

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D1107424	(X3) Date Survey Completed 05/09/2024
Name of Provider or Supplier Harmonie Medical	Street Address, City, State 902 Ponder Place Court, Evans, GA	
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
D0000	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on May 09, 2024. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
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 the laboratory tour, inspection of the flammable cabinet and an interview with the laboratory's lead MA and lab director, it was determined that the laboratory failed to check its testing reagent supply inventory for expiration dates before use in 2024 as required. Findings: 1. Laboratory tour revealed: GIL 3 Hematoxylin stain by Avantik Biogroup lot # 153984, in use, expired 01/24/2024 and GIL 3 Hematoxylin stain by Avantik Biogroup lot # 160052, in use, expired on 03/01/2024. 2. Interviews with the laboratory's lead MA TP#2 (CMS 209) during the tour and the laboratory director at approximately 2:50 PM on 05/09/2024 confirmed the reagents were expired and recommended to be discarded by surveyors during the survey on 05/09/2024.</p>
D6021	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>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</p>

director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on the laboratory tour, interview with staff and the Lab Director(LD), the laboratory failed to ensure that ALL Quality Assurance (QA) guidelines were followed to identify and fix problems in the laboratory in 2024 as required by Clinical Laboratory Improvement Amendments (CLIA). Findings: 1. The laboratory tour revealed the Lab Director(LD) who is also the Technical Supervisor (TS), did NOT recognize that the laboratory's reagents and staining dyes expired in January and March of 2024. 2. An interview with staff (TP# 2 CMS 209) and Lab director in the review room on 05/09/2024 at approximately 2:35 PM, confirmed the Lab Director failed to ensure proper oversight of the laboratory as it concerns reagent inventory and expiration dates in 2024.