

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D0322264	(X3) Date Survey Completed 04/13/2023
Name of Provider or Supplier Norton Children's Medical Group - Jeffersontown	Street Address, City, State 3840 Ruckriegel Pkwy Ste 105, Louisville, KY	
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	A recertification survey was conducted on 04/13/2023 and the facility was found not to be in substantial compliance with the laboratory requirements at 42 CFR Part 493, with deficiencies cited.
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on observation,document review and interview, the laboratory failed to monitor and document quality control (QC) activities for the hematology analyzer. Findings included: During a tour of the laboratory on 04/13/2023 at 12:45 PM, observation revealed a failed QC for level three (3) was above the acceptable range on the Sysmex XP-300, a hematology analyzer. Review of the laboratory records revealed there was no corrective action for the failed QC dated 11/10/2022. In an interview on 04/13 /2023 at 2:00 PM, the Technical Consultant (TC) confirmed the laboratory did not monitor and document failures of the QCs and a corrective action was not performed for the failures.</p>