

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0469076	(X3) Date Survey Completed 10/20/2021
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
D5791	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Through a review of laboratory policies and procedures, hematology quality control documentation for January, May, and August 2021, lack of documentation, and interviews with laboratory staff, it was determined the quality assessment failed to identify and correct the incorrectly entered hematology quality control ranges in May 2021 (one of three months reviewed). Survey findings include: A. The laboratory quality control policy states "For new lot numbers of Sysmex E-check XS series controls, the laboratory will establish its own target values. This will be done by collecting at least 10 data points per control over at least 5 days. QC limits will then be established using Sysmex Evidence Based X-S control limits." B. Through a review of hematology quality control documentation for May 2021, it was determined the acceptable ranges were incorrectly entered into the system. Control lots #10960804, #10960805, and #10960806 were documented in use for Low, Normal, and High hematology daily controls. The ranges for all constituents of the controls were entered as a target value plus or minus the same target value so that each control range was from zero to twice the target value. C. In an interview, at 1:27 p.m. on 10/19/2021, laboratory employee #2 (as listed on the form CMS-209) confirmed the ranges in May 2021 did not represent the Sysmex Evidence Based control limits and that the limits were entered incorrectly. She further confirmed that there was no documentation of quality assessment identifying the incorrect ranges on daily, weekly,</p>

or monthly reviews. Employee #2 also confirmed that quality control results had not been evaluated to determine if any would have been unacceptable if quality control ranges had been entered correctly.

D6066

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(b)(4)(ii)

Have documentation of training appropriate for the testing performed prior to analyzing patient specimens.

This STANDARD is not met as evidenced by:
Through a review of personnel records for six employees listed as testing personnel, lack of documentation, and interviews with laboratory staff, it was determined that one of six employees lacked documented training prior to analyzing patient samples. Survey findings include: A. During a review of personnel records for six employees listed as testing personnel on the form CMS-209, it was determined there was no documentation of training in the personnel record of employee #6 as listed on the form. B. In an interview, at 1:27 p.m. on 10/19/2021, laboratory employee #2 (listed as the general supervisor) confirmed the laboratory had no documentation of training for employee #6.