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Development of transcriptomic biomarkers for precision medicine: Specimens, standards, and signatures

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The future of precision medicine depends on the development of molecular biomarkers that provide more precise diagnosis and patient stratification, detect early disease, elucidate risk of disease, predict disease outcome, response to therapy, and therapeutic toxicities, and permit monitoring of therapeutic management. Currently, the high costs, long timeframes and low success rates of biomarker development represent a significant impediment to medical progress. Rigorous adherence to standards that are consistent and consistently applied across the development process is required to achieve the illusive reproducibility lacking in the process now. Of primary importance in transcriptomics is the quality of the starting materials – the bio-specimens used for analysis. Development of complex biomarkers like those from transcriptomics approaches cannot be achieved without the assurance of the provenance of the specimens being analyzed, their associated data and content for use. The pre-analytical variations to which bio-specimens for transcriptomics are subjected can and do dramatically alter their transcriptome. Bio-specimens for transcriptomic analysis must be systematically collected, processed and stabilized according to standards that render the samples fit for the analytic approach and platform. For surgical specimens, intraoperative variables in the forms of drugs and warm ischemia time may contribute further to data variation in transcriptomic analysis. The biomarker qualification program of the Center for Drug Evaluation and Research at the Food and Drug Administration emphasizes the need to document the bio-specimen quality of diagnostic biomarkers used for drug development and the Center for Devices and Radiologic Health has similar requirements for approval of diagnostic devices. It is imperative that the entire diagnostics development community address the need for standardized processes and fit-for-purpose bio-specimens to accelerate the delivery of accurate, reproducible, clinically relevant molecular diagnostics for precision medicine, but nowhere is this more important than in transcriptomics.

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