On metrological aspects of measurement on the basis of PCR

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Polymerase chain reaction (PCR) is a method used in molecular biology, which based ona significant increase of the concentration of small pieces of Deoxyribonucleic Acid (DNA) in biological material by amplification to a level at which an accurate detection can be made. PCR is widely used in biological and medical research for gene cloning, diagnostics of mutations, allocation of new gene sequencing, determination of genetically modified organisms. PCR includes 20-35 cycles, each of which consists of three stages (denaturation, annealing, elongation).

Standardization, quality assurance and quality control are important issues in any routine diagnostic testing, as well as PCR. The control of the measurements quality is carried out according the standards [1]. Different fluorescent dye labels are used for checking. At the same time the software provides accurate fixation of the threshold records and data of control samples: internal, examined, negative and positive. Negative control is required to check the components of reaction for possible contamination and quality of amplification process. Positive control enables the researcher to be sure in compliance to threshold values and significance of obtained data. It is also used for control of amplification quality and RNA/DNA sequencing. Special PCR controls are markers of the length of strands of DNA, control of the background, standarts and calibrators (for quantitative analysis mostly), internal control (is often used to rule out failure of amplification in cases where the target sequence is not detected) and control for DNA extraction (negative control).

Standardization and quality control are mandatory in ensuring that advances achieved through innovative methodologies will have maximal benefit in research and its clinical implementation to improvethe outcome of patient's treatment.

[1] ISO/TS 17822-1:2014 (en) In vitro diagnostic test systems — Qualitative nucleic acid-based in vitro examination procedures for detection and identification of microbial pathogens — Part 1: General requirements, terms and and definitions.