

Gene Profiling Array cGMP U133 P2

The proven Human Genome U133 Plus 2.0 Array, built under cGMP with a Certificate of Analysis, enabling a faster path to market for signature-based diagnostics

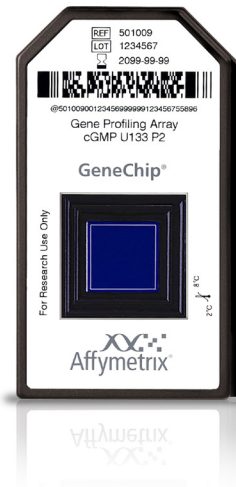
The Gene Profiling Array cGMP U133 P2 is a new addition to the Affymetrix clinical toolkit, which is specifically designed for clinical diagnostic test developers. The clinical toolkit also includes the FDA-cleared IVD and CE-marked Affymetrix® Gene Profiling Reagents and the FDA-cleared IVD and CE-marked GeneChip® System 3000Dx v.2.

Key benefits of the Gene Profiling Array:

- **Provides Human Genome U133 (HG-U133) Plus 2.0 Array content for diagnostic development**
 - The HG-U133 Plus 2.0 Array has fueled thousands of biomarker discovery studies worldwide
 - The Gene Profiling Array is ideal for clinical validation and test development of gene expression signatures discovered on the HG-U133 Plus 2.0 Array
- **Reduces array validation costs for test developers**
 - Manufactured under cGMP in a facility that adheres to quality management system requirements (ISO 13485:2003 and FDA 820), ensuring consistent high quality within and among lots
 - A Certificate of Analysis is available for each lot, significantly lowering the validation burden and costs for test developers
- **Offers a proven path to clinical development**
 - The Gene Profiling Array can be custom manufactured for incorporation as a diagnostic test component for regulatory submission
 - Multiple FDA-cleared or CE-IVD marked clinical diagnostic tests have been developed on the GeneChip® System (GCS) 3000Dx v.2 diagnostic platform by Affymetrix partners

Overview

The Gene Profiling Array, a valuable addition to the Affymetrix family of gene expression microarrays, accelerates the validation and commercialization of clinical tests based on complex gene expression signatures. Because the Gene Profiling Array



is built under cGMP guidelines and backed by a Certificate of Analysis, the array can be used by clinical test developers as a diagnostic test component for regulatory submission.

Content profile

The Gene Profiling Array is built under strict design controls using the same array design strategy and content as the HG-U133 Plus 2.0 Array (see specifications).

The Gene Profiling Array:

- Detects the expression levels of more than 47,000 transcripts and variants representing approximately 38,500 well-characterized genes (estimated by UniGene coverage), providing the most comprehensive coverage of the human genome for expression profiling.
- Uses 11 unique oligonucleotide probes to measure the expression level of each transcript, enabling multiple, independent measurements of gene expression for each transcript. This design feature ensures the critical robustness and reproducibility that signature-based clinical tests demand.
- Includes 1.3 million unique oligonucleotide features, with more than 54,000 probe sets selected from GenBank®, dbEST, and RefSeq. The reliability and value of these probe sets have been proven in more than 3,000 publications using HG-U133 Plus 2.0 Arrays.

Updated annotation information for genes and probe sets is available through the NetAffx® Analysis Center (www.affymetrix.com/analysis/index.affx). For more information on the design strategy, performance, and testing of the HG-U133 family of arrays, please download the data sheet and technical note for HG-U133 Arrays from www.affymetrix.com.

Specifications

Number of transcripts	~47,400
Number of genes	>38,500
Number of probe sets	>54,600
Feature size	11 µm
Oligonucleotide probe length	25-mer
Total unique probes per gene	9-11
Average probes per transcript	16
Median probes per transcript	11
Total average sequence measured per gene	275
Hybridization controls	<i>bioB, bioC, bioD, cre</i>
Poly-A controls	<i>Dap, lys, phe, thr</i>
Normalization control set	100 probe sets
Housekeeping/Control genes	GAPDH, beta-Actin, ISGF-3 (STAT1)

Complete clinical toolkit

The clinical toolkit from Affymetrix is a complete solution for gene expression-based diagnostic development. In addition to the Gene Profiling Array, the clinical toolkit includes:

- **Affymetrix® Gene Profiling Reagents:** The first FDA-cleared IVD and CE-marked microarray reagents for use in the development and commercialization of separately cleared clinical diagnostic tests.
- **GeneChip® System 3000Dx v.2:** The first microarray instrumentation system to receive FDA clearance for in vitro diagnostic use. The GCS 3000Dx v.2 is designed for the clinical laboratory running multiple assays and features internal tracking of all assay and system components, with test partitioning and audit controls.

References

1. Ghosh S., *et al.* Global gene expression profiling of endothelium exposed to heme reveals an organ-specific induction of cytoprotective enzymes in Sickle Cell Disease. *PLoS ONE* **6**(3):1-12 (2011).
2. Moreaux J., *et al.* Osteoclast-gene expression profiling reveals osteoclast-derived CCR2 chemokines promoting myeloma cell migration. *Blood* **117**(4):1280-90 (2011).
3. Uddin S., *et al.* Genome-Wide Expression Analysis of Middle Eastern Colorectal Cancer Reveals FOXM1 as a Novel Target for Cancer Therapy. *American J. Pathology* **178**(2):537-47 (2011).

Ordering information

Part number	Product	Description
901411	Affymetrix® Gene Profiling Array cGMP U133 P2*	Contains 8 arrays
Supporting products (Not included)		
901285	Affymetrix® Gene Profiling Reagents – RNA Control Kit (IVD Kit 1)	Sufficient for 64 reactions
901286	Affymetrix® Gene Profiling Reagents – Transcript Synthesis and Labeling Kit (IVD Kit 2)	Sufficient for 32 reactions
901299	Affymetrix® Gene Profiling Reagents – Transcript Detection Kit (IVD Kit 3)	Sufficient for 32 reactions
901228	GeneChip® 3' IVT Express Kit (RUO)	Sufficient for 10 reactions
901229	GeneChip® 3' IVT Express Kit (RUO)	Sufficient for 30 reactions
00-0334	GeneChip® System 3000Dx v.2	Includes the GeneChip® Scanner 3000Dx V.2 with AutoLoaderDx, 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
00-0362	GeneChip® System 3000 7G	Includes the GeneChip® Scanner 3000 with AutoLoader, Fluidics Station 450, and Workstation

*The Gene Profiling Array is manufactured in a facility that adheres to quality management system requirements (ISO 13485:2003 and FDA 820). Running the Gene Profiling Array on the GCS 3000Dx v.2 will require a Gene Profiling Array-specific Assay Software Module (ASM) to be installed on the Dx v.2 system before the array can be processed. The Gene Profiling Array-specific ASM is available from Affymetrix. Please inquire about installation of the ASM with your order for the Gene Profiling Array.

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