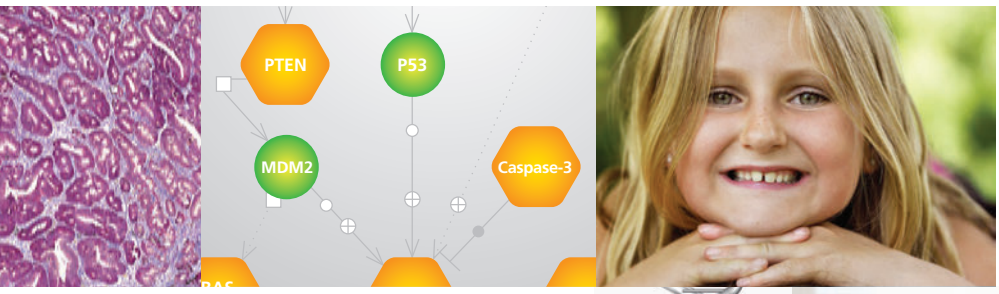
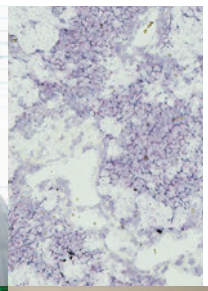
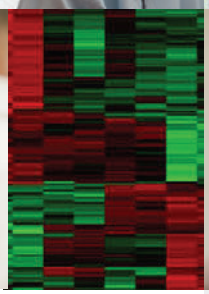
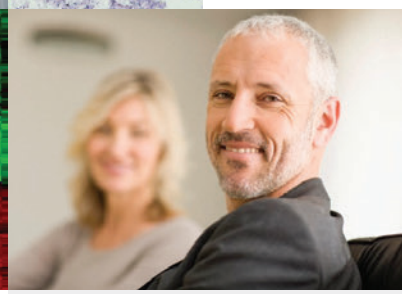
affymetrix
Biology for a better world

Solutions for **Personalized Medicine**









The Promise of Personalized Medicine

Imagine a world where we can benefit from understanding our own DNA, for example, knowing if we have inherited diseases from our parents, if we possess certain genetic risk factors, and what our response to certain medications may be. Imagine a world where we can understand disease at a molecular level, detect it earlier, and give each individual personalized effective treatment. Imagine if we could prevent disease altogether and focus on our wellness. This is the promise of personalized medicine, made possible, in part, by advances in genomics.

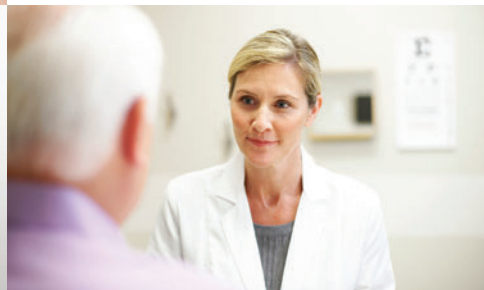
We are now living in a generation best described as the "Genome Generation," during which advances in genomics and genetics have the potential to revolutionize the way we practice medicine. Genetic and genomic information by large-scale sequencing and genetic projects is readily accessible to scientists, who analyze it and try to understand how our genes and our environment influence disease. They can use this information to create powerful new diagnostic tests to accurately detect diseases and develop safer, more potent drugs to effectively treat them.

However, before this becomes a reality, there is a great deal of research that still needs to be done to identify the genetic variations and environmental factors to correlate with phenotype and physiology, and thus contribute to an individual's unique response to disease and treatment. The detailed knowledge of our genome and its interaction with the environment will be key in making personalized medicine a reality, allowing us to:

- Make more informed medical decisions
- Achieve higher probability of successful treatment resulting in better targeted therapies
- Reduce probability of adverse drug events
- Focus on wellness through disease prevention
- Manage our lifestyle through individualized disease risk predictions
- Accomplish earlier disease detection and intervention
- Reduce healthcare costs







From Bedside to Bench and Back Again

Complex human diseases like cancer, obesity, diabetes, and cardiovascular disease are thought to be caused by the regulation of multiple genes and their interaction with the environment. Each person's genomic, clinical, and environmental factors are unique, and their manifestations of diseases will also be unique. Translational research through to translational medicine is focused on taking the scientific discoveries from the research or clinical "bench" to uncovering the clinical applications in order to improve outcomes at "the bedside" and increase wellness.

