



ADVANCED TECHNOLOGY

Integrated Analysis

Geneunity's advanced technologies support an integrated molecular and biomarker approach to evaluate disease processes. Geneunity offers technical and interpretive expertise in oncology, infectious diseases, medical genetics and clinical pathology. In addition our laboratories have a wide range of characterized clinical specimens available for development and validation of biomarker assays, new diagnostic reagents and IVD kit testing. Board certified molecular, cytogenetic and hematopathology experts are available to assist in the development of study protocols.

Molecular Imaging

Applying *in-vivo* quantitative imaging in clinical trials is recognized as a powerful window into drug effectiveness and provides strong safety and efficacy evidence at a molecular level.

Secure Information

Secure and controlled information is vital in clinical trials. At Geneunity, our laboratory information system provides secure specimen accessioning, data archival and customized reporting capabilities. Our information technology and software design services also include sophisticated data and facility security served by a dedicated backup power generation system.

Quality

Geneunity's quality expertise benefits from over 18 years of experience as a specialty testing laboratory. The quality assurance department follows GLP guidelines and ensures compliance to SOPs, GCP and GDP. Geneunity is certified by the Clinical Laboratory Improvement Amendments (CLIA) ACT 1988 for high complexity testing and accredited by the College of American Pathologists (CAP).

Technology Platforms

Our platforms are available for custom assay design and validation, clinical research and IVD manufacturer assay validation.

- Flow Cytometry: 5 color Beckman Coulter FC500[®] Cytometers
- IHC: Dako Autostainer, Ventana Benchmark XT and Zeiss MicroImaging
- FISH: Olympus Bioview imaging system, Metafer 4 Imaging system and CellTracks[®] Analyzer
- Molecular: ABI PRISM[®] 7900, 7500, 3100 and 310, Roche Taqman48, COBAS Ampliprep, Luminex[®] 100[™], Gen-Probe TIGRIS[®] / DTS[™], Digene HC Rapid Capture, Nanosphere Verigene[®]
- Siemens PET/CT scanner
- Clinical: Siemens: Immulite 2000, Centaur Immunoassay, Advia 1650 Advia 2120, Advia 120S

Molecular and Cellular Assays

Geneunity offers a comprehensive array of tests and services. Services include custom assay design, protocol optimization and validation. The following list is representative of our current assays and platforms.

Biomarker Analysis

- Cytogenetics and chromosomal analysis
- Flow Cytometry and Immunophenotyping
- Immunohistochemistry (IHC), protein expression, distribution and localization of biomarkers
- Immunomagnetic cell capture and fluorescence for circulating tumor cell detection (CellSearch[™])
- Multiplex quantitative cytokine and cell signaling detection

Molecular Analysis

- Allelic load testing e.g JAK2
- Capillary gel electrophoresis, DNA sequencing, and fluorescent DNA fragment analysis
- Cell proliferation, DNA cell cycle analysis and tunel apoptosis detection
- Fluorescence *in situ* hybridization for specific chromosomal rearrangements
- Genome-wide gene expression microarrays and exon scanning
- Genotype analysis e.g HCV, HPV, UGT1A1, CYP2C9 & VKORC1
- Multiplex PCR and microarray analysis, e.g. Luminex bead arrays
- Qualitative and Quantitative Polymerase Chain reaction (PCR) and Real Time PCR, e.g JAK2, HPV, BCR/ABL, PML/RARA
- Single Nucleotide Polymorphism (SNP) / point mutation detection
- Transcription Medicated Amplification (TMA) e.g. C.trachomatis, N.Gonorrhoeae
- Viral load testing e.g. HCV, HIV, HBV
- PET / CT imaging, *in vivo* molecular localization
- Short Tandem Repeat (STR) genetic identity

Clinical Pathology

- Allergy blood testing
- Biochemistry
- Hematology
- Immunoassay
- Serum protein electrophoresis
- Urinalysis