

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D0321483	(X3) Date Survey Completed 05/21/2024
Name of Provider or Supplier Norton Louisville Primary Care	Street Address, City, State 720 West Hill St, 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 05/21/2024. The facility was found not to be in compliance with the laboratory requirements of 42 CFR Part 493 with deficiencies cited.
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, review of Sysmex XP-300 Hematology Analyzer instructions for use, laboratory policy, laboratory maintenance records (December 2022, March 2023, October 2023, and April 2024) for the Sysmex XP-300 Hematology Analyzer, and confirmed in staff interview, the laboratory failed to document weekly maintenance for four of seven months reviewed. Findings include: 1. During a tour of the laboratory on 05/21/2024 at 10:55 a.m., a Sysmex XP-300 Hematology Analyzer (Serial Number A4970) was observed to be in use. 2. The Sysmex XP-300 instructions for use (date of last revision June 2013) stated, "To ensure proper functioning of the instrument, it is necessary to periodically clean and service the instrument. Perform maintenance according to the schedule below. And record the results in the Maintenance checklist." 3. The laboratory policy for the Sysmex XP-300 titled, "Complete Blood Count on Sysmex XP-300 Automated Hematology Analyzer, Routine Maintenance", stated, "This section includes written procedures for performing weekly, monthly, and quarterly maintenance." Section A, Weekly Maintenance stated, "Clean the SRV (sample rotor valve) Tray." Part f. of Section A stated, "Document on the Maintenance log." 4. The laboratory maintenance logs stated, "Weekly - Clean SRV tray." Further review of laboratory maintenance records revealed the laboratory failed to document performance of the weekly</p>

maintenance for the following: a. December 2022- Week 1,2,3,4 b. March 2023 - Week 4 c. October 2023 - Week 3,4 d. April 2024 - Week 4 5. In an interview on 05 /21/2024 at 12:20 PM in the conference room, the Technical Consultant (TC) was asked to provide documentation of weekly maintenance for the Sysmex XP-300. No documentation was provided. This confirmed the findings.