Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2130224	11/22/2021
Name of Provider or Supplier	**Street Address, City, State**	
Your Docs In Prmc	1135 South Salisbury Blvd, Salisbury, MD	

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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on procedure manual review and interview with the technical consultant (TC), the laboratory did not ensure that the procedure for reviewing hematology quality control (QC) accurately reflected the current practice in the laboratory. Findings: 1. The procedure, "Quality Control Policy and Procedure" "Control Review" states that the "Team leader should review Quality Control daily and ensure that all Quality Control is within the acceptable ranges and that if it is outside the acceptable ranges corrective actions have been taken and documented on the 'Quality Control Remedial Actions' worksheet before patient testing is done." 2. During an interview on 11/22 /2021 at 1:45 PM, the TC stated that the QC was not reviewed by the team leader and that the procedure manual needed to be updated.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) 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.

	This STANDARD is not met as evidenced by: Based on observation, procedure manual review, and interview with the technical consultant (TC), the laboratory did not ensure that hematology reagents are labeled with their opened and expiration dates. Findings: 1. The laboratory uses the Sysmex pocH 100-i hematology analyzer to perform hematology testing. 2. The "Complete Blood Count (CBC)" procedure under "III. Supplies and Reagents" states that the "Storage and Stability" for the "pocH-pack D" reagent is "Once opened, product stability is 60 days" and the "pocH-pack L" reagent is "Once opened, product stability expires after 90 days." 3. During a tour of the laboratory at 11:15 AM it was observed that the in-use "pocH-pack L" reagent (lot # Y1002/expiration date: 05/20/2022) and the in-use "pocH-pack D" reagent (lot # Y1007/expiration date 12/23/2027) were not labeled with an opened date. The reagents were also not labeled with their new opened expiration dates. 4. During an interview on 11/22/2021 at 1:45 PM, the TC confirmed that the in-use hematology reagents were not labeled with their opened and expiration dates.