From Bedside to Bench and Back Again

For over 20 years, Affymetrix has been making research tools to interrogate the genome so that researchers can better understand the genetic basis of disease, discover diagnostic therapeutic biomarkers, and develop prognostic and clinical tests. These tools enable research on a variety of genomic parameters, including gene expression, gene regulation (miRNA, lncRNAs, etc.), DNA copy number, SNPs, and chromosomal aberrations, which provide us with a better understanding of disease at the molecular level.

Clinical researchers can translate this knowledge into clinical tools that can help us make accurate diagnosis, predict risk, onset, and progression of disease, and make individualized treatment decisions.

With over 26,000 publications and the first FDA-cleared test for drug metabolism in partnership with Roche, FDA-cleared tissue of origin test for cancer in partnership with Pathwork Diagnostics, and the first FDA-cleared microarray instrument system, Affymetrix solutions are used in every stage of understanding disease and developing clinical tools. From discovery to the clinic, Affymetrix is your partner on the road to personalized medicine.

	Understanding Complex Disease	Biomarker Discovery and Validation	Cytogenetics and Inherited Diseases	Developing Molecular Diagnostics	Pharmacogenomics
Genotyping Solutions*					
Axiom® Biobank Genotyping Arrays	√	√			√
Axiom® Exome Array	√	√			√
Axiom® Genotyping Solution	√	√			√
Axiom® miRNA Target Site Genotyping Arrays	√				
DMET™ Plus Premier Pack					√
Gene Expression Solutions*					
Almac Xcel™ Array	√	√			√
GeneChip® Human Gene ST Arrays	√	√			√
GeneChip® Human Genome U133 Plus 2.0 Array	√	√			√
GeneChip® Human Transcriptome	√	√			√
GeneChip® miRNA Arrays	√	√			
GeneChip PrimeView® Human Gene Expression Array	√	√			√
QuantiGene® Plex Assays	√	√			√
QuantiGene® ViewRNA Assays	√	√			√
Clinical Application Toolkit					
Affymetrix® Gene Profiling Array cGMP U133 P2 (RUO)		√			
Affymetrix® Gene Profiling Reagents (FDA-cleared)		√			
GeneChip® System 3000Dx v.2 (FDA-cleared)		√			
Scientific Services*					
OncoScan™ FFPE 2.0 Express Services		√	√		
Molecular Cytogenetics*					
CytoScan® Cytogenetics HD Solution		√	√	√††	
Powered By Affymetrix Partner Tests†					
Tests in development					
Almac Diagnostics – multiple tests in development				√	
Signature Diagnostics – Detector C (colorectal cancer)				√	
Veracyte® – Afirma® Thyroid FNA Analysis				√	
FDA cleared					
Pathwork® Tissue of Origin Test				√	
IVD CE marked					
Skyline Diagnostics AMLprofiler™ (acute myeloid leukemia)				√	

†The above list is a partial selection of tests from many of our PbA partners; please contact us for a complete list.

††CytoScan® Dx Solution is being developed by Affymetrix.

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Understanding Complex Disease – Ethnicity Matters

Genome-wide association studies (GWAS) are a standard approach to finding genetic variations associated with common or complex diseases such as asthma, cancer, diabetes, heart disease, and mental illnesses. To date, most GWAS studies have been conducted using populations of European descent; however, replicating GWAS findings in non-European populations is challenging. This suggests that genetic differences between ethnicities may account for differences in disease association and prevalence. Therefore, a more focused approach of population-specific genomic diversity must be taken into account for more reliable GWAS studies.

Affymetrix has developed the Axiom® Genotyping Solution*, a microarray-based platform, for GWAS studies in European, African, Asian, and other populations and is committed to working with scientists to develop further population-optimized arrays.

One size does not fit all – choose population-optimized genotyping
Choose from a portfolio of population-optimized, pre-designed Axiom® Arrays for African, Asian, and other populations.
It is no longer necessary to settle for a European or generic array design to study genetically complex or admixed populations.
Population-optimized designs are available for genome-wide association, replication, and population genetics studies.

Optimized pre-designed arrays offer increased power in diverse populations and applications.

