

Abstract

As our society evolves, all of the scientific fields evolve as well. Thanks to this phenomenon, the demands on peoples' work, methods and techniques increase. New drugs and new diagnostic procedures are developed constantly. Consequently, there exists a need to authenticate all the procedures to ensure that everything works as it is supposed to and that the measurements meet the requirements. Therefore, every procedure has to be validated or verified. Validation is also one of the requirements of ISO's international standards.

This bachelor thesis' topics were validations and verifications of diagnostic procedures in oncohematologic laboratory. The theoretical part is dedicated to defining the basic terms related to molecular genetics, the immune system and to work in clinical laboratory. The experimental part describes the use of validation in practice as performed in the accredited laboratory at the Institute of Hematology and Blood Transfusion.

The main objectives of the thesis were validations of kits HLA – SuBiTo, PowerPlex® CS7 System and validation of biallelic sequence polymorphism G42863. Each of the objectives was specific and was conducted with a different purpose. As a result, it was confirmed that validation and verification is integral element of work in clinical laboratories and its use is very diverse.

Key Words

Allele, deoxyribonucleic acid, major histocompatibility complex, chimerism, polymerase chain reaction, sequencing, validation, verification