Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0226281	07/25/2023
Name of Provider or Supplier	**Street Address, City, State**	
Louisa Family Practice Plc	101 Woolfolk Street, Louisa, VA	

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	An announced CLIA recertification survey was conducted at Louisa Family Practice on July 25, 2023 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) 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. This STANDARD is not met as evidenced by: Based on a review of the manufacturer's instructions for use, hematology analyzer maintenance records, lack of documentation, and an interview, the laboratory failed to document performance of required annual instrument preventative maintenance in calendar year 2022 (record review timeframe from October 2021 until July 25, 2023). The findings include: 1. Review of the Beckman Coulter DxH 520 Instructions for Use revealed manufacturer's instructions to "Yearly-Lubricate the pistons. Yearly or every 18,000 cycles-Replace the rinsing head O-ring." 2. Review of the laboratory's DxH 520 hematology analyzer's maintenance logs from October 2021 to the date of the inspection on July 25, 2023, revealed documentation of instrument installation on October 6, 2021 and the performance of the required annual maintenance outlined above on July 14, 2023. The inspector requested to review documentation of the piston syringe maintenance and replacement of the O-ring in calendar year 2022. The laboratory provided no documentation to review. 3. In an exit interview with the primary testing personnel on July 25, 2023, at approximately 1:00 PM, the above findings were confirmed.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES

	CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on the review of Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel (TP) records, lack of documentation, and interview the Technical Consultant (TC) failed to perform and document the semi-annual and annual competency assessment for one (1) of 1 new TP (record review timeframe October 2021 until July 25, 2023). The findings include: 1. Review of the CMS-209 form revealed that TP A was trained and performing patient testing on 12/23/2021. (See attached personnel code sheet.) 2. Review of TP A's personnel records revealed lack of documentation by the TC of the performance and review of the semi-annual and annual competency assessments at the date of survey on July 25, 2023. The surveyor requested to review TP A's semi-annual and annual competency assessments for calendar year 2022. The laboratory provided documentation of an assessment performed in April 2023. The laboratory provided no documentation of calendar year 2022's assessments. 3. In an exit interview with the primary testing personnel on July 25, 2023, at approximately 1:00 PM, the above findings were confirmed.