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Development of laboratory standards for next-generation sequencing as a clinical tool

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Recently, there has been a remarkable growth in the number of laboratories offering clinical tests using next generation sequencing (NGS) technologies as well as an expansion in the volume and types of NGS clinical tests. Currently, all NGS based clinical tests are considered to be laboratory developed tests that must be conducted under Clinical Laboratories Improvement Act (CLIA) regulations. The College of American Pathologists (CAP) has deemed status under CMS to accredit laboratories for CAP/CLIA certification and importantly, CAP's standards are considered to be of the highest level in the field. In 2012, CAP published its first set of standards - the CAP Checklist for NGS- that labs seeking accreditation and offering NGS-based test need to follow. This session will cover the CAP NGS Work Group's process and methodologies of development of standards for both the wet bench (DNA, RNA sample preparation, sequence generation) and the dry bench (bioinformatics analysis) workflows of NGS tests that include requirements for documentation, validation, data storage, quality assurance, reporting and interpretation. Dr. Aziz will also discuss CAP's standard for non-invasive pre-natal screening and proficiency tests currently under development

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