Target populations	Common variant studies	Common and rare variant studies	Common and rare variant studies
Northern Europe		Axiom® CEU	Axiom® EUR
Asia	Axiom® CHB	Axiom® ASI	Axiom® EAS
African		Axiom® PanAFR	Axiom® AFR
Southern European and Latin American			Axiom® LAT
	MAF >5%	**MAF >2.5%**	**MAF >1%**

Finding variations that matter: more discovery, more power, your way
Finding variations that cause disease is critical for developing personalized medicine solutions, but narrowing down on the variations that matter—the variations with functional consequences—can be difficult. One way to reduce the search is to focus on the exome. The exome, comprising the protein coding regions and only 1.5% of the genome, is the site of over 85% of causal mutations in single-gene disorders. In genetic studies of common or complex disorders, the exome is implicated in approximately 60% of disease susceptibility regions discovered to date. Focusing on variants that alter protein sequence—non-synonymous mutations and small insertions/deletions (indels)—further increases a researcher's chances of finding a variant that causes disease. A recent study, Mills, *et al,*[1] hypothesized that small indel variations are likely to be key factors underlying inherited human traits and diseases.

Axiom® Exome Genotyping Arrays* offer the highest coverage of novel, putatively functional coding variants available.

More discovery –
Identify more novel disease-relevant associations with the most coding SNPs available today and unique, innovative indel content at the cutting edge of human genetics.
- >300,000 exonic SNPs
- >30,000 single-base and complex indels

More power –
Identify the strongest candidate causal variants for high-value functional studies. Rare variants cannot be efficiently tagged or imputed. It is crucial that as many rare variants as possible are physically interrogated on the array.

Your way –
Add up to 100,000 of your own *de novo* SNPs of interest from NGS or prior GWAS to create your exome array.

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High-valued genotyping for large sample cohorts to explore genetics of complex diseases

Axiom® Biobank Genotyping Arrays are a high-powered solution for affordable genotyping of large sample collections such as those screened at biobanks, genome centers, and core labs. The arrays include a genome-wide association study (GWAS) panel of markers for genome-wide coverage in major ethnic groups, rare coding SNPs and indels for exome analysis, pharmacogenomic markers, eQTLs, and newly discovered loss-of-function variants, including sequence insertions and deletions from recent exome sequencing initiatives.

Explore gene regulation at the DNA level

Genetic variants affecting miRNA pathways have been implicated in diseases such as cancer, neurological disorders, cardiovascular disease, and type 2 diabetes. Axiom® miRNA Target Site Genotyping Arrays offer the only comprehensive tool for genome-wide evaluation of miRNA target sites that influence translation. Over 80% of the 238,000 SNPs and indels on the array are not available on any other commercially available genotyping arrays.

Your study, your content, your way

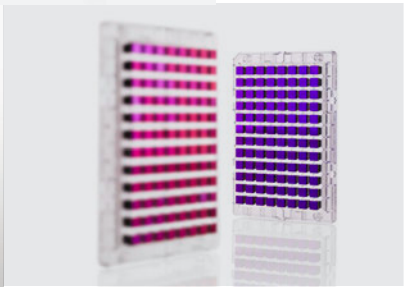
A customized array, the Axiom® myDesign™ Array*, allows you to choose the most biologically-relevant content for your own research. You can create your own genotyping panel with the most relevant markers for your GWAS, replication, fine mapping, and candidate gene studies. Each variant is extensively validated in a large number of biological samples to ensure that: (1) the SNP is not due to sequencing error, (2) the minor allele can be reliably detected, and (3) the SNP has undergone rigorous functional testing to ensure highly reliable and reproducible performance.

The Axiom® Genomic Database* is at your disposal to select from millions of wet-lab validated and annotated variants from international discovery projects. Markers in this database are fully annotated to enable designs from 1,500 to 2.6 million markers for targeted genotyping of genes, pathways, regions, diseases, or for whole-genome applications.

Use the Axiom® Design Center for easy marker selection to create the microarrays to suit your study:

- >11 million common and rare SNPs and indels
- Confirmed polymorphisms with no false positives
- > 95% "marker success rate" on Axiom myDesign Arrays*

Affymetrix® Axiom® Arrays* deliver more genotype-verified information in less time, maximizing the effectiveness of genotyping studies at every stage, from discovery to validation. Affymetrix is committed to working with scientists to develop further population-optimized arrays.



