

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2050900	(X3) Date Survey Completed 09/04/2018
Name of Provider or Supplier Duly Health And Care - Aurora Lab	Street Address, City, State 4205 Westbrook Dr, Naperville, IL	
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
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with technical consultant (TC) #2; the laboratory failed to follow manufacturer's instructions for calibration verification requirements related to complete blood count (CBC) testing on the Sysmex pocH-100i analyzer. Findings include: 1. Review of the laboratory's policy and procedure manual identified the procedure, "Sysmex pocH-100i Automated Hematology Analyzer CLSI Procedure", which stated on page 9 of 29, "Calibration verification of the analyzer is to be performed upon receipt of the analyzer as described in the implementation manual." 2. Review of the pocH-100i maintenance logs found in the comments section of the January 2018 log which stated the analyzer was sent out for repair on 1-2-2018 and was put back into use on 1-10-2018. 3. Review of calibration records for the pocH-100i analyzer found no documented calibration verification was performed upon receipt of the repaired analyzer. 4. Further review of calibration verification records found that calibration verification was performed on July 12, 2018. 5. Review of patient testing data found 205 CBCs were performed between 1-10-2018 to 7-11-2018. 6. During survey date on 09-04-2018, at 3:35 PM, the laboratory TC#2 confirmed that no calibration verification was performed upon receipt of the pocH-100i analyzer after major repairs.</p>