 in the speciality of hematology.
D5821	TEST REPORT CFR(s): 493.1291(k) When errors in the reported patient test results are detected, the laboratory must do the

	following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to detect the hematology incorrect and/or no laboratory test results reported for six (#2-#4, #6-#8) of eight patient charts audited . Findings include: 1. On November 28, 2018 at 12:15 PM, record review for six patient charts audited revealed the final test report in the patient's electronic medical record (EMR) did not contain the correct and/or no result for the hematology complete blood cell count as follows: a. patient #2 - incorrect results for the lymphocyte % and absolute count b. patient #3 - incorrect results for the lymphocyte % count, lymphocyte absolute count, monocyte absolute count, and the mean platelet volume c. patient #4 - incorrect results for the lymphocyte % count, lymphocyte absolute count, granulocyte % count, and the mean platelet volume d. patient #6 - incorrect results for the lymphocyte % count, lymphocyte absolute count, monocyte % count, monocyte absolute count, granulocyte % count, and the granulocyte absolute count e. patient #7 - incorrect results for the lymphocyte % count, lymphocyte absolute count, monocyte % count, monocyte absolute count, granulocyte % count, and the granulocyte absolute count f. patient #8 - no results for the lymphocyte, monocyte, and granulocyte absolute counts 2. During the interview on November 28, 2018 at 12:15 PM, testing personnel #3 as listed on the CMS-209 confirmed results were entered incorrectly or not present in the patient's electronic medical records.
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 failed to ensure for five (1st-3rd events in 2017 and 2nd-3rd events in 2018) of five testing events the final proficiency testing reports were not reviewed by the appropriate testing personnel and the laboratory director. Findings include: 1. On November 28, 2018 at 10:33 AM, record review of the American Association of Bioanalysts (AAB) final proficiency testing reports revealed for five of five events the laboratory director and the testing personnel did not document review of the laboratory's performance. 2. During the interview on November 28, 2018 at 10:33 AM, testing personnel # 3 as listed on the CMS-209 confirmed there was no documentation to show the final reports had been reviewed. ***Repeat Deficiency from November 12, 2017 survey***