

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2085108	(X3) Date Survey Completed 03/19/2026
Name of Provider or Supplier Patients Emergency Center	Street Address, City, State 10133 Interstate 10 East, Baytown, TX	
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	The laboratory was found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, CLIA requirements for laboratories as a result of an announced validation survey on 03/19/2026. Standard level deficiencies were cited.
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 the surveyor's direct observation, the review of the manufacturer's QC package insert, CMS 116 application, and confirmed in an interview, the laboratory failed to document the revised expiration dates on the used CBC QC vials on 1 of 1 lot number in use for 2 of 2 Medonic M hematology Analyzer. The findings were: 1. Review of the manufacturer's QC package insert titled Boule Tri-Level Hematology control under STORAGE AND STABILITY revealed "Open vial stability 14 days after opening when returned to refrigerator after each use." 2. Direct observation of the surveyor from the lab refrigerator on 3/19/2026 at 1:15 pm in the laboratory revealed no revised expiration dates documented on the used CBC QC vials for 1 of 1 lot number in use for 2 of 2 Medonic M hematology Analyzers. (SN: 62395 and 62401.) Boule Con-Diff Low: Lot# 22601-31 Exp. 2026-06-10 Normal: Lot# 22601-32 Exp. 2026-06-10 High: Lot# 22601-33 Exp. 2026-06-12 3. Review of the CMS 116 application signed by the laboratory director on 03/09/2026 revealed the annual CBC volume was 87618. 4. An interview with the technical consultant (as listed on CMS 209 form) on 3/19/2026 at 1:20 pm in the laboratory confirmed the above</p>

findings Key: QC=Quality Control CBC=Complete Blood Count CMS=Center of Medicare and Medicaid Services