

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D0886267	(X3) Date Survey Completed 02/14/2024
Name of Provider or Supplier Prohealth Physicians Pc	Street Address, City, State 950 Yale Ave, Wallingford, CT	
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
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observations, record review and staff interview, the laboratory failed to document the expiration date on the hematology quality control (QC) material once put in use in the specialty of hematology. Findings Include: 1) Surveyor observation on 02/14/2024 at 10:00 AM of the hematology laboratory refrigerator revealed the following QC materials were in use for the Sysmex XN 9100 hematology analyzer: a. L1 XN check QC material (Lot# 40051101) with a prep/open date. b. L2 XN check QC material (Lot# 40051102) with a prep/open date. c. L3 XN check QC material (Lot# 40051103) with a prep/open date. d. Lack of documentation of an expiration date on all three levels of XN check hematology QC materials listed above. 2) Record review on 02/14/2024 of the 'XN Check Hematology Control for Sysmex XN-L Analyzers' package insert revealed an 'open vial stability of 7 days if stored at 2-8 degrees Celsius'. 3) Record review on 02/14/2024 of the laboratory 'CBC Sysmex XN9100' standard operating procedure revealed the following: a. 'Open vial stability is 7 days when promptly refrigerated after each use'. b. 'Record the date on each vial upon opening or cap piercing'. c. Lack of procedure to document the expiration date on each vial listed in 1a, b, and c above once opened. 4) Staff interview on 02/14/2024 at 10:10 AM with the laboratory's technical supervisor (TS) confirmed the above findings. The TS further commented that the date on the QC vial is the open date and</p>

that the testing personnel does not write down the expiration date on the QC vials. 5) The laboratory performs 169,411 complete blood count tests annually in the specialty of hematology.

D5807

TEST REPORT
CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:
Based on record review and staff interview, the laboratory failed to ensure the patient final test report's reference ranges matched the laboratory's established reference ranges in the specialty of hematology. Findings include: 1. Record review on 02/14/2024 of the 'CBC Sysmex XN9100' hematology procedure manual revealed the following laboratory established reference ranges: a. Hemoglobin (HGB): Male Patient, 12.7 - 17.7 g/dL. Female Patient, 11.5 - 15.7 d/dL. b. Hematocrit (HCT): Male Patient, 37.7 - 54.0%. Female Patient, 34.5 - 47.0%. c. Mean Corpuscular Hemoglobin Concentration (MCHC): 32 - 36 g/dL. d. Red Cell Distribution Width (RDW-CV): 11.0 - 14.5%. 2. Record review on 02/14/2024 of two complete blood count patient test reports revealed the following reference ranges: a. HGB: Male Patient, 12.7 - 17.5 g/dL. Female Patient, 11.5 - 15.5 d/dL. b. HCT: Male Patient, 38.5 - 52.0%. Female Patient, 35.0 - 47.0%. c. MCHC: 31 - 35 g/dL. d. RDW-CV: 12.0 - 16.1%. 3. Record review on 02/14/2024 of the 'Bio-Rad D-100 A1C' procedure manual revealed an established Hemoglobin A1C (HA1c) reference range of 4.0 - 6.0%. 4. Record review on 02/14/2024 of a patient test report revealed a HA1c reference range of 4.3 - 6.1%. 5. Staff interview on 02/14/2024 at 1:00 PM with the laboratory's technical supervisor (TS) confirmed the above findings. The TS further commented that he/she only updates the reference range master sheet for all testing and not the individual standard operating procedures. 6. The laboratory performs 169,411 complete blood count tests and 81,157 HA1c tests annually in the specialty of hematology.