

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0988096	(X3) Date Survey Completed 03/10/2022
Name of Provider or Supplier Unity Health North Cabot Family Medicine	Street Address, City, State 1911 North 2nd Street, Cabot, 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 hematology quality control documentation, technical consultant's quality assurance reviews, a review of Sysmex peer data, and interviews with laboratory staff it was determined the laboratory failed to correct quality control shifts identified in quality assurance reviews. Survey findings include: A. The surveyor reviewed hematology quality control records for July 2021, November 2021, and February 2022. In three of three months the White Blood Cell Count (WBC) results were shifted above the mean all month for all three levels of control. In three of three months Hemoglobin results were shifted above the mean all month for at least two of three controls. B. In an interview, at 10:40 on 3/10/2022, the Technical Consultant (listed as employee #2 on the form CMS-209) stated that the shifts are occurring on every lot of control that has been used. During the interview, the surveyor asked if peer data from other Sysmex users indicated that other laboratories were having the same problem. The Technical Consultant stated that the laboratory had not obtained peer data. C. A review of six quality assurance reports, written by the Technical Consultant, revealed that six of six quality assurance reports included notes stating that the controls were shifted above the mean. May 2021 report stated that quality control results were shifted above the mean. June 2021 report noted that the WBC and Hemoglobin were shifted above the mean and included a note, "will watch to see if controls look better next month". August 2021 report stated that the WBC and Hemoglobin were shifted above the mean. September 2021 report noted QC for WBC and Hemoglobin were above the mean and stated, "Service called due to problem".</p>

October 2021 report again noted that the WBC and Hemoglobin were shifted above the mean. November 2021 included a note that the Technical Consultant will not comment on shifts and thinks its just normal for this machine. D. The surveyor requested that the laboratory provide peer data from the manufacturer, in order to determine that all instruments of this model were reporting elevated WBC and Hemoglobin results. At the time of the survey the laboratory obtained peer data but were not able to provide it to the surveyor. Laboratory personnel emailed the peer data to the surveyors office. E. On 3/11/2022 at 12:59, the surveyor received an email from the technical consultant which stated, "I spoke with tech support for the Sysmex they sent someone out today. I spoke with the service tech, found out when they put in controls they are running them in patient mode not the control mode which makes it run just a little higher because it's in whole blood mode on the machine. All the checks were good like in the past. He watch them run the controls and found the problem. He reviewed his run values verses theirs in the patient mode and it is higher. He is showing them to correct way to pick control mode. I will let them run a few days and go look to make sure that's is the problem." This confirms the problem was ongoing at the time of the survey and had not been identified or corrected.