Current Evaluation of Biochips in KFDA

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Biochip is defined that cell or biological molecules is arrayed on a solid slide in a high-density. The development of biochip technology is closely connected with the transition of molecular biology from its classical phase into its post-genomic era. Biochips have been emerged as indispensable research tools for gene expression profiling and mutation analysis. New classification of cancer subtypes, dissecting the yeast metabolism and large-scale genotyping of human single nucleotide polymorphisms are important results being obtained with this technique. Realizing the microsphere-based massively parallel signature sequencing techniques as fluid microarrays, building new types of protein arrays and constructing miniaturized flow-through systems, which can potentially take this technology from the research bench into industrial, clinical and other routine applications, exemplify the intense developments that are now ongoing in these fields of genomics or proteomics. And this technology can be applied in diagnosis of disease, prognosis, monitoring of drug responses, assessment of sensitivity to drug and screening of drug candidates. Two oligonucleotide biochip products are approved as *in vitro* diagnostics for HPV subtyping in Korea, many other biochip products are under investigation and are being prepared for regulatory submission. However, there have been no international guidelines to evaluate its efficacy, safety and quality. New diagnostics using '-omics' technology require new aspects for evaluation. We need to establish a new standard for evaluation on these products based on available scientific knowledge. This is a key issue for new diagnostics in post-genomic era.

So Here we introduce the interim guidelines for biochip evaluation prepared by KFDA , which especially focused on manufacture and quality control.