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Tools for Biomarker Discovery, Validation, and Beyond

The first step towards translational research, understanding a disease at the molecular level and building diagnostic and clinical applications is the generation and validation of suitable biomarkers: DNA or RNA molecules that can be measured easily and serve as indicators of normal or pathogenic processes and/or indicators of responses to therapeutics and other interventions. Several DNA or RNA molecules can serve as disease biomarkers, according to the FDA draft guidance for industry.[2]

DNA
Single nucleotide polymorphisms (SNPs)
Variability of short sequence repeats
Haplotypes
DNA modifications
Deletions or insertions of (a) single nucleotide(s)
Copy number variations
Cytogenetic rearrangements

RNA
RNA sequences
RNA expression levels
RNA processing, e.g., splicing and editing
microRNA levels

Affymetrix provides a vast portfolio of tools that allow scientists to detect and validate biomarkers for particular diseases. These tools provide the flexibility to interrogate RNA or DNA molecules, 10 or even 10,000 samples, entire genomes or individual molecules, and empower scientists in every step of the biomarker discovery, qualification, and validation processes. Affymetrix has developed a series of specific tools for cancer biomarker discovery and validation:

DNA biomarkers for cancer

Affymetrix® OncoScan™ FFPE Express 2.0 Services* provides high-resolution, cancer-relevant, whole-genome coverage that explores the link between copy number amplification and disease progression and enables biomarker signature discovery. Optimized for handling formalin-fixed paraffin-embedded (FFPE) samples, OncoScan™ Services* provides researchers with a window into the vast number of archival tumor samples waiting to be explored.

"Some of our experiments have samples that are up to 15 years old, and we're still able to get very clean copy number data from very little DNA, as little as 75 ng."

Joshua Schiffman, MD, University of Utah

Affymetrix also offers the CytoScan® HD technology*, which supports cytogenetics research. With whole-genome coverage and the highest density of SNPs that can be detected by genotypic methods, cancer researchers can now explore the genetics of hematological malignancies to discover diagnostic and prognostic signatures. Only a whole-genome SNP microarray can provide affordable, highly reproducible, high-resolution copy number detection, high-resolution loss of heterozygosity (LOH) visualization, and the ability to detect low-level mosaics from mixed clonal populations.

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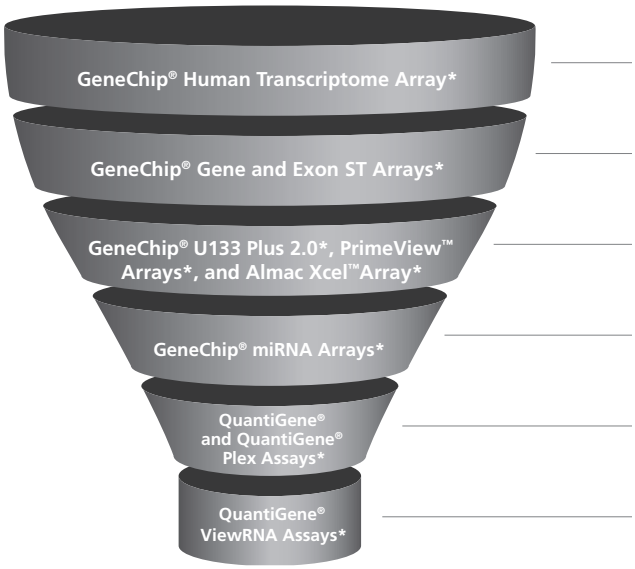
RNA biomarkers for cancer

Affymetrix has created a number of products to allow interrogation of gene regulation, gene expression on multiple levels and provide solutions for gene expression, mRNA quantitation, alternative splicing detection, RNAi screening, and single-cell resolution of *in situ* hybridization.



Multiple views of the transcriptome

Broadest view of the human transcriptome

The GeneChip® Human Transcriptome Array* developed by Xu, *et al,*[3] using Affymetrix® Array technology*, provides a robust platform that can sensitively:

- measure differential gene expression
- detect alternative splicing
- detect low abundance transcripts and non-coding RNAs

With sensitivity equal to 400 million mapped reads of RNA-Sequencing (RNA-Seq), the human transcriptome array can be used to screen the thousands of samples needed to validate the initial RNA-Seq findings.

