Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0969939	12/04/2018
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
D0000	An allegation investigation (intake MO00148778) was conducted in conjunction with a routine CLIA recertification survey on 12/04/18. The allegation was found to be unsubstantiated. Findings related to the recertification survey are noted below.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of laboratory procedure manuals and interview with technical supervisor #2, the procedure manuals failed to include all applicable requirements to the test procedures. Findings: 1. Review of the procedure manual for the "electrochemiluminescence immunoassay to detect antibodies against AMG 145 in

	human serum" (GCL-277) revealed the manual did not include reference intervals (normal values) and criteria for specimen acceptability and rejection. 2. Review of the procedure manual for the "ELISA for the determination of anti-EPO antibodies in human serum" (GCL-529) revealed the manual did not include reference intervals (normal values) and criteria for specimen acceptability and rejection. 3. On interview December 4, 2018 at 1:20 PM, the technical supervisor said the procedure manuals did not include normal values and criteria for specimen acceptability and rejection. Interview confirmed the procedure manual did not include all requirements to the test procedures.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the "electrochemiluminescence immunoassay to detect antibodies against AMG 145 in human serum (GCL-277)" and the "proficiency testing" procedure and interview with technical supervisor # 2 on December 4, 2018 at 1:20 PM confirmed, the laboratory failed to have documentation to show the current laboratory director approved, signed and dated the procedures.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on the lack of instrument comparison activities for two MSD 600 plate readers during 2017 and to date December 4, 2018 and interview with technical supervisor #1, the laboratory failed to evaluate and define a relationship between test results using the different instruments for the same test at least twice a year. Findings: 1. No documentation was available to show the laboratory evaluated and defined a relationship between two MSD 600 plate readers used for the same test during 2017 and to date December 4, 2018. 2. Interview with technical supervisor #1 on December 4, 2018 at 1:30 PM confirmed the laboratory failed to perform instrument comparisons for the MSD 600 plate readers at least twice a year.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or

	continuing education to improve skills. This STANDARD is not met as evidenced by: Based on review of the procedure manual, personnel documentation and interview with the technical supervisors#1, #2, the laboratory director failed to establish and perform 2 of 2 competency evaluations for 2017 and to date December 4, 2018. Findings: 1. Review of the procedure manual showed the laboratory director failed to ensure that polices and procedures were established to monitor competencies for personnel. 2. Review of 2017, 2018 employee competencies revealed the laboratory director failed to perform competencies for 2 of 2 competencies for technical and general supervisors. 3. Interview with the technical supervisors #1, #2 on December 4, 2018 at 2:00PM confirmed the laboratory director failed to perform competencies for 2017 and to date December 4, 2018 to assure that personnel are competent.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of personnel documentation and interview with the technical supervisors #1, #2, the technical supervisors failed to perform 3 of 3 competency evaluations for 2017 and to date December 4, 2018. Findings: 1. Review of 2017, 2018 employee competencies revealed the technical supervisors failed to perform competencies for 3 of 3 testing personnel of high complexity testing. 2. Interview with the technical supervisors #1, #2 on December 4, 2018 at 1:30PM confirmed the technical supervisors failed to perform competencies for 2017 and to date December 4, 2018 to assure that personnel are competent.