

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2004089	(X3) Date Survey Completed 08/05/2024
Name of Provider or Supplier Methodist Healthcare Community Care Associates	Street Address, City, State 130 Flicker St, Memphis, TN	
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	During a recertification survey on 08/05/24, the laboratory was found OUT OF COMPLIANCE with the following conditions: 493.1290 Condition: Postanalytic Systems
D5800	<p>POSTANALYTIC SYSTEMS CFR(s): 493.1290</p> <p>Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in 493.1291 unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7) that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the postanalytic systems and correct identified problems as specified in 493.1299 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on observation of the laboratory, review of the January 2024 quality assessment document, review of patient test results, review of the laboratory's quality assessment plan, review of subsequent quality assessment documents, and staff interview, the laboratory's quality assessment corrective action and monitoring was not effective in preventing errors with discrepant Complete Blood Count with White Blood Cell Differential (CBC w/Diff) final patient results (Refer to D5893).</p>
D5893	<p>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(b)(c)</p> <p>(b) The postanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities.</p>

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, review of the January 2024 quality assessment document, review of patient test results, review of the laboratory's quality assessment plan, review of subsequent quality assessment documents, and staff interview, the laboratory's quality assessment corrective action and monitoring was not effective in preventing future errors with discrepant final CBC w/Diff results for two of two subsequent patients with discrepant results in 2024. The findings include: 1.

Observation of the laboratory on 08/05/24 at 8:45 a.m. revealed the Medonic M series CBC instrument (serial # 62158) used for patient testing. 2. A review of the January 2024 quality assurance report revealed the following: "Major discrepancy with results-see attached." Corrective action performed did not include staff discussion, retraining, or change in policies or procedures as a result of the error. 3. A review of subsequent patient CBC w/Diff test reports revealed the following: Patient number 1119452, performed on 04/04/24, with discrepancies in the final patient test results as follows: Run #1 performed at 14:17/Run #2 performed at 14:23. #1--WBC = $15.5 \times 10^9/l$ #2--WBC = $11.9 \times 10^9/l$ #1--RBC = $6.32 \times 10^{12/l}$ #2--RBC = $5.04 \times 10^{12/l}$ #1--HGB = 12.9 g/dl #2--HGB = 10.5 g/dl #1--HCT = 39.8 % #2--HCT=31.6 % Patient 1763581 performed on 05/13/24 with discrepancies in the final patient test results as follows: Run #1 performed at 16:25/Run #2 performed at 16:31. #1--WBC = $17.9 \times 10^9/l$ #2--WBC = $13.6 \times 10^9/l$ #1--RBC = $3.85 \times 10^{12/l}$ #2--RBC = $5.58 \times 10^{12/l}$ #1--HGB = 13.1 g/dl #2--HGB = 18.6 g/dl #1--HCT = 37.9 % #2--HCT= 55.7 % Word Key: % =Percent dL= HCT=Hematocrit HGB=Hemoglobin l=Liter RBC=Red Blood Cell Count WBC=White Blood Cell Count 4. A review of the policy titled "LAB QUALITY ASSURANCE PLAN" revealed that the laboratory would identify problems, apply corrective actions, and ensure accurate and reliable test results by reviewing final patient test results. 5. A review of the April 2024 and May 2024 quality assessment reports revealed no evidence that the discrepant results were detected or corrective action performed. 6. The technical consultant confirmed during an interview on 08/05/24 at 12:30 p.m. that the laboratory's quality assessment process failed to prevent discrepancies in the final patient test results for CBC w/Diff.