Look beyond the 3′ end of the gene with whole-transcript expression arrays

- GeneChip® Exon* and Gene ST Arrays* enable you to measure gene expression, gene regulation by long intergenic non-coding (linc) RNA, and detect alternative splicing events, which are recognized by scientists as a major source of proteome diversity and highly relevant to disease status and therapy selection. Gene ST Arrays* provide comprehensive coverage of annotated genes while Exon 1.0 ST Arrays* include additional predicted genes for novel detection of genetic variation. Whole-transcript expression arrays offer the greatest single-array coverage of the transcriptome.
- Ability to detect transcripts not found with other microarray platforms
- Multiple levels of analysis: gene, exon, alternative splicing, regulation

Confidently detect gene expression changes with GeneChip® 3′ IVT Arrays*

You can build on the knowledge of thousands of publications to find signature groups of genes and identify promising biomarkers with the GeneChip® 3′ IVT Arrays*. Affymetrix now offers the expression Clinical Toolkit, which includes the GeneChip® System 3000Dx v.2 for IVD use, the first FDA IVD CE-marked Gene Profiling Reagents, and the Gene Profiling Array cGMP U133 P2*—the cGMP version of the GeneChip® Human Genome U133 Plus 2.0 Array*. The Clinical Toolkit is the first microarray-based clinical toolkit for diagnostic development, signature discovery for companion diagnostics, and translational initiatives. This combination enables researchers to perform biomarker signature discovery on the same system used for clinical test development.

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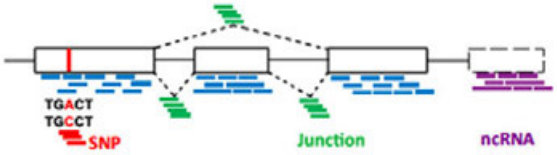
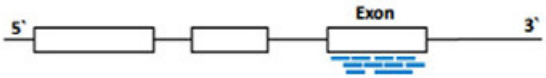
GeneChip® Human Transcriptome Array*



GeneChip® Exon and Gene ST Arrays*

GeneChip® Human Genome U133 Plus 2.0*
and GeneChip PrimeView® Human
Gene Expression Arrays*



"Affymetrix microarrays allow us to survey the entire set of genes and their cellular activity in a single, straightforward experiment. They're ideally suited for identifying biomarkers." *Avrum Spira, MD, Boston University*

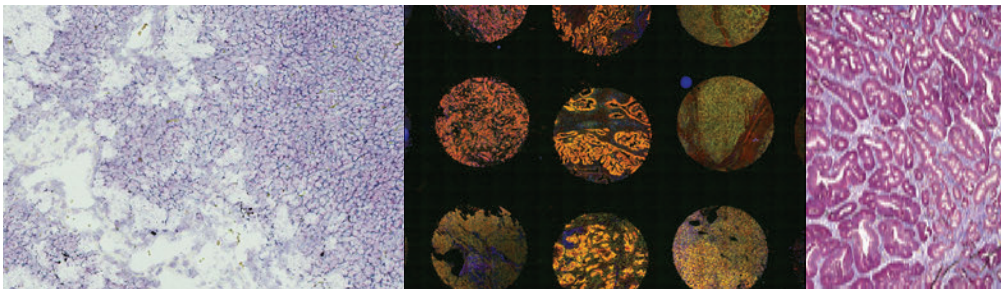
Understand gene regulation with the GeneChip® miRNA Array*

miRNAs have taken center stage, as they have been implicated as having important roles in cancer, heart disease, and other complex diseases. The GeneChip® miRNA Array* has the most comprehensive coverage of miRNAs on a single array, making it a powerful tool for probing the mechanisms by which miRNAs regulate gene expression and how they are implicated in disease progression.

RNA biomarkers for cancer from single cells

The QuantiGene® ViewRNA Assay* is the only RNA *in situ* hybridization (RNA-ISH) product on the market that can provide reliable measurements down to single molecule levels at single-cell resolution.

