

| | | |
|--|--|---|
| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 01D2208239 | (X3) Date Survey Completed 04/01/2025 |
| Name of Provider or Supplier Health Partners Of New Site | Street Address, City, State 12761 Hwy 22 East, Daviston, AL | |
| 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>(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on direct observations, a review of the SYSMEX EIGHTCHEK 3WP XTRA Hematology control package insert, and an interview with the Technical Consultant (TC), the laboratory staff failed to write the new expiration date on the Hematology Quality Control (QC) materials. The surveyor noted three out of the three levels of QC currently in use did not have the open stability date written on the vials. The findings include: 1. During the laboratory tour on 04-01-2025 at approximately 9:19 AM, the surveyor observed the three levels of Hematology QC in use had no dates written on the vials and the testing personnel had not recorded the new expiration date upon opening. 2. A review of the SYSMEX EIGHTCHEK 3WP XTRA Hematology control package insert revealed the following instructions, Storage and shelf life after opening: "Open and recapped vials and vials whose caps have been pierced will retain stability for 14 days ..." 3. The TC confirmed the above findings during the exit conference on 04-01-2025 at 2:00 PM.</p> |
| D5437 | <p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (a)(1) Following the manufacturer's test system instructions, using calibration materials provided or</p> |

specified, and with at least the frequency recommended by the manufacturer; (a)(2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (a)(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 (a) (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (a)(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 a review of the Hematology calibration records and an interview with the Technical Consultant (TC), the Laboratory failed to perform calibration on the Sysmex XP-300 Hematology analyzer according to the manufacturer's specification. This was noted for one of the three possible calibrations from 2023-2024. The findings include: 1. A review of the Hematology calibration records revealed the Sysmex XP-300 was calibrated on 10-03-2023 and 03-29-2024. The 03-29-2024 Sysmex Certificate of Calibration had indicated a due date of 09-29-2024 for the next calibration but no calibration was performed and documented. 2. An interview with the TC on 04-01-2025 at 11:13 AM revealed an email from BIOMEDICAL ENGINEERING dated 12-05-2024 was sent to inform her that the Sysmex user manual procedure intervals did not include a 6- month or 12-month intervals. Surveyor also noted on the same email that effective 2025, a service vendor will be onsite at 12-month interval to address the necessary parts replacement of the Sysmex XP-300.