

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0469076	(X3) Date Survey Completed 06/12/2025
Name of Provider or Supplier Mercy Hospital Paris	Street Address, City, State 500 East Academy, Paris, AR	
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
D3023	<p>REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(c)(2)</p> <p>The facility must establish and follow policies to ensure positive identification of a blood or blood product recipient.</p> <p>This STANDARD is not met as evidenced by: Based upon review of the laboratory policy and procedure "PR SAR LABBBB Blood Bank Armband System", directions for use of Typenex barcode blood band for pre-printed labels, and interview with laboratory staff members, the laboratory failed to follow the policy to ensure positive identification of a blood product recipient. Findings follow: A) Step #2 in the laboratory policy and procedure states; "check with Blood Bank Tech to determine if a specimen must be collected". B) Step #2 in the 8-step directions for use of the Typenex barcode blood band for pre-printed labels is to attach the arm band to the patient immediately prior to obtaining the specimen for crossmatching. C) In an interview on 6/12/25 at 08:40 a.m., the laboratory staff member (# 3 on the form CMS 209) was asked why a specimen might not need to be collected for a crossmatch. The laboratory staff member stated that if a specimen was in the laboratory for other testing, as an example for a complete blood count or electrolyte assay, that specimen would be taken to the blood bank, labeled with the Typenex system, and the arm band then be affixed to the patient. This practice does not conform to the procedure provided in the directions for use of the Typenex Barcode Blood Band system.</p>
D5783	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)</p> <p>(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</p>

determine if patient test results have been adversely affected. The 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 upon review of Levey-Jennings graphs for quality control (QC) Detail reports for prothrombin time (PT) testing performed on the Stago Satellite coagulation analyzer, and interview with laboratory staff, the laboratory failed to take corrective action when QC for PT testing failed to meet the laboratory's criteria for acceptability on 2 of 2 occasions reviewed. Findings follow A) Review of the QC Statistic Report for normal control level lot# 265970 performed on the Stago Satellite coagulation analyzer revealed that the normal control was unacceptable on four successive runs on 7/18/24 at 1537, 1603, 1630, and 1656 before being acceptable at 1730; B) Review of the QC Statistic Report for normal control level lot# 265970 performed on the Stago Satellite coagulation analyzer revealed that the normal control was unacceptable on two successive runs on 7/19/24 at 1548, 1616, before being acceptable at 1656. C) Review of statements of corrective action revealed that the corrective action was listed as "rerun" for all the instances identified above. Retesting QC does not represent corrective action. D) In an interview on 6/11/25 at 10:50 a.m., the laboratory staff member (# 3 on the form CMS 209) confirmed the only action taken in the instances identified above was to rerun the QC.