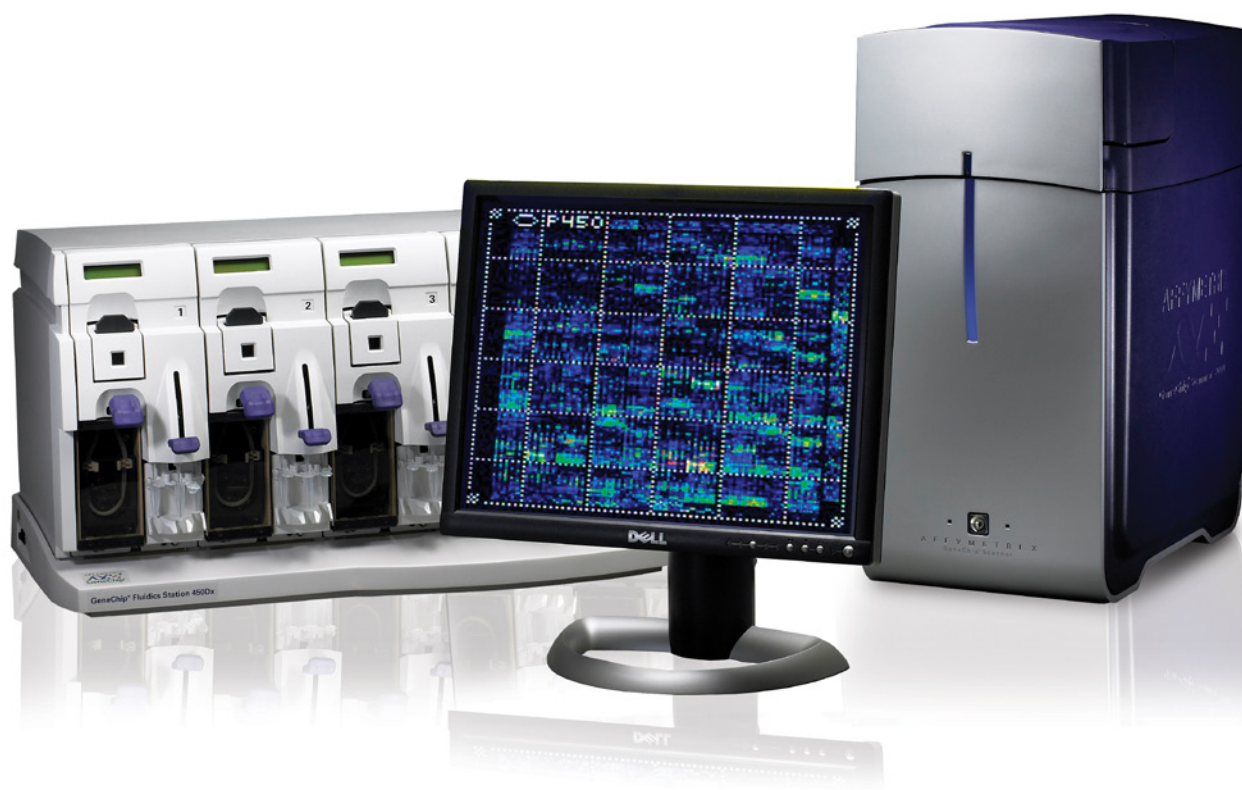


GeneChip[®] System 3000Dx v.2

FDA-cleared, CE-IVD system for molecular diagnostics



GeneChip® System (GCS) 3000Dx v.2



Take the proven path to market

Microarray technology is the platform of choice for molecular diagnostics

Microarrays have been used to discover an impressive number of clinically informative genomic and pharmacogenomic biomarkers. However, converting promising gene signatures into clinical diagnostic or prognostic tests can be an expensive endeavor with significant development and regulatory risks.

The GeneChip® System (GCS) 3000Dx v.2 is the most robust system for clinical research and **the only FDA-cleared, IVD and CE-marked microarray system** for RNA- and DNA-based clinical tests. The GCS 3000Dx v.2 is the foundation of the expanding Clinical Toolkit from Affymetrix that includes the **FDA-cleared IVD and CE-marked Affymetrix® Gene Profiling Reagents** and the Gene Profiling Array cGMP U133 P2, the cGMP-manufactured version of the widely cited GeneChip® Human Genome U133 Plus 2.0 Array. The Affymetrix Clinical Toolkit provides a proven path to market, enabling test developers to save time and money while reducing regulatory risks.

