

Product Spotlight

Affymetrix® Gene Profiling Arrays and Reagents

The only cGMP-manufactured gene expression clinical microarray toolkit for rapid and cost-effective diagnostic test development



Take the faster, proven path to market

The clinical toolkit, which includes Affymetrix® Gene Profiling Reagents, the Gene Profiling Array cGMP U133 P2, and the GeneChip® System (GCS) 3000Dx v.2 instrument platform, is used by clinical researchers and Powered by Affymetrix™ partners to confidently develop, commercialize, and run diagnostic tests.

Gene Profiling Arrays and Reagents allow you to:

- **Speed your progress to market**
 - Manufactured under current Good Manufacturing Processes (cGMP); reagents that are FDA-cleared and CE-marked for IVD use
 - Minimal revalidation when transitioning from research-use-only (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 quick, reproducible, and reliable results
- **Benefit from the success of others**
 - More than 3,000 scientific publications on the GeneChip® Human Genome U133 Plus 2.0 Array
 - Two FDA-cleared and one CE-marked clinical diagnostic test developed by Powered by Affymetrix™ partners with more on the way

The Affymetrix clinical toolkit includes:

Affymetrix® Gene Profiling Reagents

Affymetrix Gene Profiling Reagents are FDA-cleared for *in vitro* diagnostic use and manufactured under cGMP. The reagents are designed to limit hands-on time and reduce error, while improved technology and optimized master mixes result in:

- Low total input RNA (tested at 100 ng), suitable for fresh or frozen human tissue specimens
- Fewer pipetting steps
- A full day shorter process

The reagent kit is comprised of three sub-kits, which can be used as a set or individually according to your processing needs:

- **Kit 1:** Affymetrix® RNA Control Kit
- **Kit 2:** Affymetrix® Transcript Synthesis and Labeling Kit
- **Kit 3:** Affymetrix® Transcript Detection Kit

Gene Profiling Array cGMP U133 P2

The Gene Profiling Array cGMP U133 P2 is manufactured under stringent cGMP guidelines. This cGMP version of the proven GeneChip® Human Genome U133 Plus 2.0 Array is used routinely by Affymetrix clinical partners and clinical researchers developing novel diagnostic or prognostic gene expression signatures.

The Gene Profiling Array is backed by more than 3,000 clinical publications and the largest *in silico* research database for gene expression data analysis, quality control, and signature development.

GeneChip® System 3000Dx v.2

Gene Profiling Arrays and Reagents are designed for use with the GCS 3000Dx instrument platform, the first microarray instrumentation system with FDA 510K clearance and CE-marked for *in vitro* diagnostic use.

The GCS 3000Dx v.2 system 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.

For more information about the clinical toolkit, please visit www.affymetrix.com/toolkit.

Intended Use Statement

For In Vitro Diagnostic Use

Affymetrix® Gene Profiling Reagents are intended for the preparation of labeled complementary RNA target from purified total RNA from fresh or frozen clinical tissue specimens for hybridization to Affymetrix GeneChip® microarrays and the measurement of fluorescence signals of labeled RNA target using the Affymetrix GeneChip Microarray Instrumentation System. Intended for use with separately FDA-cleared Affymetrix GeneChip microarray assays specifying the use of the Affymetrix Gene Profiling Reagents.

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