Researchers like Ting, *et al,*[4] are using QuantiGene ViewRNA Assays* for RNA-ISH to detect RNA-based signals of cancer. Ting, *et al,* found that non-coding RNAs (ncRNAs) from satellite repeats in heterochromatin were overexpressed in pancreatic ductal adenocarcinomas. Using QuantiGene ViewRNA Assays, they were able to localize overexpression of these ncRNAs to metastatic lesions, and, more remarkably, detect overexpression of ncRNA in endoscopic-guided fine needle aspirates of pancreatic masses in several cases where the histopathology was non-diagnostic.



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Cytogenetics and Inherited Diseases

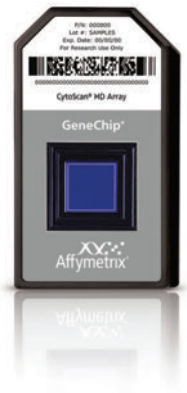
For detection of chromosomal aberrations and mutations, whether inherited or *de novo*, Affymetrix and its partners offer solutions for detection and screening.

Chromosomal aberrations are linked to a number of human diseases. Traditional cytogenetics techniques such as karyotyping and fluorescent *in situ* hybridization (FISH) have been used to study chromosomal abnormalities for decades; however, these techniques are limited to only providing low-resolution copy number information based on qualitative visualization. Designed to empower next-generation cytogenetic studies, the CytoScan® HD Cytogenetics Solution* provides a genome-wide approach that enables high-resolution DNA copy number analysis to detect gains, losses, loss of heterozygosity (LOH), regions identical-by-descent, and uniparental isodisomy (UPD) on a single array.

Highest resolution detection of chromosomal aberrations for constitutional and cancer cytogenetics
Affymetrix created the CytoScan® HD Array* by empirically selecting probes from a pool of over 20 million probes and then further screening them with greater than 3,000 samples to choose the highest performing probes for whole-genome cytogenetic applications.

The image below illustrates the importance of including two different probe types (SNP and non-polymorphic probes) on a whole-genome array. The competing array shown detects only SNPs. Since the gene FANCB, for example, does not contain SNPs, the technology is unable to effectively interrogate the region. With the CytoScan HD Array*, every gene in the genome is covered with SNP and non-polymorphic probes based on the structure of the genome to ensure high-resolution coverage of all genes.

Marker comparison



- Analyze allele-specific copy number and SNP genotypes
- Independently confirm copy number changes with SNP allelic information
- Differentiate triploidy, sample heterogeneity, and sample contamination
- Enable visualization of low-level mosaicism
- Assess array and sample quality

The high-density CytoScan HD Array includes 2.67 million markers for copy number (CN) analysis, approximately 750,000 SNP probes, and 1.9 million non-polymorphic probes for comprehensive whole-genome coverage.

- 100% Sanger cancer gene coverage
- 100% ISCA constitutional gene coverage
- 12,000 OMIM® genes
- 36,000 RefSeq genes

Unlike other arrays, which are restricted in their ability to deliver true whole-genome coverage due to probe density and probe placement limitations, the CytoScan HD Array* offers the highest resolution gene-level coverage for all constitutional, cancer, X-chromosome, and RefSeq genes.

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Fueling Research and Development of Molecular Diagnostics Clinical Tools

Clinical tools

Clinical tests have been developed on Affymetrix® Arrays* and marketed by partners such as Pathwork® Diagnostics†, Roche® Diagnostics†, and Skyline Diagnostics‡.

Making accurate diagnosis

Pathwork® Diagnostics develops and delivers innovative molecular diagnostics for oncology. The Pathwork® Tissue of Origin Test is an innovation in molecular diagnostics. Cleared by the FDA in 2010, this gene expression-based test uses a tumor's own genomic information to aid in identifying challenging tumors, including metastatic, poorly differentiated, and undifferentiated tumors. The test provides objective clinical information previously unavailable to physicians for tissue of origin identification.

Pathwork's unique microarray-based data, based on Affymetrix® technology*, enables the Tissue of Origin Testing Service to measure the expression pattern, comprising nearly 5,000 genes, in a challenging tumor. The test compares it to expression patterns of a panel of 17 known tissue types, representing 95% of all solid tumors, in order to identify the primary tumor type.

