Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	18D0949146	07/27/2026
Name of Provider or Supplier	**Street Address, City, State**	
Bullitt County Family Practitioners	170 Dr Arla Way, Unit 101, 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 07/27/2026 and concluded on 07/27/2026. The facility was found to not be in compliance with the laboratory requirements of 42 CFR Part 493 with standard deficiencies cited.
D2014	TESTING OF PROFICIENCY TESTING SAMPLES (b)(6) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) events for years 2024, 2025, and 2026, review of American Proficiency User Guide/API instructions, and confirmed in staff interview, the laboratory failed to have director/designee signed attestation forms for 9 of 9 events. Findings include: Review of the laboratory API proficiency testing events revealed the following: a. 2024 Hematology/Coagulation 3rd Event - No Laboratory director/designee signature b. 2024 Chemistry Miscellaneous 3rd Event - No Laboratory director/designee signature c. 2025 Hematology/Coagulation 1st Event- No Laboratory director/designee signature d. 2025 Chemistry Miscellaneous 1st Event- No Laboratory director/designee signature e. 2025 Hematology/Coagulation 2nd Event - No Laboratory director/designee signature f. 2025 Chemistry Miscellaneous 2nd Event - No Laboratory director /designee signature g. 2025 Hematology/Coagulation 3rd Event - No Laboratory director/designee signature h.2026 Hematology/Coagulation 1st Event - No Laboratory director/designee signature i. 2026 Chemistry Miscellaneous 1st Event-

	No Laboratory director/designee signature Review of American Proficiency User Guide titled "Program Overview" stated: "Test proficiency testing samples according to the provided instructions." Review of American Proficiency Institute (API) instructions stated: "SIGNATURES REQUIRED: For all PT results, an attestation statement must be signed by testing personnel and the laboratory director (or designee) and retained for a minimum of 2 years. An attestation statement can be found either online or in your worksheet packet." In an interview on 07/27/2026 at 11: 30 AM in the break room area two suites down from laboratory, the Technical Consultant (TC) was asked if the attestation forms were signed for the PT events. The TC confirmed the attestation results were not signed for the PT events. This confirmed the findings.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) 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 direct observation, review of Sysmex XP-300 Hematology Analyzer instructions for use, laboratory maintenance records for years 2024/2025/2026, and staff interview, the laboratory failed to document weekly maintenance for 16 of 16 months reviewed. Findings include: During a tour of the laboratory on 07/27/2026 at 10 AM, a Sysmex XP-300 Hematology Analyzer (Serial Number C0116) was observed to be in use. Review of the Sysmex XP-300 instructions for use 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." The laboratory maintenance logs stated, "Weekly - Clean SRV tray." Further review of the laboratory maintenance records revealed the laboratory failed to document performance of the weekly maintenance for the following: November 2024 - Week 2,3,4 December 2024 - Week 1,2,3,4 January 2025 - Week 2,3,4 February, March, April, May, June, July, August, September, October, November, December 2025 - Week 1,2,3,4 March 2026 - Week 2,3,4 April, May 2026 - Week 1,2,3,4 In an interview on 7/27/2026 at 11:40 AM in the break room area, 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.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) (e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) events for years 2024, 2025, and 2026, review of American Proficiency User Guide/API instructions, and confirmed in staff interview, the laboratory failed to review 7 of 9 proficiency testing events. Findings include: Review of the laboratory API proficiency testing events revealed the following: a. 2024 Hematology/Coagulation 3rd Event - No evaluation b.

	2024 Chemistry Miscellaneous 3rd Event - No evaluation c. 2025 Hematology /Coagulation 1st Event- No evaluation d. 2025 Chemistry Miscellaneous 1st Event- No evaluation g. 2025 Hematology/Coagulation 3rd Event - No evaluation h.2026 Hematology/Coagulation 1st Event - No evaluation i. 2026 Chemistry Miscellaneous 1st Event- No evaluation Review of American Proficiency User Guide titled "Program Overview" stated: "Test proficiency testing samples according to the provided instructions." Review of American Proficiency Institute (API) instructions, section Proficiency Testing Performance Evaluation stated: "After reviewing the evaluation reports, complete the information below and retain this form along with the enclosed reports for your records." "Reviewed by (Lab Director/designee):" "Corrective action taken (if indicated):" In an interview on 07/27/2026 at 11:35 AM in the break room area two suites down from laboratory, the Technical Consultant (TC) was asked if evaluation forms were signed for the PT events. The TC confirmed the evaluation forms were not signed for the PT events. This confirmed the findings.