Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0969939	03/18/2025
Name of Provider or Supplier	**Street Address, City, State**	
Eurofins Pharma Bioanalytics Services	15 Research Park Dr, Saint Charles, MO	

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
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 2023, 2024 and 2025 proficiency testing (PT) records and interview with the technical supervisor (TS), the laboratory director failed to ensure appropriate staff evaluated PT results in 2023, 2024 and 2025. Findings: 1. Review of GCL 529 analyte EPO results revealed event July 2023 and December 2023 showed no review by appropriate staff. 2. Review of GCL 529 analyte EPO results revealed event January 2024 and December 2024 showed no review by appropriate staff. 3. Review of GCL 529 analyte EPO results revealed event February 2025 showed no review by appropriate staff. 4. Interview with TS on March 18, 2025 at 2:00 PM confirmed the laboratory director failed to ensure appropriate staff evaluated PT results.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) (b)(9) Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individuals performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with the technical supervisor

	(TS), the TS failed to evaluate and document competency/performance for one of one testing personnel (TP) at least annually during 2024. Findings: 1. Review of personnel records showed the TS did not evaluate competency/performance for TP #1 performing patient testing during 2024. 2. Interview with the quality assurance director on March 18, 2026 at 2:00 PM, confirmed competency/performance evaluations were not conducted at least annually in 2024.