GeneChip® technology from Affymetrix has been relied upon by thousands of researchers to obtain reproducible results for all their microarray applications.

“In clinical research where irreplaceable human specimens are used, you do not have a second chance. Once you use the sample, it is gone. Thus, it is highly beneficial to use Affymetrix® IVD reagents and system with an established good analytical performance.”

Catherine Dumur, PhD,
Director of the Molecular Morphology
Genomics Facility and Associate Professor at
Virginia Commonwealth University.

GCS 3000Dx v.2 for:

Research

- Analyze or study precious human samples with confidence

Diagnostic test development

- Several FDA-cleared in vitro diagnostic and CE-IVD diagnostic tests have been developed and commercialized by Powered by Affymetrix™ partners

- Many more molecular diagnostic tests in development

Routine testing

- One system, multiple applications

One platform—multiple applications

GeneChip® System 3000Dx v.2 assay menu		
Application area	RUO*	IVD**
3' IVT expression analysis	√	√
Whole-transcript expression analysis	√	√
Genotyping/copy number	√	
Cytogenetic analysis	√	
Drug metabolism/pharmacogenomics	√	√
miRNA gene regulation	√	
Targeted resequencing	√	
Custom assays	√	√

* Each “Research Use Only” (RUO) array requires an array-specific Assay Software Module (ASM). A custom ASM can be developed for any GeneChip® Array. A Data Transfer Server (DTS) is required to export .CEL files.
** FDA-cleared, IVD or CE-marked test developed by a third-party company on the Affymetrix® GCS 3000Dx platform.

Powered by Affymetrix™ Program

Enabling diagnostic development...with more applications on the way

The Powered by Affymetrix (PbA) Program provides outstanding design, development, and regulatory support for clinical researchers, entrepreneurs, and pharmaceutical companies interested in the development and commercialization of separately cleared molecular diagnostics.

Powered by Affymetrix™ partners

- Roche Diagnostics
- Pathwork Diagnostics
- Skyline Diagnostics BV
- Almac Diagnostics
- Signature Diagnostics
- Sysmex Corporation
- Medical Prognosis Institute
- bioMérieux
- Ipsogen
- TessArae
- Veridex LLC
- Lineagen

“Affymetrix provides the tools to make it easy for Skyline to concentrate on diagnostic content. Building our AMLProfiler test on the FDA-cleared, CE-marked GCS 3000Dx v.2 microarray system using the FDA-cleared, CE-marked Gene Profiling Reagents greatly reduces our regulatory and operational risks, providing a faster path to market.”

Henk Viëtor
CEO, Skyline Diagnostics BV

GeneChip® System 3000Dx v.2 microarray system for clinical research and molecular diagnostics

IVD CE

Sample
GeneChip® Cartridge Array



- Proven microarray technology, legacy data, and path to cost-effective custom design
- GeneChip® microarrays have the capacity for redundancy of genes and controls for a robust signature

Hybridize
GeneChip® Hybridization Oven 645



- Precise temperature and rotation control
- Hybridize up to 64 GeneChip Cartridge Arrays in a single run
- Ordered separately (not part of the GCS 3000Dx v.2)

Wash and stain
GeneChip® Fluidics Station 450Dx v.2



- Walk-away automation of array wash and stain
- Process up to four arrays on one fluidics station
- Run up to eight stations simultaneously for increased throughput

Scan
GeneChip® Scanner 3000Dx v.2 with AutoLoaderDx



- Precise scanning of all GeneChip® Cartridge Arrays
- Process up to 48 microarrays in a single run with the AutoLoaderDx

Analyze (IVD testing)
Workstation with Affymetrix® Molecular Diagnostics Software (AMDS)



Designed for running multiple clinical assays

- Features internal tracking of all assay and system components and audit controls
- Monitors array hybridization, fluidics, and scanning
- Connects up to two hybridization ovens, eight fluidics stations, and one scanner

or

Analyze (Research use)
Data Transfer Server plus Assay Software Module (ASM)



- Data Transfer Server (DTS) allows use of the GCS 3000Dx v.2 in an RUO setting with catalog and custom arrays
- Assay Software Modules (ASMs) enable .CEL file export for downstream analysis

