

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2042545	(X3) Date Survey Completed 02/24/2022
Name of Provider or Supplier North Baldwin Primary Plus	Street Address, City, State 2115 Hand Avenue, Suite B, Bay Minette, 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
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on a review of Hematology quality control (QC) logs, patient CBC (Complete Blood Count) records and an interview with the Technical Consultant and Testing Personnel #1, the laboratory failed to ensure testing personnel checked expiration dates, and did not utilize expired QC material on days of patient testing. Expired controls were used on three days of patient CBC testing in March 2021 by two different testing personnel. The findings include: 1. A review of Hematology records revealed expired QC material was used on the Medonic M Series Hematology analyzer 3/23/2021 through 3/30/2021 (eight days) by two previous testing personnel. 2. During an interview on 2/24/2022 at 1:50 PM the Technical Consultant confirmed the above noted findings. The surveyor then asked if patient CBC's were performed on these eight days. Testing Personnel #1 checked the patient records, and stated three patient CBC's were run on 3/25/2021, one patient on 3/26/2021, and two patients on 3/30/2021. .</p>
D5783	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The</p>

laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:

Based on a review of Hematology quality control (QC) logs, patient CBC (Complete Blood Count) records and an interview with the Technical Consultant and Testing Personnel #1, the laboratory failed to perform and document corrective actions to ensure patients results were not impacted when expired QC material was used three days of patient testing in March 2021. The findings include: 1. A review of Hematology records revealed expired QC material was used on the Medonic M Series Hematology analyzer 3/23/2021 through 3/30/2021 (eight days) by two previous testing personnel. [Refer to D5417.] 2. During an interview on 2/24/2022 at 1:50 PM the Technical Consultant confirmed the above noted findings. When the surveyor asked if patient testing was performed, Testing Personnel #1 checked the patient records, and stated three patient CBC's were run on 3/25/2021, one patient on 3/26/2021, and two patients on 3/30/2021. 3. As the interview continued, the surveyor then asked if the laboratory had documentation of corrective action for these six patient to ensure the results were reliable, and patient care was not compromised. The Technical Consultant confirmed the laboratory had not performed and documented correction actions for the patient CBC's. SURVEYOR ID#32558 Licensure and Certification Surveyor