Pathwork has developed unique processes that enable the company to bring microarray data from the realm of research into practical daily clinical use—solving critical technological challenges such as:

- Obtaining meaningful and easy-to-interpret information from highly complex data-sets
- Working with heterogeneous tissues that include variable amounts of tumor
- Developing the ability to work with FFPE tissue specimens that may contain degraded RNA
- Normalizing gene expression patterns for consistency across different instruments with different operators
- Incorporating reliable and effective data quality control processes
- Providing the combination of microarray, instrumentation, informatics in a reliable system that ensures diagnostic-quality data every time

Pathwork Diagnostic's Tissue of Origin Test, the first FDA-cleared microarray-based gene expression test, uses an RNA signature to aid in the diagnosis of the origin of tumors of unknown primary origin. Validated in both fresh and FFPE samples, the Tissue of Origin Test provides robust tumor origin identification to aid in proper diagnosis and treatment.

For more information see www.pathworkdx.com.

†FDA cleared and IVD/CE marked in Europe

‡IVD/CE marked in Europe

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Personalizing cancer therapy

skyline DIAGNOSTICS

Skyline Diagnostics has developed the AMLprofiler, which simplifies the challenging task of classifying AML subtypes, enabling clinicians to make individualized therapy decisions. Using Affymetrix® technology, the test determines relevant diagnostic and prognostic markers for AML in one single microarray-based assay. Compared to traditional methods, the AMLprofiler delivers faster results and significantly improved patient classification on our fully integrated and CE IVD-marked microarray platform.

Key benefits of the AMLprofiler test†‡ include:

- Best classification: re-classification of more than 50% of the intermediate risk group and full identification of the favorable group with one test.
- Seven assays in one: the AMLprofiler replaces 7 separate assays based on 3 different technologies: cytogenetics, mutation analysis, and expression analysis.
- Three days to diagnosis: use of the AMLprofiler significantly reduces the time between sampling and diagnosis down to 3 days.
- Validated technology: Skyline Diagnostics has developed the AMLprofiler to meet strict regulatory standards, and this was enabled using a standardized procedure on a CE IVD-marked Affymetrix® platform.

"Affymetrix technology has enabled us to get one step closer to personalized medicine. We used the Affymetrix microarrays from the initial research phase through to validation of our signature and the development of the clinical test for AML on an FDA-cleared microarray platform."

Henk Vietor, Founder and Member of the Board of Directors, Skyline Diagnostics

†AMLprofiler not available in the United States.
‡In Europe the AMLprofiler test is CE IVD-marked.

Sequencing in the clinic

Sequencing has long been used in the clinic as a diagnostic tool for monogenic disorders. Sanger sequencing of known genes or gene regions to determine polymorphisms, point mutations, or small indels that pertain to a specific Mendelian diseases can require significant effort to optimize for implementation. While next-generation sequencing (NGS) is proving to be a useful disease research tool, it is not yet ready to supersede Sanger sequencing for routine clinical use.

Several Affymetrix partners have developed sequencing-based diagnostics tests on arrays, which maximize the sensitivity of PCR with the specificity of DNA sequencing. Array technology lends itself very well to diagnostic sequencing test development due to the accuracy and reproducibility of results and relatively simple, quick processing, which yields more rapid results at a lower cost compared to Sanger or NGS.

In 2009, during the outbreak of the H1N1 Influenza A virus, TessArae® was granted Emergency Use Authorization by the FDA for their resequencing-based assay based on Affymetrix' GeneChip® platform. The TessArray® RM-Flu test sequences multiple flu strains in one assay, and using an algorithm, is able to determine the presence of a particular seasonal flu variant.

In addition to direct diagnosis, sequencing arrays also have utility for detection of genomic variations that can influence drug efficacy and adverse drug reactions. The Amplichip® CYP450 Test developed by Roche Molecular Diagnostics was the world's first microarray-based pharmacogenomic test cleared for clinical use. The AmpliChip® CYP450 Test provides comprehensive detection of gene variations—including deletions and duplications—for the CYP2D6 and CYP2C19 genes, which play a major role in the metabolism of an estimated 25% of all prescription drugs. It is intended to be an aid to clinicians in determining therapeutic strategy and treatment dose for therapeutics metabolized by the CYP2D6 or CYP2C19 gene product. The sequencing-based assay distinguishes 29 known polymorphisms in the CYP2D6 gene, including gene duplication and gene deletion, as well as two major polymorphisms in the CYP2C19 gene. Detection of these CYP2D6 polymorphisms results in the identification of 33 unique alleles, including seven CYP2D6 gene duplication alleles.

