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MANAGEMENT AND QUALITY ASSURANCE IN A MOLECULAR DIAGNOSTIC LABORATORY (ONCOLOGY): SCOPE AND CHALLENGES

Rekha Chaubey
All India Institute of Medical Sciences, India

Molecular diagnostic testing has an ever expanding role in clinical laboratory assessment. The frequently used molecular techniques in a modern molecular diagnostic lab for oncology includes nucleic acid isolation, gel electrophoresis, different types of PCR, RT-PCR and real time PCR, microarray, FISH, sequencing and restriction enzyme analysis. Recently, NGS is also becoming an indispensable part of a molecular lab. A false genetic test results can have serious repercussions for patients and their families. Presently, compared with other laboratory disciplines, the quality control (QC) practices for molecular diagnostic tests have fallen behind. QC in the molecular diagnostic lab includes QC at different steps: assay validation, pre analytical, analytical and post analytical. QC for molecular diagnostic tests encounters the following challenges: new and rapidly evolving technologies, high expectations of accuracy for once in a lifetime genetic tests, lack of quality control materials, lack of quantitative test system outputs and the almost daily appearance of new genetic test targets. In the face of such issues, clinical laboratories are struggling to develop appropriate quality assurance programs for the molecular diagnostic tests they conduct. The Clinical Laboratory Improvement Amendments (CLIA) addresses the issues related to laboratory quality. FDA also plays a role in regulating molecular diagnostics, including the authority to regulate laboratory developed tests (LDT). Due to uniquely difficult challenges, good QC practices for molecular diagnostics have taken longer to evolve than other laboratory disciplines. However, by continuing to work together, the *in vitro* diagnostics (IVD) industry and the laboratory community can improve molecular QC practices and overcome challenges to promote good medicine and avoid burdensome legislation.

drrekhacgupta@gmil.com