The Affymetrix Clinical Toolkit enables gene expression microarray-based diagnostic development
www.affymetrix.com/toolkit

Speed your progress to market

- Minimal revalidation when transitioning from RUO reagents
- cGMP components enable you to focus on validating your diagnostic test
- Certificates of Analysis reduce verification burden for new reagent lots

Save time and money while conserving precious human specimens

- Robust technology produces reproducible and reliable results

Benefit from the success of others

- 3,000+ scientific publications on the GeneChip® Human Genome U133 Plus 2.0 Array
- FDA-cleared and CE-marked diagnostic tests developed by Affymetrix partners



FDA-cleared, CE-marked Gene Profiling Reagents



Gene Profiling Array cGMP U133 P2 (RUO)

“ The need for an FDA-cleared microarray platform was an important consideration in choosing the Affymetrix GCS 3000Dx system for Pathwork’s two FDA-cleared Tissue of Origin (TOO) tests, one that uses FFPE and the other frozen tumor samples. **The Pathwork-Affymetrix PbA partnership continues to create value for both parties.**”

David Craford
Chief Commercial Officer,
Pathwork Diagnostics

GCS 3000Dx v.2 component specifications

GeneChip® Scanner 3000Dx v.2 with AutoLoaderDx	
Weight	~100 lb (45.4 kg)
Dimensions	13" W x 22" D x 18" H (33 cm x 56 cm x 46 cm)
Loading clearance	36" (91.4 cm) above laboratory bench Additional 18" (46 cm) in clearance for AutoLoaderDx
Power	Voltage: 100–240 VAC; Current: 4–2A; Frequency: 50–60 Hz

GeneChip® Fluidics Station 450Dx v.2	
Weight	~80 lb (36.3 kg)
Dimensions	28" W x 16 1/8" D x 15 13/16" H (71.1 cm x 41 cm x 40.2 cm)
Loading clearance	Additional 4" (10.2 cm) at the back for ventilation
Power	Voltage: 100–240 VAC; Current: 3A; Power: 300 Watts

Workstation with Affymetrix® Molecular Diagnostics Software (AMDS) v1.0 and higher	
Weight	Computer monitor – 26 lb (11.8 kg) Computer tower – 43 lb (19.5 kg)
Dimensions	Computer monitor – 20 1/4" W x 11" D x 21" H (52 cm x 28 cm x 54 cm) Computer tower – 6 3/4" W x 18 1/2" D x 17 2/3" H (17 cm x 47 cm x 45 cm)
Power	Voltage: 100–240 VAC

Ordering information

Part number	Product name	Description
00-0334	GeneChip® System 3000Dx v.2*	Includes the GeneChip® Scanner 3000Dx v.2 with AutoLoader Dx, Fluidics Station 450Dx v.2, and Workstation with Affymetrix Molecular Diagnostics Software (AMDS)
00-0349	GeneChip® System 3000Dx v.2 with Data Transfer Server*	Also includes Data Transfer Server

*Requires GeneChip Hybridization Oven 645 (see below)

GeneChip® Hybridization Oven 645

GeneChip® Hybridization Oven 645	
Weight	~67 lb (30.4 kg)
Dimensions	18" W x 21" D x 20" H (46 cm x 54 cm x 53 cm)
Loading clearance	Additional 4" (10.2 cm) at the back for ventilation
Power	Voltage: 100–240 VAC

Ordering information

Part number	Product name
00-0331	GeneChip® Hybridization Oven 645

The GCS 3000Dx v.2 offers multiple dimensions for developing commercial assays and tests. Supporting both DNA and RNA analysis, this integrated system provides the versatility to develop virtually any type of genetic or genomic assay with accurate, reproducible results.





World-class support

Affymetrix offers an expanding portfolio of customer support and services—from training and instrument maintenance to consulting and compliance—led by our world-class team of multilingual technical experts, field application scientists (FAS), and regional field service engineers (FSE). For more information please visit www.affymetrix.com/service.

Affymetrix, Inc. Tel: +1-888-362-2447 ■ Affymetrix UK Ltd. Tel: +44-(0)1628-552550 ■ Affymetrix Japan K.K. Tel: +81-(0)3-6430-4020
Panomics Solutions Tel: +1-877-726-6642 www.panomics.com ■ USB Products Tel: +1-800-321-9322 www.usb.affymetrix.com

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