

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2307895	(X3) Date Survey Completed 03/17/2025
Name of Provider or Supplier GI Clinical Laboratory And Research Llc	Street Address, City, State 7911 Nw 72nd Avenue Suite 115, Medley, FL	
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	An announced CLIA initial survey was conducted at GL CLINICAL LABORATORY AND RESEARCH LLC on March 17, 2025. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the Laboratory Director (LD) failed to approve, sign and date the procedure manual before use since 02/26/2025 Findings included: 1-Review of the procedure manual showed that the LD approved, failed to sign and date the procedure manual before testing since 02/26/2025 when the laboratory started testing patients. 2-During an interview on 03/17/2025 at 10:35 AM, the supervisor acknowledged that the LD failed to review, approve and sign procedure manual before testing patients.</p>
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>

This STANDARD is not met as evidenced by:
Based on observation, record review and staff interview, the laboratory failed to label the three hematology controls for the Diatron Abacus 5 Complete Blood Cell count (CBC) analyzer with open and expiration before patient testing since 02/26/2025. Findings included: 1-During the Laboratory tour on 03/17/2025 at 10:30 AM, the surveyor found that the laboratory had one box in the refrigerator labeled CBC-3K for Abacus with lot number KK124, this box was labeled with a reception date on 02/22/2025, this box had two sets of three control levels. The laboratory had one set in use but failed to label the opening date and the new expiration date. 2-Review of the manufacturer instructions for use R&D systems for the CBC controls, revealed the following: Stability and Storage "Unopened tubes are stable through the expiration date. Opened tubes are stable for 8 days, provided they are handled properly." 3-During an interview on 03/17/2025 at 12:30 PM with Testing Person, she confirmed that the laboratory failed to label the CBC controls with the opening date and new expiration date.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

(d) 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.

This STANDARD is not met as evidenced by:
Based on observation, record review and staff interview, the laboratory used expired reagents on the Beckman Coulter Analyzer AU 480 since 09/30/2024. Findings included: 1-During the laboratory tour on 03/17/2025 at 10:30 AM, the surveyor found that the laboratory used for patient testing the following expired reagents on the Beckman Coulter AU480: from Caroline (Glucose with lot number D2412 expired on 09/30/2024, Gamma Glutamyl Transferase (GGT) with lot number L2304 and expired on 10/31/2024, Aspartate Amino Transferase (AST) with lot number C2406 expired on 10/31/2024, Alanine Alkaline Phosphatase (ALP) with lot number L2314 expired on 10/31/2024, Albumin with lot number A2414 and expired on 11/30/2024, Lactate Dehydrogenase (LDH) with lot number 51271 and expired on 01/31/2025, HDL-Cholesterol Direct with lot number D2419 and expired on 01/31/2025 and Blood Urea Nitrogen (BUN) with lot number A2422 expired on 01/31/2025) and from Beckman Coulter (Triglyceride with lot number 2718 expired on 01/01/2025 and Total Bilirubin with lot number 2610 expired on 12/01/2024. 2- Review of patient reports, revealed that the laboratory tested three patients on 02/26/2025 with the expired reagents listed above. 3-During an interview on 03/17/2025 at 5:41 PM , with Testing Person she confirmed that the laboratory tested the 3 patients with the expired reagents listed above.