Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D2159950	05/14/2019
Name of Provider or Supplier	**Street Address, City, State**	
Eurofins Donor & Product Testing, Inc	615 Elsinore Place, Suite 215, Cincinnati, OH	

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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) 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. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on record review and an interview with the Senior Quality Assurance Officer (SQAO), the laboratory failed to correctly document the handling, preparation, processing, examination and each step in the testing and reporting of proficiency testing (PT) results on 3 of 3 attestation pages. All patients tested with the PT events below have the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's College of American Pathologist (CAP), 2019 NAT-A, VR3-A and G-A attestation pages found the technical supervisor's signature on the "Director (or Designee) (signature required)" line. 2. The surveyor requested the designee letter from the Laboratory Director, from the SQAO. 6. The SQAO confirmed a designation letter was in place, however it did not list the Technical Supervisor as a designee. The interviews occurred on 05/14/2019 at 11:30 AM.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12)

	The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on record review and an interview with the Senior Director of Quality Assurance (SDQA), the Laboratory Director failed to ensure prior to testing patients' specimens, the General Supervisor (GS), had received the appropriate training and had demonstrated they could perform all testing operations reliably to provide and report accurate results for the high complexity procedures performed. This deficient practice has the potential to affect all patients between January 2, 2019 through May 14 2019. Findings Include: 1. Review of the laboratory's policy and procedure titled "VGN-016 Competency Evaluations", provided on the date of the inspection found the following statement: 3.2.5. "The competence of supervisory staff shall be evaluated through periodic performance reviews that include, but are not limited to an assessment of the ability of the supervisory to fulfill the responsibilities appropriate for their job description and: compliance with policies and procedures; 3.2.5.2. communication, including bringing problems and non-conformities to the attention of laboratory management; leadership and problem-solving capabilities; allocation of resources; and personnel management." 2. The Surveyor requested the laboratory's GS training and competency assessment documentation from the SDQA. The SDQA provided training documents for *GMP from another location. The SDQA confirmed the laboratory did not establish and follow an initial training and competency assessment policy and procedure for the GS per location and per job description, did not train and assess the competency of the GS prior to the high complexity microbiology, immunology and hematology tests performed and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 05/14/2019 at 11:10 AM. *GMP = Document title on training records. No key provided.