

|                                                                                                                            |                                                                                  |                                                     |
|----------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|-----------------------------------------------------|
| <b>Statement of Deficiencies</b>                                                                                           | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>26D0969939       | <b>(X3) Date Survey Completed</b><br><br>07/18/2023 |
| <b>Name of Provider or Supplier</b><br><br>Eurofins Pharma Bioanalytics Services                                           | <b>Street Address, City, State</b><br><br>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. |                                                                                  |                                                     |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|---------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>D6128</b>              | <p><b>TECHNICAL SUPERVISOR RESPONSIBILITIES</b><br/>CFR(s): 493.1451(b)(9)</p> <p>The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of personnel records and interview with the quality assurance director, the technical supervisor (TS) failed to evaluate and document competency /performance for one of one testing personnel (TP) at least annually during 2022.<br/>Findings: 1. Review of personnel records showed the TS did not evaluate competency /performance for TP #1 performing patient testing during 2022. 2. Interview with the quality assurance director on July 18, 2023 at 10:00 AM, confirmed competency /performance evaluations were not conducted at least annually in 2022.</p> |