Services of the ACTION UNC Molecular Reference Laboratory

The Alliance for Clinical Trials in Oncology Molecular Reference Laboratory at University of North Carolina provides a range of molecular assays for use in clinical trials (prospective or retrospective).

For example, DNA and RNA or microRNA-based tests can be developed to:
1. Understand tumor biology and response to intervention,
2. Develop test panels of medical importance,
3. Establish indications for testing and define intended use of a novel test in patient management (e.g. for diagnosis, classification of disease, prognosis, predicting response to specific intervention, confirmation, screening, prevention).

Services Include:
1. Prepare a tissue section or a cytology slide; obtain pathologist estimate of the percentage of lesional cells (e.g. tumor/stroma/necrosis). Enrich for tumor, if indicated.
2. Design and apply a molecular test, such as NextGen Sequencing, microarray RNA expression profile, SNP chip for gene copy number, or 384-well Q-rtPCR panel.
3. Devise quality assurance measures (e.g. specimen collection and handling, pathologist vetting of input tissue, acceptance limits on spiked/endogenous/exogenous controls).
4. Prepare spreadsheets of results for statistical analysis and clinicopathologic correlation by the Alliance for Clinical Trials in Oncology Statistical Center.
5. Ready the test system for transition to routine patient care, once it is vetted as being analytically sound and clinically useful by a CLIA-certified testing laboratory.

Specimen Requirements: Formalin-fixed paraffin-embedded tissue, fresh tissue (about the size of a baby green pea) stabilized upon collection (e.g. freeze at -80°C, immerse in RNAlater), blood, marrow, fine needle aspirate, or DNA/RNA from pathologist-vetted specimens.

Protocols and costs: Study investigators meet with Reference Lab personnel to establish a protocol for testing, including pre- and post-analytic phases, and to develop a standard operating procedure including quality assurance parameters that are suited to the specimen type and to intended use of results. Charges are per specimen, with a prorated charge for specimens not tested by virtue of exceeding pre-defined quality limits.

Technologies and instrument platforms that simultaneously measure multiple human and/or pathogen DNAs, RNAs, or microRNAs:
1. DNA sequencing (MiSeq, HiSeq, Ion Torrent PGM & Proton, Sanger, or pyrosequencing).
2. RNAseq, mRNA & microRNA profiles on Agilent, Affymetrix, Nanostring, Exiqon, or Roche systems.
3. Gene copy number variation (loss, gain, loss of heterozygosity, selected rearrangements) on DNA using Agilent, Affymetrix 6.0 SNP chip, Nanostring, or Roche LC480 platforms.

CLIA-certified, clinical-grade testing: Many assays can be provided in an analytically validated form, thus permitting consented patients to be managed based on test results (e.g. qualify for enrollment, assign study arm, select dose). Before use in routine patient care, assays must be vetted as analytically and clinically valid by UNC Hospitals CLIA-certified, CAP-accredited clinical laboratories or equivalent clinical facility.


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