Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	18D0326049	07/09/2026
Name of Provider or Supplier	**Street Address, City, State**	
Jennie Stuart Medical Oncology	1717 High St Suite 1a, Hopkinsville, 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 initiated on 07/09/2026 and concluded on 07/09/2026. 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 year 2024,2025, and 2026, review of Laboratory Policy, and confirmed in staff interview, the laboratory failed to have signed attestation forms for 6 of 6 events. Findings include: Review of the laboratory API Proficiency Testing (PT) events revealed the following: a. 2024 Hematology/Coagulation 2nd Event - No Laboratory director/designee signature b. 2024 Hematology/Coagulation 3rd Event - No Laboratory director /designee signature c. 2025 Hematology/Coagulation 1st Event - No Laboratory director/designee signature d. 2025 Hematology/Coagulation 2nd Event - No Laboratory director/designee signature e. 2025 Hematology/Coagulation 3rd Event - No Laboratory director/designee signature f. 2026 Hematology/Coagulation 1st Event - No Laboratory director/designee signature Review of E.C. Green Cancer Center General Laboratory Manual (director signature review 7/7/2026) titled "Proficiency Testing Policy" stated: "14. The Medical Director shall then sign the attestation statement." In an interview on 07/09/2026 at 12:45 PM in the office area, the

	Laboratory Director (LD) was asked if the attestation forms were signed for the PT events. The LD confirmed the attestation results were not signed for the PT events. This confirmed the findings.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on direct observation, policy review, document review, and confirmed in staff interview, the laboratory director failed to review and approve two of two Performance Verification Studies for a new Hematology analyzer for patient testing, effective October 2025. Findings include: During a laboratory tour on 07/09/2026 at 11:20 PM, a Sysmex XN530 Hematology Analyzer, Serial Number 12411, was observed in operation for testing patient samples. A review of E.C. Green Cancer Center General Laboratory Manual (laboratory director reviewed on 07/07/2026) titled " Laboratory Delegation of Duties", section Laboratory Medical Director, stated: "8. Ensure that the performance specifications for new tests, instruments, and methods introduced to the laboratory have been properly validated or verified prior to being used for patient testing." A review of XN-Series Automated Hematology Systems/XN-L Automated Hematology Analyzers Method Verification Manual revealed: a. Certificate of Certification - Studies Reviewed By: - No Laboratory Director Signature b. Hematology Method Comparison - Accepted by: - No Laboratory Director Signature In an interniew on 07/09/2026 at 12:50 PM in the office area, the Technical Supervisor (TS) was asked for documentation for Laboratory Director review of the two verification studies. The TS confirmed no signatures for the studies. This confirmed the findings.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(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) Proficiency testing events for year 2024, 2025, and 2026, laboratory policy, and confirmed in staff interview, the laboratory failed to evaluate Proficiency testing (PT) events for 2 of 6 testing events. Findings include: Review of API Proficiency Test Events revealed the following: a. 2025 Hematology/Coagulation 1st Event: No Record Review v. 2026 Hematology /Coagulation 1st Event - No Record Review Review of E.C. Green Cancer Center General Laboratory Manual, (director signature review 7/7/2026) titled "Proficiency Testing Policy" stated: "The Oncology Lab Section Supervisor and the Medical Director then review and sign all API survey evaluation reports and indicate when additional actions are necessary." In an interview on 07/09/2026 at 12:45 PM in the office area, the Laboratory Director (LD) was asked for documentation for record review of the 2 events. The LD confirmed the events did not have documentation. This confirmed the findings.