Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	18D0326049	11/29/2021
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
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on staff interview and record review of proficiency testing (PT) results from American Proficiency Institute (API) on 11/29/2021, the laboratory director failed to ensure proficiency test results were reviewed for one (1) out of three (3) events for 2020, and one (1) out of two (2) events for 2021. Findings include: 1. The laboratory scored an eighty percent (80%) for the analyte Hematocrit (Hct) for the API PT 3rd event of 2020 and an eighty percent (80%) for the analyte Hct for API PT 1st Event of 2021. Record review revealed that the laboratory failed to document a corrective action for that event. 2. The testing staff acknowledged in an interview at 10:15AM on 11/29/2021, that the laboratory director failed to establish a system to ensure proficiency testing results were evaluated.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if

	applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on staff interview and record review on 11/29/2021, the laboratory failed to monitor and document the humidity in the laboratory from 11/5/2019 through 11/28 /2021. Findings include: 1. Humidty readings were not recorded from 11/5/2019 through 11/28/2021. 2. Laboratory staff acknowledged in an interview at 11:20AM on 11/29/2021, that the laboratory failed to have a system in place to ensure the humidity was monitored and documented daily, using the manufacturer's recommended range for the Horbida Complete Blood Cell (CBC) Count analyzer.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) results from the American Proficiency Institute (API) and staff interview on 11/29/2021, it was determined the laboratory director failed to establish a corrective action plan to follow when testing analytes were found to be unsatisfactory or unsuccessful. Findings include: 1. Review of proficiency testing results revealed the laboratory received a score of eighty percent (80%) for the analyte Hematocrit (Hct) for the 3rd PT event of 2020, and score of eighty percent (80%) for the analyte Hct for the 1st PT event of 2021. There was no evidence of corrective action performed. 2. Testing Personnel acknowledged in an interview at 10:15AM on 11/29/2021, the laboratory failed to have an established policy to ensure corrective action was performed and documented when testing analytes were found to be unsatisfactory.