Pharmacogenomics

Pharmacogenomics is an essential discipline on the road to personalized medicine. One of the most clinically useful areas of genomic medicine today is the ability to use genomic information to make targeted therapy decisions, predict response to therapy, optimize dosing, and reduce adverse drug events—the right treatment, at the right dose, for the right patient, at the right time and for the right outcome.

Genetic-based drug efficacy and safety response information exists for a number of compounds—there are over one hundred FDA-approved drugs that list pharmacogenomic information in their labels—and companion diagnostics are not only being approved worldwide, in many instances they are being required prior to treatment.

Clearly when it comes to medical drugs, one type and one dose does not fit all. An individual's genome plays a role in the efficacy and toxicity of a drug. There is also the issue of underrepresented populations in the clinical trial and drug development process, which clearly has implications when drugs are dispensed to populations not previously included in clinical trials, most often non-European.

The search for genetic variants that affect drug metabolism and drug toxicity required researchers to interrogate hundreds of samples and thousands of SNPs. The Affymetrix DMET™ Plus Premier Pack* helps researchers efficiently navigate the maze of data and quickly identify the variants that matter. With the most comprehensive coverage of pharmacogenetic markers available on any array, the DMET Plus Premier Pack* accelerates discovery and measurement of genetic variation associated with drug response and supports standardization of drug metabolism studies.

A drug may become available to a population that was underrepresented in the original clinical trial and for which pharmacogenomics studies either don't exist or are cost-prohibitive.

PGENI Treating the Population. Impacting the World.

Pharmacogenetics for Every Nation Initiative

One potential solution has been devised by Howard McLeod, who leads the Pharmacogenetics for Every Nation Initiative (PGENI) at the University of North Carolina. The PGENI project is based on the assumption that while one size does not fit all when it comes to drugs, tailoring therapies to the individual level would be too cost-prohibitive in some countries. The innovative approach taken by PGENI aims to genotype genetically distinct populations to allow drug dosing recommendations on a population-specific basis. This study uses the Affymetrix DMET™ Arrays* to genotype various ethnic groups and provides guidance to ministries of health on the risk of adverse drug reactions or altered efficacy in populations within the partnering country. The PGENI project also hopes to provide country/population-specific recommendations for formulary creation, drug buying strategy, and pharmacovigilance.

"The DMET™ Plus platform gives us key content to identify markers of toxicity risk across the broad spectrum of disease for which we are researching drug selection and dosing specific to selected populations."

Howard McLeod, MD, Fred Eshelman Distinguished Professor, Director,
UNC Institute for Pharmacogenomics and Individualized Therapy, University of North Carolina, Chapel Hill

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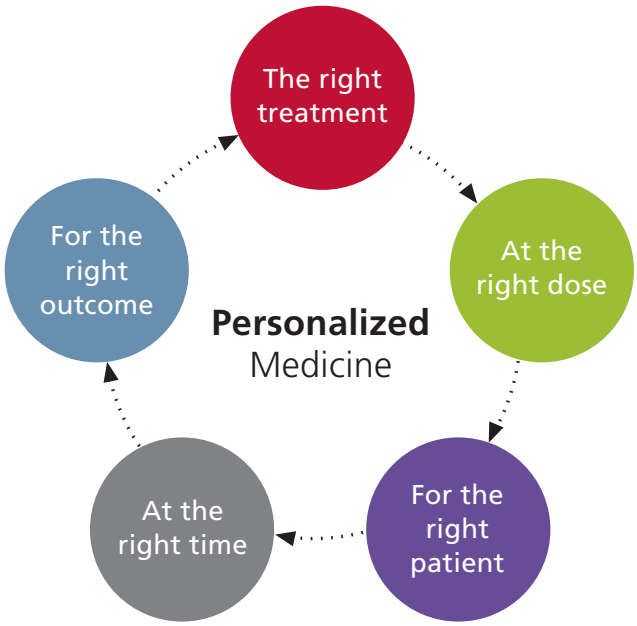

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