



Package Insert

Gene Profiling Array cGMP U133 P2



REF 901411

Summary

The Gene Profiling Array is one microarray comprised of 1,300,000 unique oligonucleotide features covering over 47,000 transcripts and variants, which, in turn, represent approximately 39,000 of the best characterized human genes. The majority of the probe sets used in the design of the array were selected from GenBank®, dbEST, and RefSeq.

Oligonucleotide probes are synthesized *in situ* complementary to each corresponding sequence. Eleven pairs of oligonucleotide probes are used to measure the level of transcription of each sequence represented.

The Gene Profiling Array cGMP U133 P2 is manufactured in a facility that adheres to Quality Management System Requirements (ISO 13485:2003 and Title 21 CFR Part 820).

Chemical and Physical Principles

Critical Specifications	
Feature Size	11 µm
Probe Pairs/Sequence	11
Hybridization Controls:	<i>bioB</i> , <i>bioC</i> , <i>bioD</i> , and <i>cre</i>
Poly-A Controls:	<i>dap</i> , <i>lys</i> , and <i>phe</i>
Normalization Controls:	100 probe sets
Housekeeping/Control Genes:	GAPDH
Array Format	49
Hybridization Volume	200 µL. The total fill volume of the cartridge is 250 µL.

Kit Components

The certificate of analysis is available in the Affymetrix website.

Component	P/N	Description
Gene Profiling Array	901411	8 Arrays

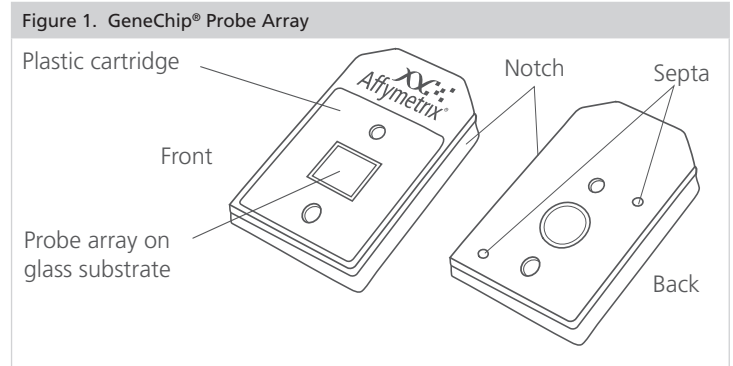
Other Gene Profiling Products

Product Name	P/N	Description
GCS3000Dx v.2 with DTS	00-0349	
Gene Profiling Assay Module for GCS3000Dx v.2	610428	
Gene Profiling Reagent Kit		Sufficient for 32 Reactions, Consists of:
	901285	■ RNA Control Kit
	901286	■ Transcript Synthesis and Labeling Kit A, B
	901299	■ Transcript Detection Kit A, B, C
GeneChip Hybridization Oven 645	00-0331	

Warnings and Precautions

The probe array consists of a square glass substrate mounted in a plastic cartridge (Figure 1). The glass contains an array of oligonucleotides that, when mounted, is on the inner glass surface. A chamber in the plastic housing directly under the glass acts as a reservoir where hybridization and washing occur.

Although the inner glass surface of the probe array is protected, any contamination or scratches on the outer surface of the glass can compromise the accuracy of the scan. Avoid touching the surface of the glass with your fingers. Skin oils and other substances, such as lotions or ink, can fluoresce. If the surface of the glass is noticeably dirty, it can be carefully cleaned with a non-abrasive laboratory tissue.



The GeneChip® probe arrays should be stored at 2° to 8°C. Refer to the expiration date on the package label. Do not use probe arrays or reagents after the expiration date.

1. Avoid microbial contamination, which may cause erroneous results.
2. **WARNING: All biological specimens and materials with which they come into contact should be handled as if capable of transmitting infection and disposed of with proper precautions in accordance with federal, state, and local regulations. This includes adherence to the OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030) for blood-derived and other samples governed by this act. Never pipet by mouth. Avoid specimen contact with skin and mucous membranes.**
3. **CAUTION:** Exercise standard precautions when obtaining, handling, and disposing of potentially carcinogenic reagents.
4. Exercise care to avoid cross-contamination of samples during all steps of this procedure, as this may lead to erroneous results.
5. Use powder-free gloves whenever possible to minimize introduction of powder particles into sample or probe array cartridges.

Patents

Products may be covered by one or more of the following patents: U.S. Patent Nos. 5,445,934; 5,744,305; 5,945,334; 6,140,044; 6,399,365; 6,420,169; 6,551,817; 6,733,977; 7,629,164; 7,790,389 and D430,024 and other U.S. or foreign patents. Products are manufactured and sold under license from OGT under 5,700,637 and 6,054,270.

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Symbol Table

Table below shows the legend of the graphic symbols used for Affymetrix product label, Package Inserts and User Guide.

Symbol / Letters	Statement
	Part/Catalog Number
	Lot Number
	Expiration Date
	Temperature Limitation
	Contains Sufficient for < n > Tests
	Consult Instructions for Use
	Manufacturer
cGMP	Current Good Manufacturing Practice

Contact Information



Affymetrix, Inc.,
3420 Central Expressway,
Santa Clara, CA 95051 USA

Affymetrix, Inc.

3420 Central Expressway
Santa Clara, CA 95051 USA
E-mail: support@affymetrix.com
Tel: 1-888-362-2447 (1-888-DNA-CHIP)
Fax: 1-408-731-5441

Affymetrix UK Ltd

Voyager, Mercury Park,
Wycombe Lane, Wooburn Green,
High Wycombe HP10 0HH
United Kingdom
E-mail: supporteurope@affymetrix.com
UK and Others Tel: +44 (0) 1628 552550
France Tel: 0800919505
Germany Tel: 01803001334
Fax: +44 (0) 1628 552585

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